Sunshine Act Meetings

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Thursday, August 26, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:04 a.m. on Tuesday, August 24, 1993, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider the following:

Recommendations concerning administrative enforcement proceedings.
Matters relating to the Corporation's corporate activities.

In calling the meeting, the Board determined, on motion of Mr. Stephen R. Steinbrink, acting in the place and stead of Director Eugene A. Ludwig (Comptroller of the Currency), seconded by Mr. John F. Downey, acting in the place and stead of Director Jonathan L. Fiechter (Acting Director, Office of Thrift Supervision), concurred in by Acting Chairman Andrew C. Hove, Jr., that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(i), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(i), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550—17th Street, N.W., Washington, D.C.

Dated: August 24, 1993.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 93–20901 Filed 8–24–93; 3:33 pm]

BILLING CODE 6714–01–M

FEDERAL HOUSING FINANCE BOARD

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 58 FR 44401, August 20, 1993.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 9:00 A.M., Wednesday, August 25, 1993.

CHANGES IN THE MEETING: The following topic was withdrawn from the open portion of the meeting.

- Report on the Proposed Revision to the Finance Board's Private Sector Adjustment Factor ("PSAF") Methodology

The Board determined that agency business required its consideration of this matter on less than seven days notice to the public and that no earlier notice of this change in the subject matter of the meeting was practicable.

CONTACT PERSON FOR MORE INFORMATION: Elaine L. Baker, Secretary to the Board, (202) 408–2837.

Philip L. Conover,

Managing Director.

[FR Doc. 93–20903 Filed 8–24–93; 3:46 pm]

BILLING CODE 6725–01–M

MERIT SYSTEMS PROTECTION BOARD

TIME AND DATE: 10:00 a.m., Wednesday, September 15, 1993.

PLACE: Eighth Floor, 1120 Vermont Avenue, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: Briefing and discussion of the Board's fiscal year 1994 research agenda.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Robert E. Taylor, Clerk of the Board, (202) 653–7200.

Dated: August 23, 1993.

Robert E. Taylor,

Clerk of the Board.

[FR Doc. 93–20849 Filed 8–24–93; 2:25 pm]

BILLING CODE 7400–01–M

UNITED STATES POSTAL SERVICE BOARD OF GOVERNORS

Amendment to Meeting

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 58 FR 44401, August 20, 1993.

PREVIOUSLY ANNOUNCED DATE OF MEETING: August 31, 1993.

CHANGE: Delete the following item from the open meeting agenda:

5. Additional Space for the National Postal Museum.

CONTACT PERSON FOR MORE INFORMATION: David F. Harris, (202) 268–4800.

David F. Harris,

Secretary.

[FR Doc. 93–20831 Filed 8–24–93; 11:24 am]

BILLING CODE 7710–12–M

federal register

Thursday
August 26, 1993

Part II

Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

45 CFR Part 96

Substance Abuse Prevention and Treatment Block Grants: Sale or Distribution of Tobacco Products to Individuals Under 18 Years of Age; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

45 CFR Part 96

Rin: 0905–AE03

Substance Abuse Prevention and Treatment Block Grants: Sale or Distribution of Tobacco Products to Individuals Under 18 Years of Age

AGENCY: Substance Abuse and Mental Health Services Administration, PHS, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: Sections 1921 to 1954 of the Public Health Service (PHS) Act authorize the Secretary to provide Block Grants to States for the purposes of prevention and treatment of substance abuse. This notice of proposed rulemaking seeks comments on proposed regulations implementing section 1926 of the Public Health Service (PHS) Act regarding the sale or distribution of tobacco products to individuals under age 18.

DATES: Written comments must be received on or before October 25, 1993.

ADDRESSES: Written comments on this proposed rule may be sent to Gale A. Held, Director, State Prevention Systems Program, Center for Substance Abuse Prevention (CSAP), Rockwall II Building, 9th Floor, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patrick G. Talmon, at (301) 443–7942.

SUPPLEMENTARY INFORMATION: Sections 1921 to 1954 of the PHS Act, 42 U.S.C. 300x–21—330x–64, authorize the Secretary to provide Block Grants to States for the purposes of prevention and treatment of substance abuse. All but section 1926 of the PHS Act, 42 U.S.C. 300x–26, affect fiscal year 1993 Block Grants. Section 1926 does not become effective until fiscal year 1994 and, in some cases, fiscal year 1995. The regulations implementing all but section 1926 of the PHS Act were published as an interim final at 58 FR 17062 (March 31, 1993) and subsequent corrections at 58 FR 21218 (April 19, 1993). For purposes of this proposed rule implementing section 1926, it should be noted at the onset that the term "State" is defined to include the District of Columbia and the territories.

This Notice of Proposed Rulemaking (NPRM) seeks comment on proposed regulations to implement section 1926 of the PHS Act. Section 1926 of the PHS Act stipulates that the Secretary may not make a grant to a State for the first applicable year and all subsequent fiscal years unless the State has in effect a law prohibiting any manufacturer, retailer, or distributor of tobacco products from selling or distributing any such products to any individual under the age of 18. For States whose legislature does not convene a regular session in fiscal year 1993 or in fiscal year 1994, the first applicable year is fiscal year 1995. For all other States, the first applicable fiscal year is 1994.

The Secretary proposes to implement this statutory provision by requiring States to have in place a law which prohibits the sale or distribution of any tobacco product to persons under the age of 18 through any sales or distribution outlet. This would include such sales or distribution from any location which sells at retail or otherwise distributes tobacco products to consumers including (but not limited to) locations that sell such products over-the-counter or through vending machines. The Secretary believes that vending machines must be covered, since they are an unsupervised and easy source of access for younger smokers. Although controlling access by minors to tobacco products is not an easy process and may be particularly difficult with regards to vending machines, the Secretary believes reducing the availability of tobacco products as required by the law is an important public health measure. Beyond this, the Secretary does not propose specifying the provisions of the States' laws. However, appended to this NPRM is a copy of a model law the States may wish to consider. It should be noted that these proposed regulations in this NPRM would be considered minimum standards and would not supersede any State or local law or ordinance that is more restrictive regarding minors' access to tobacco products.

With regard to enforcement, the Secretary proposes that for the first applicable fiscal year and for subsequent fiscal years, the State (directly or through local government or private entities) must, at a minimum, enforce the law using both random and targeted unannounced inspections of both over-the-counter and vending machine outlets. Random, unannounced inspections must be conducted annually and must be conducted in such a way as to ensure a scientifically sound estimate of the success of enforcement actions being taken throughout the State. Thus, the State shall give due consideration to the methodological design of the inspection effort and the adequacy of the sample design. The sample must reflect the distribution of the population of those under 18 throughout the State and the distribution of outlets throughout the State. The sample must further reflect that, because of location (e.g. near schools) or other factors, some outlets are more likely to be used by minors. States are to ensure that the inspections occur at times when minors are likely to purchase tobacco products. Targeted inspections are to focus on outlets which have a history of prior violations.

In addition, the Secretary proposes that the State must have in place other well-designed procedures for reducing the likelihood or prevalence of violations. Examples of well-designed procedures include a tobacco sales or distribution licensing system similar to that used for alcoholic sales, a graduated schedule of penalties for illegal sales or distribution culminating in loss of license, controls on tobacco vending machines in locations accessible to youth, publication of the names of outlets making illegal sales, and use of local enforcement to supplement central enforcement. Such measures, the Secretary believes, will assist in ensuring that the law is enforced in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18.

Section 1926(b)(2)(B) of the PHS Act requires the State to annually submit to the Secretary a report describing, among other things, its activities for enforcing the law for the preceding year. The Secretary proposes that this report be filed with the State's application. For applications submitted for the first applicable fiscal year, the Secretary proposes that States be required only to submit a copy of the statute enacting the law described earlier and a description of the strategies to be utilized by the State for enforcing such law in the year for which they are applying for a grant. The Secretary is not proposing that for an application for the first applicable year the State be required to submit a description of how it had enforced the law in the previous year, if such law was in place, since section 1926 of the PHS Act does not require the States to have and enforce such law for fiscal year 1993 and, in some cases, fiscal year 1994. However, the Secretary strongly encourages the States to describe activities to enforce such a law during the previous year, if such law was in place. This information will be used only for informational purposes; it will not be used to determine compliance with any Block Grant requirements.

For subsequent years, the State is to describe its activities to enforce the law regarding sales or distribution of

tobacco products to minors, as well as the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought. The State is also to describe the extent of success the State has achieved during the previous year in reducing the availability of tobacco products to individuals under the age of 18. The Secretary proposes that such description include the results of the random and targeted unannounced inspections. The results of over-the-counter and vending machine outlet inspections are to be reported separately. In addition, the Secretary proposes that the State submit as part of its report a summary of how it went about conducting its random, unannounced inspections.

The Secretary proposes that the annual report be made public within the State and public comment be obtained and considered by the State prior to submission. The Secretary believes public comment is an excellent means of obtaining ideas on ways the enforcement measures may be improved.

Section 1926(c) of the PHS Act requires that, before making an award to a State under the Block Grant, the Secretary must make a determination as to whether the State has maintained compliance with the requirements to enact and effectively enforce a law against sale or distribution of tobacco products to individuals under the age of 18. As indicated by section 1926(a), the Secretary may award a Block Grant to a State for the first applicable fiscal year and each subsequent year only if the State has a law in place making it unlawful to sell or distribute tobacco products to individuals under the age of 18. In determining enforcement compliance, the Secretary proposes the following: The State must demonstrate that its random, unannounced inspections were conducted in a scientifically sound manner, and the data submitted by the State in the annual report must how that the percentage of the retailers or distributors involved in the random, unannounced inspections that make illegal sales do not exceed more than fifty (50) percent during the first applicable fiscal year, forty (40) percent during the second applicable fiscal year, thirty (30) percent during the third applicable fiscal year, and twenty (20) percent during the fourth applicable fiscal year and subsequent fiscal years.

If a State is not in substantial compliance with the above-mentioned criteria, the Secretary, in extraordinary circumstances, may consider a number of factors, including scientifically sound data showing that the State is making significant progress toward reducing use of tobacco products by children and youth, data showing that the State has progressively decreased the availability of tobacco products to minors, aggressive enforcement by the State through targeted inspections, composition of the outlets inspected, and the State's plan for improving the enforcement of the law in the fiscal year for which the State is applying for a grant. The Secretary encourages all States to provide the Department with related data showing that the State is making significant progress toward reducing use of tobacco products by children and youth.

The Secretary believes this compliance criteria will allow States time to develop and implement effective enforcement actions. Some studies in which unannounced inspections were used to measure access by minors to tobacco products show a significant reduction in the availability of such products when enforcement is strengthened. Feighery and Altman showed that the percentage of times in the unannounced inspections a minor was able to buy tobacco products over-the-counter, after stronger enforcement measures were taken, decreased from 71% to 24% over a two-year period, but a 1% increase in vending machine sales. Feighery, E., M.S., Altman, D., Ph.D., *et al.*, "The Effects of Combining Education and Enforcement to Reduce Tobacco Sales to Minors: A Study of Four Northern California Communities," Journal of the American Medical Association, Vol. 266, No. 22, pp. 3168–3171 (December 11, 1991). Altman and Foster showed a reduction from 74% to 39% in six months, with stronger enforcement, but no reduction in vending machine sales. Altman, D., Ph.D., Foster, V., M.P.H., *et al.*, "Reducing the Illegal Sale of Cigarettes to Minors," Journal of the American Medical Association, Vol. 261, No. 1, pp. 80–83 (January 6, 1989). Jason and Ji saw a reduction from 70% to 5% in over-the-counter sales from stores over a year and a half period. Jason, L., Ph.D., Ji, P., *et al.*, "Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors," Journal of the American Medical Association, Vol. 266, No. 22, pp. 3159–3161 (December 11, 1991). Further, Forster, Hourigan and McGovern found a reduction from 53% to 38% in over-the-counter access and a decrease from 82% to 80% in vending machine sales following an increased penalty for sale to minors. Forster, J., Ph.D., M.P.H., Hourigan, M., M.P.H., and McGovern, P., Ph.D., "Availability of Cigarettes to Underage Youth in Three Communities," Preventive Medicine, Vol. 21, No. 3, pp. 320–328 (May 1992). Finally, Forster, *et al.*, found that installation of locking devices on vending machines significantly reduced access from these machines and that removing children's access to vending machines by various types of bans greatly reduced or eliminated illegal sales. Forster, Jean L., *et al.*, "Vending Machines: Evaluation of a City Ordinance," American Journal of Public Health, Vol. 82, No. 9, pp. 1217–1220 (September 1992). These studies suggest that States using reasonable enforcement measures should be able to reduce the availability of tobacco products to minors. If States' experience indicates that States can reasonably achieve a failure rate lower than the 20 percent that is proposed to be required for the fourth applicable year, the Secretary may consider lowering the failure rate further. These percentages, however, all represent "safe harbors" rather than the Department's intended goals. The Department expects every State to attempt to achieve zero failure rates.

The determination of substantial compliance in enforcing the law is within the discretion of the Secretary, and the Secretary, in extraordinary circumstances, may, as indicated above, consider a number of factors. Nevertheless, if, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not incompliance with the regulations, the Secretary will reduce the amount of the allotment in such amounts as is required by section 1926 of the PHS Act.

The Secretary invites comments on the appropriateness of the proposed State performance criteria and on other strategies that may achieve the statutory objective in a more cost-effective manner. Alternative strategies or performance measures could include: (1) State-specific performance measures reflecting demographic variations; (2) measures developed by State consensus; (3) criteria that would require a certain percentage decrease in the failure rate of the random, unannounced inspections from year to year; (4) separate performance criteria for over-the-counter sales versus vending machine sales; (5) reliance on the more general Secretarial process; or (6) criteria based on different percentage reductions.

The Secretary also proposes that States not be permitted to use program funds to enforce this provision; however, they may use part of the 5 percent allowed for administrative expenses under section 1931(a)(2) of the PHS Act. The Secretary believes that enforcement, such as prosecution of

entities or individuals who illegally sell tobacco products to minors, is not a true prevention and treatment activity. The Block Grant Program funds may be used, however, to provide technical assistance to communities to maximize procedures for enforcing the law regarding tobacco as provided in § 96.125(a)(6).

Finally, the Secretary believes that decreasing access of tobacco products to minors is a very important health issue, and the Secretary welcomes comments on how to implement the requirements. The Secretary recognizes that tobacco is the single most preventable cause of disease and premature death, killing more than 434,000 Americans every year. It is responsible for more then $65 billion annually in health and economic costs. An estimated 3.7 million U.S. teenagers (16 percent) are current smokers and nearly 3,000 young people become regular smokers every day. More than half of all smokers start using tobacco before age 18. Despite the fact that it is illegal to sell cigarettes to minors in a vast majority of States, nearly one billion packs of cigarettes are sold each year to children under the age of 18. Studies have also found that smoking is positively correlated with the use of alcohol and other drugs, with escalation from cigarettes to alcohol the most prevalent pattern found. Accordingly, the Secretary believes that by requiring States to have laws prohibiting access to minors is a first step in reducing this national health problem.

To assist States in implementing the requirements of the statute, the Department will provide technical assistance after issuance of the final rule. We envision such assistance covering matters such as effective enforcement practices and the development of scientifically valid inspections, as well as acceptable alternative mechanisms for funding enforcement activities.

Economic Impact

Executive Order 12291 requires the Department to prepare and publish a Regulatory Impact Analysis (RIA) for any regulation that is likely to have an economic impact of $100 million or more, cause a major increase in costs or prices, or meet other threshold specified in the Order. For purposes of compliance, HHS treats a $100 million effect within five years of regulatory promulgation as requiring preparation of an RIA. In addition, as required by the Regulatory Flexibility Act, the Department prepares a Regulatory Flexibility Analysis (RFA) for any regulation which is likely to have a significant economic impact on a substantial number of small entities.

Teenagers purchase and smoke approximately 1 billion packs of cigarettes each year, with a retail value of over $1.5 billion (DiFranza, J.R. and Tye, J.B., "Who profits from tobacco sales to children?", JAMA, 1991, vol. 266, pp. 3149–3153). As little as a 7 percent total reduction in sales within five years would have an economic effect of $100 million. We believe that a much greater reduction than this is likely to occur, possibly $1 billion a year within three years, depending on the emphasis that the States place on enforcement of their statutes and other factors.

In addition to overall reductions in tobacco sales, enforcement will affect the retail market. The money which would have been spent on tobacco products will be spent on other goods and services. Much may be spent in the same stores which sell tobacco products. However, in some instances (e.g., sales from free-standing vending machines) it is not clear that alternative products will raise the same volume of revenue for the store. Therefore, the statute and the Department's final rule may have a significant effect on some small businesses that currently sell tobacco products to minors. Thus, based on this information, both a RIA and an RFA are required.

The following analysis, in conjunction with the remainder of this preamble, presents a combined Regulatory Impact Analysis and Regulatory Flexibility Analysis, in compliance with E.O. 12291 and the Regulatory Flexibility Act.

In this analysis, the Department focuses mainly on cigarette sales, which account for the overwhelming majority of tobacco product sales to youth. Almost all of the analysis is, however, equally applicable to cigars as well as snuff, chewing, and pipe tobacco.

Magnitude of Effects

For purposes of the analysis, the Department assumes that States will take actions which reduce tobacco sales to minors by between one-third and two-thirds within three to four years. The reduction could be larger or smaller, however, depending upon how many minors are able to get cigarettes from older youths who can legally purchase cigarettes, the emphasis that States place on enforcing the laws, and the ease with which minors can purchase cigarettes by going to other outlets including vending machines which are harder to monitor.

Because minors will, in some cases, find other sources of cigarettes, a one-third or two-thirds reduction in illegal sales volume will only occur if there is an even greater reduction in the percentage of outlets making illegal sales. (For purposes of this analysis, the term "outlet" means any location that sells at retail or otherwise distributes tobacco products to consumers, including (but not limited to) locations that sell such products over-the-counter or through a vending machine.)

The proposed rule would require that States bring the percentage of outlets making illegal sales down to 20 percent within four years or risk loss of drug abuse funds. Some States, perhaps most States, may be able to bring failure rates well into the single digit range. The Department is aware of one community—Woodbridge, Illinois—that used a tobacco vending license and other tools to reach a failure rate of well under 5 percent for all types of outlets. (Jason, Leonard A., *et al.*, "Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors," JAMA, pages 3159–3161, December 11, 1991, Vol. 266, No. 22.) In this same community, cigarette use by youth decreased by half, despite the availability of illegal sales outlets in adjoining areas near the enforcing community.

Thus, even though we are proposing to set the compliance level for States at 20 percent after four years, our expectation is that actual violation levels in most States will be driven far lower by new State enforcement programs, perhaps near the level achieved in Woodbridge. We do not know, however, either what level the States will on average achieve, or precisely how that level will translate into reductions in teen smoking. Therefore, our estimates of actual smoking reductions by youth range from one-third to two-thirds.

A reduction in teen smoking implies an almost equally large reduction in adult smoking, over time. Some evidence suggests that approximately 71 percent of adult daily smokers became daily cigarette smokers by age 18 (Office on Smoking and Health, unpublished data from the 1991 SAMHSA National Household Survey on Drug Abuse). If most of the reduction in youth smoking translated into non-smoking adults, there would be a corresponding reduction over time in tobacco use by adults. This effect would be over and above the effects of smoking cessation programs, education, family pressures, and other public and private influences on the prevalence of smoking.

Thus, while the Department estimates a probable reduction in cigarette sales is valued on the order of $500 million to

$1 billion a year (i.e., from one-third to two-thirds) in the near term, this reduction would translate into an annual multi-billion dollar effect over the long run, as each cohort of non-smoking youth ages into non-smoking adults.

Benefit Estimates

The benefits of reducing tobacco use lie primarily in reducing the costs created by tobacco. There is a considerable amount of literature on the costs of smoking. Probably the best of these studies—and certainly the most careful at distinguishing among costs to smokers themselves and costs to the rest of society—is "The Taxes of Sin—Do Smokers and Drinkers Pay Their Way?" (Manning, Willard G. *et al.*, JAMA, pages 1604–1609, March 17, 1989, Vol. 261, No. 11).

This study estimated the net present value cost for 1986 to members of society other than the smokers of cigarettes, by comparing the excess costs of services used by smokers to the taxes and premiums paid by smokers. Several estimates of the cost were calculated, based on varying assumptions and discount rates. The best estimate for our purposes is a "present value" (discounted) cost of $0.39 per pack to persons other than the smokers themselves, under the assumption of a 5 percent discount rate applied to future costs. This cost contained the following component costs per pack: Employer and taxpayer share of excess medical bills incurred by smokers ($0.26); sick leave and group life insurance subsidies ($0.06); lost taxes on smokers' unrealized earnings ($0.09); the value of lives lost to passive smoking ($0.14); the material cost of fires caused by smoking ($0.02); and the value of lives lost to fires caused by smoking ($0.09). These costs were then offset by the reduction in pensions and nursing home benefits paid to smokers due to their premature deaths (−$0.27).

This study omitted several major components of external costs, such as cleaning costs in buildings where smokers are employed. Most importantly, it made no allowance for the cost of low-birthweight infants. Over 200,000 such infants are born each year in the United States. These 6 percent of all births account for over 50 percent of all acute inpatient infant care costs. (These data come from Schwartz, Rachel M., "What Price Prematurity?", pages 170–174, Family Planning Perspectives, August 1989, Vol. 21, No. 4.) The risk of having a low-birthweight infant doubles if the mother smokes. A recent study estimated the effects of smoking-induced perinatal problems to include 2,250 excess perinatal deaths and about 39,000 excess low-birthweight infants (one-half of these subsequently hospitalized in intensive care units). (Marks, James S. *et al.*, "A Cost-Benefit/Cost-Effectiveness Analysis of a Smoking Cessation Program for Pregnant Women", American Journal of Preventive Medicine, pages 282–289, Vol. 6, No. 5, 1990.) Extrapolating from the data in this study, the total costs of tobacco use by expectant mothers in 1989 were about $500 million for use of neonatal intensive care units, about $500 million in present value of future long-term care costs for disabled newborns, and about $8.7 billion for the value of 2,250 lost lives (using the same $1.66 million value for a lost life as in the paper written by Manning *et al.*). On the same discounted cost per pack basis used by Manning *et al.*, these costs would add at least 15 cents a pack more.

Thus, in 1989 the net external costs borne by non-smokers exceeded 50 cents for every pack of cigarettes sold (lost earnings and medical care costs borne by smokers themselves were shown by Manning *et al.* to be over $1 a pack). In 1989, this was equivalent to over one-third of the then-current price of cigarettes.

Translated into the terms of this initiative, the $½ to $1 billion annual reduction in cigarette purchases by youth that the Department postulates achieving in three or four years is worth one-sixth to one-third of a billion dollars annually to the rest of our society (in addition, of course, to the $½ to $1 billion that youth save from not purchasing cigarettes).

Over the longer run, and assuming that adult smoking is reduced correspondingly, the benefits of better law enforcement will be many billions of dollars annually. We do not calculate a precise estimate because there are so many uncertainities as to future outcomes. None of these uncertainties, however, are likely to reduce our estimates of benefits.

Costs

The primary cost of improved enforcement lies in enforcement costs themselves (see section below for estimates of transfer and other effects). The Department has no good data on the costs of enforcement because so little has been attempted in the past and because new methods may be needed. However, these costs need not be substantial in relationship to other costs of State and local law enforcement, or to other duties faced by retail business.

The Department assumes, for purposes of this cost analysis, that the upper end of possible enforcement costs will result if each State adopts the Model Law recommended by HHS. This Model Law is appended to this NPRM.

An HHS Inspector General's report, also appended here, contains an appendix showing the elements of each State's enforcement scheme in 1991, using headings corresponding to many elements of the Model Law. For example, 22 States have some form of vending machine restriction, and 14 provide for revocation of a license to sell tobacco products if illegal sales are made to minors. Most of these restrictions are relatively new and are not reflected in the studies summarized earlier in the preamble showing that about two-thirds of outlets sell tobacco products illegally.

The Model Law represents a substantial enforcement effort compared to current practice, but nowhere near the greatest effort possible. The Model Law would require a licensing apparatus to be set up, stores to be notified of their obligations, hearing procedures to be developed, inspections organized, fines to be levied, and the like. Even if a State were to piggyback this system on top of an alcohol licensing and enforcement system, it would require a staff of one or two dozen people and an annual budget of approximately $1 million. Across all jurisdictions, this implies costs on the order of $50 million for an effective enforcement effort.

The most cost-effective method of compliance enforcement appears to lie in well-designed "sting" operations in which clearly underage youth without false identification attempt to make illegal purchases under adult supervision. Assuming that 200–400 stings a year are conducted in the average State, that each sting requires 10 person-hours of participant time (for training, travel, etc.), and that the average hour is valued at $10, the total national cost of conducting stings would be $1–$2 million annually. Individual businesses may have to train staff, post signs, check for compliance, relocate vending machines, and the like. Annual compliance costs could average as much as $100 a retail store (much less in small stores, much more in the larger stores). The largest component of this would be time spent in instructing sales clerks that they must avoid selling to minors and in dealing with occasional lapses. The average store has only about 12 employees, but assuming that 1 million outlets sell cigarettes or other tobacco products, national compliance costs might reach $100 million.

Counting both public and private costs, the national cost total for careful enforcement using this model would be

on the order of $150 million. Assuming that States financed their costs by licensing fees, as suggested by the Model Law, the net budgetary cost to States would be close to zero, and retail outlets would bear the entire $150 million annually.

These gross cost estimates include no offset for present enforcement efforts. However, studies have consistently shown that many businesses do not sell tobacco products to minors. Effective staff training may already be in place in a third or more of all businesses. Most States have at least some pieces of enforcement machinery in place, even if none has a comprehensive scheme (see Appendix A of the appended Inspector General report). Therefore, the *net* costs of stringent enforcement efforts may be a third less, perhaps $100 million a year rather than $150 million, taking into account current levels of effort.

Enforcement costs could also be reduced if States undertook less comprehensive enforcement actions. For example, an "informational" strategy of publishing in local newspapers the names of stores caught selling illegally to minors might be effective in signalling consumers who would wish to steer their patronage to stores which do not violate the law. Presumably, outlets selling tobacco as one of many product lines would police themselves vigorously to avoid this much larger loss of business. Concentrating enforcement resources and levying large, multiple fines on repeat offenders might also prove less costly than creating a moderate, graduated penalty system as set forth in the Model Law. The compliance standard proposed in this NPRM—reducing the proportion of outlets selling illegally to 20 percent or less within 4 years—could probably be met by efforts less substantial than adoption of the entire model law. This could reduce gross enforcement costs to near the $100 million level, and net enforcement costs even lower. It is unlikely that net costs could go below $50 million, however, because the major costs arise from actions which outlets would have to take to make a serious reduction in illegal sales, regardless of precise target level and regardless of the precise enforcement approach used by the State.

As discussed further below, there may be some additional costs due to market dynamics over time. For example, some stores that barely break even on tobacco sales may decide to drop this product line rather than spend resources on efforts to prevent illegal sales of tobacco to minors, such as paying a licensing fee and training staff. Some vending machines currently located in businesses that cater to minors may have to be relocated or withdrawn prematurely from use, and vending machine sales will drop. Some adult consumers will be inconvenienced if fewer outlets sell cigarettes. The Department has no basis at this time for estimating the magnitude or actual costs of these effects. However, the Department sees no reason to expect that these will exceed a few million dollars a year.

These are very imprecise estimates. The Department welcomes comments on the estimates and suggestions for improvement. Note, however, that States remain free to devise any enforcement approaches that they find cost-effective. The Department encourages the public to provide us information on effective and economical approaches which can be shared with the States.

Comparison of Benefits to Costs

Based on the estimates above, the Department expects that in three or four years net enforcement costs on the order of $50 and possibly $100 million will generate social benefits on the order of one-sixth of a billion dollars and possibly one-third of a billion dollars, a return of potentially 2 or 3 to 1, depending on the cost estimate and actual effects on smoking by youth. The lower end of the range of both costs and benefits is most likely to arise from serious but modest State efforts, and the higher end of both from more substantial State efforts.

Over the longer run, the Department expects enforcement costs to decrease slightly and benefits to increase greatly. Costs will decrease as compliance approaches 100 percent because there will be fewer violations, and fewer enforcement actions. Benefits will increase because as larger cohorts of non-smoking youth pass into adulthood without addiction, smoking is expected to drastically decrease. The packs of cigarettes affected by these regulations are the packs that cause addiction. A smoking reduction now will itself cause a smoking reduction later. Thus, the benefits from not smoking these particular packs of cigarettes are likely to be many times the benefits from not smoking the "average" pack of cigarettes studied by Manning, *et al.*

Distributional and Transitional Effects

The estimates above deal with the ultimate effects of smoking reductions and activities directed toward reductions. There are additional economic consequences which are not part of these calculations but which are of concern.

First, this law enforcement effort will increase jobs and profits in the economy. When a teenager does not spend $1.50 or $2 for a pack of cigarettes, there is no loss to the economy. The money is spent on some other good or service instead. True, some particular jobs (ultimately, those in cigarette, cigar, snuff, and chewing and pipe tobacco factories, and in cancer wards of hospitals) will be affected by any large scale redirection of resources away from tobacco purchases. However, other jobs will be created instead. For example, if the money is spent on chewing gum and music tapes, there will be increases in jobs in gum factories and music studios. In fact, the excess of benefits over costs involved represents a pure gain to the economy, much of which will show up in increased productivity and job growth.

Second, there will be negligible adverse effects on the great majority of retail outlets. It is true that stores that currently sell tobacco products to minors will lose sales in the short run. These sales may or may not be offset by increases in sales of other items. However, with the single exception of vending machines (discussed below), we believe that these effects on sales will be small. There are approximately 1½ million retail sales outlets in the United States, and about two-thirds of these sell tobacco products (all data in this paragraph are obtained from the Statistical Abstract of the United States 1992, table 1284, p. 761). On average, tobacco products represent 5 percent of total sales in those outlets that sell tobacco. In 1987, according to the Statistical Abstract, retail establishments sold $23 billion of tobacco products (at current prices this number would exceed $30 billion). The potential $1 billion reduction (assuming a two-thirds reduction in smoking by youth) that the Department estimates in the near future represents less than 5 percent of that amount, and one-fourth of 1 percent of total sales in stores selling tobacco products. Considering that in many if not all cases the money not spent on tobacco will be spent on other products in the same stores, the negative economic effects on sales, costs, and profits will be negligible. Moreover, some outlets will actually increase tobacco sales as others decide to drop cigarettes and various forms of chewing tobacco as marginal product lines.

Third, the Department expects significant drops in vending-machine sales of tobacco products because of the actions that will have to be taken to prevent sales to minors from these devices. The access studies have shown

that vending machines provide by far the easiest method for youth to make purchases. For the youngest minors, they are often the only easy sources of purchase. A study for the vending machine industry shows that only 23 percent of smoking youth now use vending machines often or occasionally (Response Research, Inc., "Findings for the Study of Teenage Cigarette Smoking and Purchasing Behavior," June/July 1989). However, in the future this percentage would rise greatly—perhaps close to 100 percent—if enforcement eliminated other sources of illegal sales but left vending machines available to youth.

There are several options for preventing illegal sales from vending machines, including installing locking devices on tobacco vending machines—which allow use only after an employee verifies that the prospective purchaser is not under-age, and removing tobacco vending machines from locations where youth can legally approach them (e.g., removing them from all locations except bars where minors are not permitted). The experience of St. Paul, Minnesota, illustrates the difficulty of enforcement options short of bans: A year after enforcement began, about 30 percent of merchants had not installed locking devices, and even where these were installed, employees allowed illegal purchase about 40 percent of the time. On the other hand, communities that have banned these machines altogether show complete or near complete compliance. (See Forster, Jean L. *et. al.*, "Vending Machines: Evaluation of a City Ordinance," American Journal of Public Health, pages 1217–1220, September 1992, Vol. 82 No. 9). Quite apart from compliance, the St. Paul experience shows that locking devices are inconvenient to stores, cost as much as $100 a machine, and that a quarter of the merchants either switched to over-the counter sales or dropped tobacco vending when faced with a requirement for locking devices.

Based on these data, the Department would expect that States will face significant challenges in complying with the new law unless they impose strict controls on tobacco vending machines in locations accessible to minors. Data from the vending-machine industry sheds some light on the consequences of partial or total bans. (See the Statement of Richard W. Funk on behalf of the National Automatic Merchandising Association, Tobacco Issues (Part I), Hearings before the Subcommittee on Transportation and Hazardous Materials of the Committee on Energy and Commerce, U.S. House of Representatives, July 25, 1989, Serial No. 101–85, pages 240–245.) This testimony indicates that there are at least 1,400 vending-machine companies, of which 1,000 operate some 370,000 cigarette-vending machines, with average annual revenues of about $4,000 per machine. For the entire industry, including companies which do not sell tobacco, these machines account for 9.5 percent of vending sales in dollars and 3.6 percent of vending sales in units (taking into account taxes, it appears that vending sales represent about 7 percent of non-tax revenue for all these companies, and 10 percent for those companies selling tobacco products). About one-third of these machines are located in bars or cocktail lounges, but many are in motels, colleges, restaurants, and other locations readily accessible to youth. Depending on what actions States decided to take, two-thirds or more of these machines might be affected by ban or locking device. Assuming, for purposes of this analysis, that two-thirds of these machine were eliminated over a phased, three-year period, and that there were no offsetting increases in tobacco sales from the remaining machines, by the end of the third year 1,000 companies would face an annual loss of sales averaging about 7 percent of non-tax revenue (7 percent is ⅔ of the 10 percent discussed above). The sales reduction could be less than this or greater than this, depending on the precise actions taken by the States. It would also vary significantly from company to company. Companies could, of course, take actions to overcome such losses, such as replacing tobacco products with other products. States could mitigate these effects by phasing, banning only locations accessible to youth, and allowing use of locking devices. The Department solicits comments on this issue and on whether any other alternatives would be cost-effective.

Alternatives

Elsewhere in this preamble the Department has requested comment on several modifications to our proposed regulations. The main alternative the Department has considered and has temporarily rejected was to impose a more stringent standard on the States. There is a strong line of argument that near-100 percent compliance can be achieved over some period of time. One community, the city of Woodbridge, Illinois, essentially ended illegal sales to minors, apparently by using a licensing law (not rigidly enforced) and the part-time efforts of one police officer. (See Jason, Leonard A. *et al.*, "Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors," JAMA, pages 3159–3161, December 11, 1991, Vol. 266 No. 22). However, it would not be prudent to rely on the experience of one community in setting a national policy, and even in Woodbridge success took a number of years to achieve. Moreover, States have not had consistent success in enforcing laws against sale of alcohol to minors (see "Youth and alcohol: Laws and Enforcement," Office of the Inspector General, HHS, September 1991). Tobacco-law enforcement may turn out to pose similar hazards. Therefore, the Department believes that risking an error which would force us to take vitally needed drug-treatment funds from a State despite a serious enforcement effort is too dangerous at present. Hence, on an interim basis, and until the Department and the States gain some experience from serious State-wide efforts at enforcement, we have allowed the States both time and leeway to achieve compliance. Nonetheless, we welcome comments addressed to the feasibility and fairness of a stricter standard, such as penalizing States in which outlets with illegal sales exceed 20 percent in the third year, or 20 percent in the fourth year and 10 percent in the fifth year.

Second, the Department also considered specifying particular enforcement measures that States must take, such as requiring that stores illegally selling to minors lose a license to sell tobacco products, or imposing strict controls on vending machine sales of tobacco products. However, the same uncertainty that would make a near-100 percent compliance standard imprudent until we have more information appears to make imposing uniform processes on all States unwise. Furthermore, the Department believes that governors and States should have maximum flexibility to devise their own solutions. The Model Law represents the Department's best judgment as to cost-effective steps States might take, but the current state of knowledge does not necessarily justify imposing its components as requirements.

Third, the Department considered more stringent approaches to compliance measurement. As indicated above, stings are a low-cost and highly effective method of determining which outlets violate the law. The Department considered requiring States to conduct a minimum number of stings, such as 1 sting annually at 50 percent of all sales outlets. However, we decided that it would be premature to force a particular standard upon all States.

Fourth, the Department considered creating a special review process by which private groups could bring the

results of their own unannounced inspections directly to our attention, if they believed that States were not honestly reporting progress. This was rejected because the public is free to provide such information to the Department for its consideration.

Finally, a State could reduce use by minors, as well as increase State revenue, by placing higher taxes on cigarettes. Research has shown that youth are particularly sensitive to tobacco prices (Grossman, M., Coate, D., Lewit, E.M., and Shakotko, R.A. "Economic and other factors in youth smoking." Washington, DC: National Science Foundation; 1983. Final Report, Grant No. SES–8014959; and Lewit, E.M., Coate, D. and Grossman, M. "The effects of government regulations on teenage smoking. Journal of Law and Economics. Vol. XXIV, No. 3, pp. 545–569 (December 1981)). Thus, a State may choose to impose taxes so high as to discourage most youth purchases.

The Department requests comments on these and any other alternatives which might reduce costs or increase benefits.

Paperwork Reduction Act

This proposed rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Minors' Access to Tobacco—42 CFR 96.122—NPRM.

Description: Data to be reported is required by 42 USC 300x–26 and will be used by the Secretary to evaluate State compliance with the statute, to report to Congress as required under 42 USC 300x–59, and to publish special analytic studies from time to time.

Description of respondents: State or local governments.

Estimated Annual Reporting Burden:

Section	Annual number of respondents	Annual frequency	Average burden/response	Annual burden hours
Application/Annual Report: 45 CFR 96.122(f)(5) and .130(d)	60	1	30 hrs	1800

We will submit a copy of this proposed rule to OMB for review of these information collections. Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing burden, may be sent to the agency official whose name appears in the FOR FURTHER INFORMATION section above, and to Allison Eydt, SAMHSA Desk Officer, Office of Information and Regulatory Affairs/OMB, room 3001, 725 17th St., NW., Washington, DC 20503.

Appendix A to Preamble—Model Sale of Tobacco Products to Minors Control Act; A Model Law Recommended for Adoption by States and Localities To Prevent the Sale of Tobacco Products To Minors

U.S. Department of Health and Human Services, May 24, 1990

Introduction

The great majority of states prohibit sale of tobacco products to minors. Yet over one million teenagers start smoking each year, and minors buy about one billion packs of cigarettes each year. Because nicotine is an addicting drug, a minor who starts smoking is likely to be a lifelong customer—and one in four will die prematurely of lung cancer or other smoking-related disease. Illegal tobacco sales dwarf illegal alcohol and hard drug sales to minors, and the resulting mortality is many times greater—390,000 deaths a year. These are preventable deaths, and many of them occur because youth can obtain tobacco products with ease. Over eighty percent of teenagers correctly believe that it is very easy for them to buy cigarettes.

Access of minors to tobacco is a major problem in every state of the Nation. About three-fourths of the million outlets which sell cigarettes to adults also sell cigarettes to minors. These stores ignore the laws of their states because enforcement is almost non-existent. Many retailers are even unaware that such sales are illegal. Yet there are straightforward enforcement approaches which can eliminate almost all sales to minors while yielding revenues to cover the cost of enforcement. Teenage smoking can be greatly reduced without disruption either to governments or to sales to adults.

Data on the nature and extent of the enforcement problem, and information on successful community efforts to prevent illegal sale of tobacco products to youth, are presented in the report of the Office of the Inspector General titled "Youth Access to Cigarettes," dated May, 1990. Additional information on this issue can be obtained from the Office on Smoking and Health, within the Centers for Disease Control of the Public Health Service.

The Department of Health and Human Services has reviewed options for improving enforcement. The approach we have developed is embodied in a draft model law. We recommend that each of the 50 states enact this model. No state now uses all of the tools needed to make enforcement effective. In states which are not immediately willing to adopt the model law, counties and cities can enact most features by ordinance and prevent children's access to tobacco products.

No enforcement scheme is perfect. Many of those who are already addicted will find ways to get tobacco to meet their craving for nicotine. But for most teenagers, easy access to tobacco products and addiction can be eliminated. For others, reductions in frequency and numbers of cigarettes smoked will decrease the likelihood of becoming long-term smokers.

Summary of the Model Law

The model law has several key features. These are summarized below and discussed further in the section-by-section analysis. Some of these features can and should be modified by each state to reflect its internal organization and processes. But the underlying approaches, however implemented, are key to effective enforcement. The model law would:

- Create a licensing system, similar to that which is used to control the sale of alcoholic beverages, under which a store may sell tobacco to adults only if it avoids making sales to minors. Signs stating that sales to minors are illegal would be required at all points of sale.
- Set forth a graduated schedule of penalties—monetary fines and license suspensions—for illegal sales so that owners and employees face punishment

proportionate to their violation of the law. Penalties would be fixed and credible. Those who comply would pay only a license fee.

- Provide separate penalties for failure to post a sign, and higher penalties for sales without a license.
- Place primary responsibility for investigation and enforcement in a designated state agency, and exclusive authority for license suspension and revocation in that agency, but allow local law enforcement and public health officials to investigate compliance and present evidence to the state agency or file complaints in local courts.
- Rely primarily on state-administered civil penalties to avoid the time delays and costs of the court system, but allow use of local courts to assess fines, similar to traffic enforcement. This would provide flexibility to both state and local authorities to target enforcement resources. (An illegal sale could not result in two fines, but a local conviction would be reported to the state and count towards possible license suspension).
- Set the age of legal purchase at 19. This is higher than under many existing state tobacco statutes, but lower than the age for alcohol. States may wish to consider age 21, because addiction often begins at ages 19 and 20, but rarely thereafter.
- Ban the use of vending machines to dispense cigarettes, parallel to alcohol practice and reflecting the difficulty of preventing illegal sales from these machines. (This is another area where states should examine options carefully; allowing sales in places not legally open to minors, or use of store-controlled electronic enabling devices, may be acceptable alternatives. States could also consider phasing of the ban to minimize disruption.)
- Contain a number of features to minimize burdens on retail outlets: Requiring identification only for those who are not clearly above the age of 19, allowing a driver's license as proof of age, setting a nominal penalty for the first violation, disregarding one accidental violation if effective controls are in place, having the state provide required signs, and setting license fees lower for outlets with small sales volume.

The model law does not explicitly address several topics, including possession of tobacco by minors, earmarking revenues for enforcement, allowing local ordinances to be stronger than the state law, and authorizing use of minors in "sting" operations to detect violations. This does not mean that states should not consider including such provisions, as discussed further below, but that we did not believe them necessary or appropriate within the statute. For example, use of stings will be vital to effective enforcement of this law, but like other investigative procedures need not be detailed in statute.

In summary, the model law attempts to create workable procedures which will provide retail outlets the incentive and tools to refuse to sell to minors, as already required by law in almost all states. Stores which comply will have no burden other than a licensing fee and, in some cases, replacement of vending machine by over-the-counter sales. Compliance by responsible stores, which would quickly become the great majority, will enable state and local authorities to concentrate enforcement efforts on a small number of recalcitrant outlets. The few stores which are unable or unwilling to prevent sales to minors may elect to stop carrying tobacco products, or will lose the license to sell tobacco products. Adults will continue to be able to buy cigarettes and other tobacco products at a wide range of outlets.

Ultimately, the effectiveness of this legislation depends on the willingness of concerned citizens to report violations to authorities who are responsible for taking investigatory and, if necessary, enforcement action. We are sure that enough citizens are concerned; the model law simply provides an effective and efficient system to handle their complaints, filling voids in almost all state enforcement schemes. Indeed, merely putting an effective enforcement mechanism in place is the single most important reform. The better the mechanism, the less likely it will have to be used.

Section-by-Section Analysis

Section 1 states the title of the bill, here suggested as "Sale of Tobacco Products to Minors Control Act."

Section 2 presents appropriate findings of fact. Most important, in this context, are that tobacco products are addicting, that addiction almost always starts in teenage years, and that smoking causes death on a large scale. States exploring these issues may wish to consult recent reports of the Surgeon General, which summarize and synthesize the large body of knowledge extant.

Section 3 establishes a state "Office of Tobacco Control" and the key powers of that office. Whether that office would best be located in the Department of Health or the state alcohol sales licensing agency, or established as an independent agency, is uniquely a matter for state-specific decision.

Two key provisions of section 3 require the Office to operate a licensing system and to prepare and distribute to licensed outlets signs concerning sales to minors. Requiring a license for sale of tobacco products conditions the privilege of sale on compliance with the law. Later in the bill heavy penalties are provided for any sales (or free distribution) to any persons without such a license. Failure of licensed outlets to prevent sale to minors leads to financial penalties and revocation of the license. The text is worded to allow licensing mobile vendors—it is not the purpose of the law to harm any small businesses.

The state agency is empowered to investigate and enforce the law. The investigative and enforcement techniques are not specified in detail, since these are generally routine and well-established administrative functions. However, the most powerful technique for both investigation and enforcement will in most circumstances involve testing compliance by sending underage persons to stores which sell tobacco products—especially those which have been reported for illegal sales. A request to purchase cigarettes is then made and the sale, if consummated, provides evidence of violation of the statute. Properly designed and supervised by state or local officials, such testing can readily and inexpensively establish whether an outlet violates the law, and provide the basis for a formal complaint and enforcement decision. States and communities now using this approach often hire teenagers to perform this function as temporary employees, to provide insurance protection to the teenagers and assure proper supervision. Depending on other law (e.g., whether possession by minors is illegal) and court rulings, some states may wish to authorize this approach explicitly. Tennessee does so now.

The model law provides that local officials may also investigate violations, and either assist the state agency by bringing evidence before it or bring cases directly in local courts. Local officials in some cities and counties will have the resources and expertise to contribute significantly to enforcement. Such contributions will not only speed enforcement directly, but allow the state agency to allocate its resources where they are most needed. In general, the assumption of the bill is that there will be substantial state and local cooperation, similar to the kinds of arrangements used for traffic violations. A varied local role in investigation and

enforcement will also be useful in identifying techniques which are particularly effective within each state.

The license fee is suggested as $300 for most stores but only $50 for stores with a volume of tobacco sales below $5,000 a year. This should provide enough revenue to make enforcement budget-neutral, while protecting small businesses from what might be perceived as an onerous cost in relation to sales. Of course, enforcement costs will not necessarily vary by size of outlet and a state could balance these considerations differently. Regardless, a state could use additional distinctions (e.g., by size, or whether licensed to sell alcoholic beverages) or set these fees higher or lower, depending on other licensing systems, its revenue goals, and whether it wishes the tobacco control system to be fully financed through license fees. We have not suggested earmarking revenues to accrue directly to the Tobacco Control agency rather than the general fund, but some states might wish to do this.

Section 4 requires license holders to display the license and sign (section 7 provides a monetary penalty for failure to display them). A visible sign provides continuing notice to all—sales clerks, underage customers, and older customers—as to the law's requirements and the store's declared willingness to comply. The sign also aids clerks in refusing to sell to underage customers.

Section 5 provides that both licensees and their employees may not sell or give tobacco products to individuals known to be under the legal age, or to individuals who are not clearly older or who do not have appropriate proof of age such as a driver's license. It also bans entirely sales of "broken packs" (cigarettes are sometimes sold one-by-one to minors), vending machine sales, and sales other than at licensed outlets.

Two of these provisions raise significant questions. First, why age 19, when alcohol purchase is illegal below age 21 and most states now ban tobacco sales at age 18 or below? To the significant extent that tobacco, like alcohol, has been an adult privilege to which many teenagers turn at the first legal opportunity, raising the age will postpone such exposure until the adolescent has reached an age at which mature judgment has a better chance of overcoming the intense pressure to experiment with "adult" behaviors. This postponement may be even more important for tobacco than for alcohol, since nicotine is rapidly addicting. Even a month or so of regular smoking is likely to create a lifelong addiction for most persons. Also, a realistic appraisal must concede that most teenagers a year younger than the legal age can readily obtain tobacco products from friends who can legally purchase them. Thus, an age 18 limit exposes most 16 and 17 year old youth to an easily exercised temptation. Only if the age limit is at least 19 can the state be confident that most high school students will not have ready access to tobacco. Of course, a few teenagers will be able to obtain such products from family or older friends; the issue here is ready access for *most* teenagers. Finally, only if the age limit is at least 19 will smoke-free school policies be fully enforceable—no students will have legal access to tobacco products. States are encouraged to consider age 21; this will parallel alcohol practice and also protect older teenagers during years in which many are still vulnerable.

Second, why ban vending machine sales? The basic problem with these sales is that they do not require human intervention—the active participation of a clerk who sells the product only after observing or checking age. Vending machines are often used now by adolescents, and vending machines will nullify otherwise effective action preventing over-the-counter sales. Sales personnel at a register cannot effectively police even nearby machines while serving other customers. Individual states may wish to consider two variations: Allowing vending machine sales in places which minors may not legally enter at all, or electronic disabling devices which require positive action by a clerk to activate. However, Utah found that disabling devices were ineffectual in practice. Finally, states could consider allowing a grace period for elimination of these machines to minimize disruption.

Section 6 prohibits unlicensed sale or distribution of tobacco products. It allows exceptions for distribution by relatives or friends on private property not open to the public (e.g., the home) and for wholesale distribution. Section 7 provides for a find of up to $1,000, and imprisonment of up to 30 days, for unlicensed sale or distribution.

Section 7 establishes two types of financial penalties for violations committed at licensed outlets—civil money penalties and fines. These financial penalties apply both to license holders and sales personnel. Sales personnel are subject to penalties both to emphasize their responsibility under the law and to protect employers against the carelessness of employees. Financial penalties rise progressively with repeated offenses, and are designed to avoid penalizing compliant stores for truly isolated lapses occurring over wide periods of time. A license holder may also avoid one penalty in any two year period by showing that an effective system to prevent violations is in place, i.e., that the sale was a true lapse. The suggested penalty for a first offense is $100 and no suspension; the fourth violation brings a $1,000 dollar fine and a 9 to 18 month suspension of the license. In effect, law abiding stores have nothing to fear; persistent offenders will lose the right to sell tobacco products to adults.

The Department of Health and Human Services has found that use of civil money penalties assessed through administrative law judges rather than the courts has greatly improved the effectiveness and efficiency of enforcing various statutes related to fraud and abuse. The capacity of the Federal criminal justice system is so stretched that without the alternative of civil money penalties, many "minor" frauds or other crimes simply could not be prosecuted. States face similar constraints. Using civil money penalties is not an "either-or" choice—under existing Federal law, *both* civil and criminal remedies are available and the choice of which to use in particular cases greatly facilitates effective enforcement. The advantage of this added tool is not only case-specific but systemic: The mere existence of a credible and workable civil money penalty raises the potential cost of statutory violations, and thereby deters violations.

Although the model law emphasizes civil money penalties, fines are authorized as well to provide an enforcement role for both state and local authorities and to provide flexibility of approach. For any particular instance of noncompliance, only one financial penalty may be assessed. Any penalties assessed at the local level must be reported to the Tobacco Control agency so that this agency can accumulate records needed for license suspensions.

Thus, the model law allows the following kinds of flexibility:

- The Tobacco Control agency may develop a backlog of cases nonrenewal. Starting with the second offense, there are progressively steeper periods of suspension: Seven days for the second offense, up to 9 to 18 months for the fourth violation. Section 8 also provides for suspension of licenses for all outlets of a chain if more than three outlets have violated the law more than three times in a two year period. This provision creates a strong incentive for retail chains to ensure compliance by all of their outlets.

Other Matters. The model law does not prohibit purchase or possession of tobacco products by minors. Some states

and communities already prohibit these and others may wish to consider this. We left out such provisions because in our judgment they would be far harder to enforce—and of less relevance to preventing widespread availability—than prohibitions on sales. Such provisions also raise such issues as use of minors as sales clerks; establishment of enforcement procedures; establishment of penalties (small fines, community service, or attending smoking cessation programs are commonly proposed); and possible need to exempt purchase by minors in supervised "sting" operations. Regardless, any underage person smoking in public would indicate a potential violation of the sales ban even absent a possession or purchase law. Authorities could investigate the source of these tobacco products whether or not purchase or possession were banned. States willing to invest in enforcement for *both* sales and possession should consider adding possession prohibitions.

Finally, while the model law provides for a significant local role in enforcement, it does not provide for independent local statutes. States might wish to empower municipalities to levy higher fines or otherwise exercise some independent authority. The worst possible outcome would be to enact a state statute which failed to establish an effective and workable enforcement system while preempting local governments from filling this void.

Conclusion

Existing state laws prohibiting sales of tobacco products to minors have largely been ineffectual. This enforcement failure is hypocritical and contributes to a scoff-law environment. Unlike some other law enforcement problems, this is neither inherent or insuperable. Eliminating virtually all sales to minors does not even present particularly difficult enforcement problems. It simply requires workable procedures which create swift and sure sanctions for violations, with minimal cost or inconvenience to retailers and adult customers. There is a large and articulate body of citizenry—including a large proportion of teenagers and retailers—who understand the gravity of tobacco consumption as a public health problem and who would welcome reasonable laws. Enactment and responsible implementation of this model law is the single most important reform to improve the health of its citizens that any state could undertake in the decade of the 1990s.

Model Sale of Tobacco Products to Minors Control Act

Section 1. *Short Title.*

This Act may be cited as the "Sale of Tobacco Products to Minors Control Act".

Sec. 2. *Findings.*

The Legislature finds that——

(1) Approximately 390,000 Americans die each year of diseases caused by cigarette smoking,

(2) The Surgeon General of the Public Health Service has determined that smoking is the leading cause of preventable death in this country,

(3) Nicotine in tobacco has been found by the 1988 report of the Surgeon General, *The Health Consequences of Smoking: Nicotine Addiction* to be a powerfully addictive drug, and it is therefore important to prevent young people from using nicotine until they are mature and capable of making an informed and rational decision,

(4) Most adults who smoke wish to quit, a majority of current adult smokers have tried to quit without success, and one-half of all teenagers who have been smoking for five years or more have made at least one serious but unsuccessful attempt to quit,

(5) Every day more than 3,000 minors begin smoking,

(6) One-half of smokers begin before the age of 18, and 90 percent begin before the age of 21, and

(7) Minors spend more than one billion dollars on cigarettes and other tobacco products every year.

Sec. 3. *Office of Tobacco Control.*

(a) *Establishment of Office.*—There is established in the Department of _____ an Office of Tobacco Control. The Office shall be headed by a Director.

(b) *Functions of Director.*—The Director shall—

(1) Issue licenses for the sale of tobacco products,

(2) Provide without charge signs (concerning the prohibition on sales to individuals under 19 years of age) that meet the requirements of subsection (d) to persons licensed to sell tobacco products,

(3) Investigate (concurrently with other State and local officials) violations of sections 4 through 6,

(4) Enforce civil money penalties under section 7, (5) enforce (concurrently with other State and local officials) fines under section 7, and

(6) Bring license suspension, revocation and nonrenewal actions under section 8.

(c) *Licenses.*— (1) A license for the sale of tobacco products shall be issued to a specific person for a specific outlet (a fixed location or mobile unit) and shall be valid for a period of one year.

(2) The annual fee for a license is $50 for an outlet whose annual volume of tobacco sales is less than $5000, and $300 for an outlet whose annual volume of tobacco sales is $5000 or more.

(d) *Signs Concerning Sales to Individuals Under Age 19.*—Signs to be provided under subsection (b)(2) shall—

(1) Contain in red lettering at least one-half inch high on a white background "IT IS A VIOLATION OF THE LAW FOR CIGARETTES OR OTHER TOBACCO PRODUCTS TO BE SOLD TO ANY PERSON UNDER THE AGE OF 19", and

(2) Include a depiction of a pack of cigarettes at least two inches high defaced by a red diagonal diameter of a surrounding red circle.

Sec. 4. *Display of License and Signs.*

A person that holds a license issued under section 3(b)(1) shall—

(1) Display the license (or a copy) prominently at the outlet for which the license is issued, and

(2) Display prominently at each place at that outlet at which tobacco products are sold a sign that meets the requirements of section 3(d).

Sec. 5. *Prohibitions Applicable To License Holders and Their Employees and Agents.*

(a) *Prohibition on sale or distribution to individuals under the age of 19 and in certain other cases.*—A person that holds a license issued under section 3(b)(1), or an employee or agent of that person, may not sell or distribute a tobacco product—

(1) To any individual that the license holder, employee, or agent knows is under 19 years of age,

(2) To any individual (other than an individual who appears without reasonable doubt to be over @9 years of age) who does not present a driver's license (or other generally accepted means of identification) that describes the individual as @9 years of age or older, contains a likeness of the individual, and appears on its face to be valid,

(3) In any form other than an original factory-wrapped package, or

(4) Other than at an outlet for which a license has been issued under section 3(b) (@@.

(b) *Prohibition on maintaining vending machines.*—A person that holds a license issued under section 3(b)(1), or an employee or agent of that person, may not maintain at a licensed outlet any device that automatically dispenses tobacco products.

(c) *No more than one violation on any one day.*—No person shall be liable under the preceding subsections for more than one violation on any one day.

Sec. 6. *Prohibition on unlicensed sale or distribution of tobacco products.*

(a) *General rule.*—No person, other than a person who holds a license issued under section 3(b) (@@, or an employee or agent of that person, may sell or distribute a tobacco product.

(b) *Exceptions.*—Subsection (a) does not apply to—

(1) Distribution by an individual to family members or acquaintances on private property that is not open to the public, or

(2) The sale or distribution to a manufacturer of tobacco products, to a wholesaler of tobacco products, or to a person who holds a license issued under section 3(b)(1).

Sec. 7. *Penalties.*

(a) *Nature and size of penalties.*—(1) Any license holder that violates a requirement of section 4 shall be subject to a fine or civil money penalty of not more than $100.

(2) Any license holder, employee, or agent that violates a prohibition of section 5 shall each be subject to—

(A) A fine or civil money penalty of $100, for the first violation within a two year period.

(B) A fine or civil money penalty of $250, for the second violation within a two year period,

(C) A fine or civil money penalty of $500, for the third violation within a two year period,

(D) A fine or civil money penalty of $1000, for any additional violation within a two year period.

(3) Any person that violates a prohibition of section 6 shall be subject to a fine of not more than $@000, or imprisonment of not more than 30 days, or both.

(b) *Exception for license holder.*—A person that holds a license issued under section 3(b)(1) shall not be subject to a fine or civil money penalty under subsection (a)(2) for a violation by an employee or agent of a prohibition under section 5, and an assessment of a fine or civil money penalty under subsection (a)(2) for a violation by an employee or agent shall be disregarded for purposes of section 8(a), if the license holder affirmatively demonstrates that the license holder has an effective system in place to prevent violations of the prohibitions under section 5. The exception prescribed by the preceding sentence applies only once to a license holder during any two year period.

(c) *No double penalty.*—(1) If an action has been commenced against a person under subsection (a)(1) or (a)(2) for a particular violation for the payment of a fine, no action may be commenced against that person for that violation for the payment of a civil money penalty.

(2) If an action has been commenced against a person under subsection (a)(1@ or @a) (2) for a particular violation for the payment of a civil money penalty, no action may be commenced against that person for that violation for the payment of a fine.

(d) *Notification to Office of Tobacco Control of Fines Imposed.*—A court shall notify the Director of the Office of Tobacco Control of any fine imposed under subsection (a)(2).

Sec. 8. *Suspension, revocation, and nonrenewal of licenses.*

(a) *Suspension, revocation, and nonrenewal of individual licenses.*—A license issued under section 3(b)(1) for a particular outlet shall be suspended or revoked, and not renewed, for a period of—

(1) 7 days, if a fine or civil money penalty has been imposed under section 7(a)(2) for the second violation at that outlet within two years,

(2) 1 to 6 months, if a fine or civil money penalty has been imposed under section 7(a)(2) for the third violation at that outlet within two years, or

(3) 9 to 18 months, if a fine or civil money penalty has been imposed under section 7(a)(2) for any additional violation at that outlet within two years.

(b) *Suspension, revocation, and nonrenewal of all licenses for outlets under common ownership or control.*—All licenses issued under section 3(b)(@) for outlets that are under common ownership or control shall be suspended or revoked, and not renewed, for a period of 9 to @8 months, if fines or civil money penalties have been assessed under section 7(a)(2) for three or more violations at three or more outlets within a two year period.

(c) *No double counting.*—A violation committed by an employee or agent, and attributed to a license holder, shall be counted only once for purposes of the preceding subsections.

(d) *Exception.*—See section 7(b).

* * * * *

Appendix B to Preamble—Youth Access to Tobacco

December 1992

Office of Inspector General

U.S. Dept. of Health and Human Services

Executive Summary

Purpose

To assess the level and characteristics of State and local enforcement of laws limiting youth access to tobacco.

Background

In 1990, the Office of Inspector General (OIG) inspection, "Youth Access to Cigarettes" found that 45 States had laws prohibiting the sale of cigarettes to minors. However, States were not enforcing their laws. The report provided information for the development of the Secretary's "Model Sale of Tobacco Products to Minors Control Act: A Model Law Recommended for Adoption by States or Localities to Prevent the Sale of Tobacco Products to Minors."

The Office of the Secretary has asked the Office of Inspector General (OIG) to conduct a follow-up survey of the enforcement of State laws limiting youth access to tobacco. In addition, the Congressional Subcommittee on Health and the Environment has requested the OIG's assistance in determining the extent to which States have adopted and are enforcing youth access laws.

Recently, significant youth access legislation has been enacted. In July 1992, the President signed the ADAMHA Reorganization Act, PL 102-321, which requires States to ban the sale and distribution of tobacco products to anyone under the age of 18 by October 1, 1994. It also requires States to enforce their laws "in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to underage youths."

Findings

Although most States prohibit the sale of tobacco to minors, their failure to enforce their laws would place them out of compliance with the new Federal law:

All but three States ban the sale of tobacco to minors under the age of 18. Montana does not have a law prohibiting the sale of tobacco, New Mexico only prohibits the sale of smokeless tobacco and Georgia bans sales to minors under 17 years of age rather than 18.

Only two States are enforcing their laws restricting the sale to minors statewide.

In Florida and Vermont, the liquor control agencies enforce their youth access laws statewide.

A few States are funding local initiatives to reduce youth access. Four States (California, New Jersey, North Dakota and Utah) make funds available specifically to limit youth access or as part of broader tobacco education and control efforts.

Low priority by police and lack of a designated enforcer are seen as obstacles to enforcement. State respondents also

frequently cite a lack of community awareness of youth access issues and a lack of commitment to enforcing these laws as serious problems.

Despite lack of State efforts, some localities are demonstrating enforcement is possible.

These localities have developed different enforcement models. All, however, enforce State or local laws, designate an agency responsible for enforcement, and choose a method of enforcing that best meets their needs.

Vending machine restrictions are the most common initiative. In addition to their State laws prohibiting the sale of tobacco to minors, 21 States and Washington DC have passed laws that restrict vending machines.

Conclusion

Our finding that most States are not enforcing their laws limiting youth access to tobacco is a major concern given the requirements of Public Law 102–321. While we found that most States have laws that prohibit the sale of tobacco to minors, they must move quickly to enforce their laws to avoid the penalty.

State Options

The models that exist at the State and local levels present successful options for enforcing youth access laws. This report describes steps that can be taken by States that can reasonably be expected to reduce tobacco usage by youth. The States can:

Designate an enforcer
Ban vending machines
Enact provision of the model law
Educate communities and vendors
Post signs
Conduct stings

Federal Options

HHS has already taken steps to provide guidance to the States, however, as the Department implements the new law, there may be other ways to provide leadership and direction to the States. The Department can:

Provide technical assistance to the States
Monitor States activities and collect base line data
Conduct research on effective enforcement models
Develop criteria

* * * * *

Youth Access to Tobacco

OEI–02–91 December 1992
Office of Inspector General
U.S. Dept. of Health and Human Services

Introduction

Purpose

To assess the level and characteristics of State and local enforcement of laws limiting youth access to tobacco.

Background

The Office of the Secretary has asked the Office of Inspector General (OIG) to conduct a follow-up survey to a 1990 OIG inspection of the enforcement of State laws limiting youth access to tobacco. In addition, the Congressional Subcommittee on Health and the Environment has requested the OIG's assistance in determining the extent to which States have adopted and are enforcing youth access laws.

Federal Initiatives

In 1990, the OIG surveyed States regarding their laws on the sale of cigarettes to minors. The OIG inspection, "Youth Access to Cigarettes," OEI–02–90–02310, reported that 45 States had laws prohibiting the sale of cigarettes to minors. However, States were not enforcing their laws. The five States that could provide statistical information documented a total of only 32 vendor violations in 1989. The few places actively enforcing youth access to tobacco laws were mostly localities.

The inspection report provided information for the development of the Secretary's "Model Sale of Tobacco Products to Minors Control Act: A Model Law Recommended for Adoption by States or Localities to Prevent the Sale of Tobacco Products to Minors." The model law called for: (1) Licensing of vendors and revocation of their license if they sell to minors, (2) a graduated schedule of penalties so that vendors and employees are punished proportionate to their violation of the law, (3) penalties for failing to post signs, (4) designating State or local, law or health officials for enforcement, (5) civil in addition to criminal penalties to avoid overloading the criminal justice system, (6) an age of legal purchase of at least 19, (7) banning or greatly restricting access to vending machines, and (8) minimizing the burden of compliance on retail outlets.

The model law was widely distributed. Each State governor received a copy, as did State health department officials and anti-smoking groups. The law was also made available to localities active in establishing and enforcing youth access laws, and to experts in the youth smoking field. Further, the Secretary and the Surgeon General frequently spoke about the model law.

The Centers for Disease Control's Office on Smoking and Health is the focal point within the Federal government for tobacco-related efforts. The office's activities include expanding the science base of tobacco control through implementation of epidemiologic studies, surveillance activities and publications such as the Surgeon General's Report on the Health Consequences of Smoking; coordinating national media information and education campaigns to educate the public on the health hazards of tobacco use; and assisting States to build their capacity to sustain broad-based tobacco control programs.

Other Federal activity includes the National Cancer Institute's (NCI) ongoing Community Intervention Trial for Smoking Cessation (COMMIT) and its American Stop Smoking Intervention Study for Cancer Prevention (ASSIST) programs. COMMIT promotes community health concepts and technologies in 11 cities. The ASSIST program incorporates COMMIT's strategy and efforts and extends it statewide. The ASSIST program, currently in 17 States, works to create comprehensive programs to prevent and control tobacco use. The NCI collaborates with the American Cancer Society (ACS), State and local health departments and other related organizations.

Recently, significant youth access legislation has been enacted regarding youth access to tobacco. In July 1992, the President signed the ADAMHA Reorganization Act, Public Law 102–321. This new law requires States to ban the sale and distribution of tobacco products to everyone under the age of 18. It also requires States to enforce their law "in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to underage youths." The States must annually submit a report to the Secretary describing their enforcement activities and annually conduct "random, unannounced inspections," commonly called stings or observed buys. States must implement these provisions by Fiscal Year 1994, or risk a reduction in Federal funds for mental health, alcohol and other drug abuse programs.

Tobacco Use Among Youth

Despite the States' laws and national attention to the problem, tobacco use continues to be widespread among youth. The Centers for Disease Control (CDC) estimates that as many as 1 million American minors start to smoke each year, about 3,000 per day. They also estimate that in 1990 teenagers

bought 947 million packs of cigarettes and 26 million cans of smokeless tobacco, which is chewing tobacco and snuff. Further, approximately 75 percent of current smokers became addicted to tobacco by age 18, generally before it was even legal for them to purchase tobacco products. About half of the tobacco industry's profits, $3.35 billion, derives from sales to smokers who became addicted as children.[1] Tobacco is also an initial drug preferred by young people and is associated with other drug use.[2]

Other studies also suggest tobacco use is prevalent among youth. The 1990 school-based Youth Risk Behavior Survey, conducted by the CDC, found that about 36 percent of all students nationally, in grades 9–12, reported using some form of tobacco during the 30 days preceding the survey. About 32 percent of students used cigarettes, 10 percent used smokeless tobacco, and some used both.[3]

Another study indicates minors use smokeless tobacco extensively. Between 1970 and 1986, the use of snuff increased 15 times and the use of chewing tobacco four times among males ages 17 to 19.[4] An OIG inspection, "Youth Use of Smokeless Tobacco: More Than a Pinch of Trouble," P–06–86–0058, published in 1986, concluded that "addiction is a serious problem for many (smokeless tobacco) users * * * youth use of smokeless tobacco is a growing national problem with serious current and future health consequences."[5]

Research shows that children can still easily buy tobacco products. A 1990 study by Drug Free Youth, covering 93 communities in 38 States, found that "merchants readily sell cigarettes to children in every city."[6] This study, as well as others, indicates that 70 to 80 percent of merchants sell cigarettes to minors. These sale rates support Secretary Sullivan's statement that "access of minors to tobacco products is a major problem in every State." Based on current rates of smoking, he projects 5 million American children alive today will die of a smoking-related disease.

A recent study by the American Cancer Society suggests that the public supports youth access laws and their enforcement. The survey of 1,096 adults from four States found that 86 percent believe there should be stronger laws to prevent tobacco sales to minors; 90 percent believe there should be better enforcement.[7]

[1] Footnotes to appear at end of article.

Methodology

The inspection team interviewed the 51 National Network of State Tobacco Prevention and Control contacts, a group of State health department officials representing the 50 States and Washington DC. The team asked these respondents to identify legislative and enforcement activity occurring at the State level. State respondents also identified local officials enforcing youth access laws and any research evaluating the effectiveness of enforcement.

Additionally, the team reviewed all State youth access laws. We requested the laws from each State contact and analyzed them according to key components. (See Appendix A).

The team also interviewed selected local officials to assess enforcement activity and to obtain their opinions and experience about effective methods of enforcement. These methods include stings and observed buys. For the purposes of this inspection, a sting is an enforcement technique where underage youth are accompanied by an enforcement agent and attempt to buy tobacco. An observed buy is a technique whereby the enforcer checks or watches stores to see if they sell to minors. The team selected localities based upon discussions with the State respondents, informal discussion with experts in the tobacco field and a review of the Tobacco Access Law News (a compilation of current legislative and enforcement activity). The local officials interviewed were also selected to represent different geographical locations and enforcement approaches.

Findings

Although Most States Prohibit the Sale of Tobacco to Minors, Their Failure to Enforce Their Laws Would Place Them out of Compliance With the New Federal Law

All but three States ban the sale of tobacco to minors under the age of 18.

Public Law 102–321 requires States by October 1, 1994 to ban the sale and distribution of tobacco products to minors under 18 years of age. All but three States have laws that ban the sale of tobacco to minors. Montana is the only State without any law prohibiting the sale of tobacco products. Georgia prohibits sales to minors under 17 years of age rather than 18 and New Mexico only prohibits the sale of smokeless tobacco. (All other laws include both cigarettes and smokeless tobacco.) Three States (Georgia, Louisiana and Virginia) however, only address the sale of tobacco products and not distribution. Since 1990, youth access legislation has been a dynamic area of change; 23 States have enacted new legislation.

States' youth access laws vary. Alabama, Alaska, and Utah prohibit tobacco sales to minors under 19. About two-thirds (36) of the States' laws are criminal; 13 States' laws are civil. California's laws may be enforced as either a criminal law or a civil law. However, very few States (8) name a specific agency or organization to enforce the law. Enforcement is often placed, almost be default, with local police departments. All of the States with laws have fines as a penalty for violating the law, and 17 include jail.

Many of the States (29) require that signs be present at the point of sale. Thirty-one States require vendors of tobacco products to be licensed. Further, 23 States make it illegal for minors to purchase tobacco products and 21 limit minors from possessing tobacco products. Lastly, five States preempt localities from creating more stringent local ordinances that relate to minors' access to tobacco products. (See Appendix A for a summary of State law provisions.)

Only two States are enforcing their laws restricting the sale to minors statewide.

State enforcement has not changed greatly since the previous OIG report, "Youth Access to Cigarettes," two years ago. Although States have laws, interviews with the State Tobacco Prevention and Control contacts indicate that 48 States and Washington D.C. do not enforce their laws statewide. Respondents in seven of these States report enforcement is minimal and is conducted randomly at the local level; they cite only a handful of vendor violations.

Florida and Vermont are the only States enforcing their laws statewide. Since 1990 Vermont is the only State that began enforcing youth access laws statewide. Both Florida and Vermont designate the state liquor control agency for this purpose. However, Florida's law is criminal and Vermont's is civil.

In Florida, the Department of Business Regulations enforces tobacco as well as alcohol access laws. It conducts stings, observes buys, and responds to complaints from the public of vendors selling to minors. Alcohol licensing fees in the past have funded these activities. However, recent legislation, effective January 1993, requires tobacco vendors to be licensed and their fees to be used to fund full-time tobacco enforcement staff. State respondents report it is easier to convict vendors in Florida by conducting a sting or a buy in response to a complaint because it establishes a predisposition.

Some judges consider random stings to be entrapment. Last year, Florida reported 22 violations.

Vermont has only recently begun enforcing its youth access law. The Department of Liquor Control enforces it statewide. Initially, the liquor agency sent signs, posters and license applications to retailers. Following this campaign, a team of 14 liquor control inspectors began making random unannounced visits twice a week to vendors. No violations have yet been reported.

Two other States, Utah and South Dakota, enforce youth possession laws. In 1991, Utah police and school monitors issued nearly 5,000 violations to minors, but only 30 to vendors. Similarly, in FY 1991 South Dakota police issued 58 violations to minors but only 3 to vendors. Pub. L. 102–321 does not address youth possession.

A few States are funding local initiatives to reduce youth access.

While not actually enforcing their State access laws, four States make funds available to localities interested in limiting youth access to tobacco. (Utah, California, North Dakota and New Jersey). Three of them, Utah, California, and New Jersey, encourage local initiatives to reduce youth access as part of broader tobacco education and control efforts. North Dakota makes grants specifically for youth access. Further, Utah and California make grants to all counties while the other two States fund only select local sites.

Utah's Department of Health contracts with district health departments to conduct tobacco control and prevention activities. Districts choose from a number of different tobacco initiatives, ranging from youth access to worksite smoking policies. Every district addresses youth access in some way. All twelve districts have extensive vendor education campaigns; five districts educate law enforcement officers about the importance of the law. Law enforcement and/or health departments conduct observed buys in six districts. In one district, law enforcement officials have issued violations.

California provides funding for local youth access initiatives. In 1988 California passed Proposition (Prop) 99, which increased the cigarette tax to 35 cents to fund anti-tobacco education and control programs. Prop 99 created tobacco control programs throughout the State by funding county health departments, nonprofit organizations and schools. These programs include prevention education, cessation and policy initiatives. Many of the programs target youth among other groups. Prop 99 funds two projects specifically to reduce youth access, STAMP, Stop Tobacco Access to Minors Project and TRUST, Teens and Retailers United to Stop Tobacco. So far, TRUST has conducted merchant education, while STAMP has more actively enforced youth access. In conjunction with STAMP, three communities in Solano County, conduct regular stings and issue violations. STAMP also conducts merchant and community education campaigns and underage buy surveys in six counties. Three counties are currently exploring civil prosecution of vendors who have repeatedly sold to minors. A study by the University of San Diego suggests that the anti-smoking campaign has contributed to a 17 percent decline in smoking from 1987 to 1990.

New Jersey makes youth smoking prevention grants to localities. The State Health Department issued eight three-year grants to local health departments to encourage innovative education and youth cessation programs. Most of the communities receiving grants focus on educating vendors. Some local health departments visit vendors to inform them of the State law and to encourage them to voluntarily comply. However, one community also uses the grant to conduct observed buys and stings, and to enforce a local vending machine restriction. This community began enforcing the law following a highly publicized educational campaign. So far, health department officials have issued warnings to vendors who violate the law and are planning to issue citations shortly.

North Dakota also encourages local youth access initiatives. Its Department of Health made youth access grants to seven cities. These grants encourage cities to educate and work with police and retailers, and to enact city ordinances limiting vending machines. The seven cities have achieved these goals to varying degrees. Some have successfully enacted local vending machine laws. A few have also conducted observed buys. So far, none have issued violations against vendors.

Low priority by police and lack of a designated enforcer are seen as obstacles to enforcement.

State respondents cite a number of problems in enforcing youth access laws. Most State youth access laws are criminal and, therefore, only enforceable by police. State respondents most frequently cite the low priority given by police to enforcing tobacco sale laws. One respondent notes, "Law enforcement agencies are understaffed and they have no desire to enforce anything not considered pressing." Other respondents cite the lack of an agency clearly identified as responsible for enforcement as a problem. One respondent, typical of many, said, "There's no one charged with enforcement, it's not coordinated in any way."

State respondents frequently cite a lack of community awareness of youth access and smoking and a lack of commitment to enforcing the laws as serious problems. Several believe that communities do not consider tobacco and youth access important issues. "We need an evolution of attitudes—the public has a general attitude that alcohol should not be sold to kids. They don't feel the same way about cigarettes." Several respondents report that the police will not enforce the law if the community is not supportive. One reports, "The community must motivate police to enforce youth access * * * the police will respond to this pressure." A few States also mention the lack of concern by vendors as a problem.

State respondents report difficulties in convicting vendors. Several State respondents believe State legislative language is vague and causes difficulties in enforcing the law. Several States' laws contain the phrase, "to knowingly sell tobacco products to minors." Respondents claim this makes it difficult to convict vendors because vendors claim they did not know the person they sold to was underage. Further, judges are sometimes reluctant to convict clerks for selling cigarettes to minors. They often dismiss the cases, believing the vendor should be penalized, not the clerk. Also, some judges dismiss violations issued as the result of random stings, considering them as entrapment.

Despite Lack of State Efforts, Some Localities Are Demonstrating Enforcement is Possible

Based on our interviews with State respondents and experts and a literature review, we identified localities that enforce laws prohibiting the sale of tobacco to minors and/or laws prohibiting the possession of tobacco by minors. In several instances State and Federal programs have encouraged localities, through grants and contracts, to enforce youth access laws. In other instances, individuals interested in the issue and grassroots groups have taken youth access on as their own cause. Some localities have developed coalitions, working together with advocacy groups and local health departments, to raise community awareness and win the support of local merchants and police. As one local respondent comments "We needed to develop enforcement at the local level

* * * there is no enforcement at the State level and it is easier to enforce at the local level."

Regarding sale to minors laws, we identified 52 localities in 19 States that enforce these laws and have developed varying models. All, however, enforce either State or local laws, designate an agency responsible for enforcement, and choose a method of enforcing that best meets their needs. Some have conducted research to evaluate the effectiveness of their efforts. The following are examples of how local models differ on these characteristics.

Type of law: Slightly more than half of the localities enforce State laws while the others have enacted and are enforcing local laws. Several localities enforce the State law prohibiting the sale of tobacco to minors, but have enacted and enforce local ordinances restricting vending machines.

Research suggests that the effect of enacting and implementing local ordinances varies. Preliminary analyses of a study, which compared Marquette County, Michigan to a county with no access law, indicates that passing a law does not significantly change the perceived difficulty of buying tobacco, knowledge of the legal age or smoking rates among youth.[8] However, the previously mentioned study by Drug Free Youth, conducted in 95 communities in 38 States, found that passage of an ordinance has some effect on sales to minors. Stores in cities with ordinances sold to minors about 48 percent of the time; stores in cities without ordinances sold to them about 82 percent of the time.[9]

Designated Enforcer: In 23 localities, local police enforce the law. In another 21 localities, local health officials enforce the law, and in the remaining localities licensing or regulatory agencies are responsible for enforcement. A few localities have coordinated efforts between the health department and police.

Opinions differ as to who should enforce youth access laws. State respondents most frequently designate health departments. The majority of these respondents believe that health departments are more concerned about tobacco than are police. One comments, "It is not a public safety issue, but rather a health issue." However, other State respondents consider police the best enforcers. Most of these respondents believe it is more appropriate for the police to enforce because as one says, "enforcement is their business." Still others believe licensing and other regulatory agencies should be responsible; since these departments would issue the license to sell tobacco, they would have authority to suspend it.

Method of Enforcement: Localities enforce their law differently.

They enforce access by using stings, observing buys, responding to complaints by the public or a combination of these mechanisms. Frequently, localities conduct an initial sting to document that minors can easily buy tobacco and use this information to attract the media, educate retailers and raise community awareness. Twenty-one localities have conducted stings for such educational purposes.

However, research appears to indicate that education alone is not enough. A study in Santa Clara, CA reports that while a retailer education campaign reduced sales to minors, one year later sales rebounded as a result of no enforcement.[10]

Other localities enforce the law more extensively. Twenty-one localities conduct stings or observed buys and penalize violators. They issue fines and/or suspend the vendor's license. Some have taken vendors or clerks to court. Several respondents in these localities believe the only way to get compliance is to penalize vendors. Many comment that if vendors are threatened with suspension of their license to sell tobacco they will comply.

The remaining localities conduct stings or buys, but do not issue violations. They usually warn the vendors or clerks who sell tobacco illegally to minors. Some believe initially warning vendors is only fair, but in the future plan to issue violations.

Others believe conducting observed buys without issuing violations sufficiently alerts vendors and discourages them from selling to minors.

Research suggests that regular stings and violations can be effective in reducing youth access and, in some cases, smoking. In Woodridge, Illinois, police conduct regular stings and issue criminal violations to vendors. As a result, tobacco sales to minors decreased from 70 percent to 5 percent. Experimentation and regular use of cigarettes by minors reportedly decreased 50 percent.[11] Another study conducted in Everett, Washington suggests that a local ordinance enforced by the threat of fines and license revocation reduced sales to minors and significantly reduced tobacco use among girls.[12]

Other studies indicate that enforcement decreases sales to minors significantly. In Solano County, California, local police in two towns conduct stings twice a year and issue citations. Researchers report that while originally 71 percent of vendors sold to minors, only 24 percent sold after citations were issued.[13] Likewise, in Sponkane County, Washington local health departments conduct regular stings but do not issue violations. Researchers here show that passing a local regulation and conducting regular views decreased sales to about 27 percent.[14]

A study, conducted in Bollingbrook, Illinois, suggests frequent checks are necessary to maintain compliance. In 1989 and 1990, when observed buys were conducted quarterly, only 18 percent of stores were noncompliant. In 1991, buys were conducted less frequently and 35 percent were noncompliant.[15]

Regarding youth possession laws, we identified a few localities that enforce youth possession laws to reduce youth access. Some localities in North Dakota, Wyoming and Minnesota issue violations for possession of tobacco by minors. In Gillete, Wyoming, for example, police issue violations to minors to discourage youth from using tobacco. Here, the police initially wanted to stop teens from loitering and they decided to enforce the law against possession of tobacco by minors. They now work successfully with schools to educate and reduce access and tobacco use among youth. They believe possession laws limit peer pressure and send a consistent message to youth to stop using tobacco.

Opinions differ as to whether possession should be made illegal. Some respondents want minors to share the blame with vendors. They believe that possession and sale laws send an appropriate message to both youth and vendors and will effectively reduce youth smoking. However, other respondents believe that youth should not be blamed and that vendors selling to minors is the issue.

Vending Machine Restrictions Are the Most Common Initiative

Restricting tobacco vending machines is the most commonly observed way States and localities limit youth access to tobacco. In addition to their State laws prohibiting the sale of tobacco to minors, 21 States and Washington DC have passed laws that restrict vending machines in some manner.

States have adopted different types of vending machine restrictions. Nine States and Washington DC restrict the placement of vending machines to areas inaccessible to minors, such as bars, liquor stores, work areas and private clubs. Five States require that vending machines be supervised by the owner or

an employee, or that the machines be equipped with a locking device that can be released once the age of the person using the machine is verified. Seven States combine these approaches by restricting the placement and/or requiring supervision. In five of these States localities have enacted even stricter local vending machine ordinances.

Over 140 localities in 19 States have enacted local ordinances limiting vending machines. Nearly one-third of these localities have banned vending machines altogether. The remaining localities have limited placement and/or required supervision or locking of vending machines.

All State respondents interviewed agree that vending machines should be limited in some way. One respondent expressed the beliefs of many when he said, "Ban all vending machines, they are easy access (for minors)." Others believe that localities should "put vending machines only in places that can be monitored or just get rid of them altogether."

Vending machine bans and placement restrictions require minimal enforcement. One State respondent comments, "vending machines are the only part (of youth access laws) that are enforceable." Often, localities can enforce vending machine restrictions by initially reviewing their placement and sending a follow-up notice to vendors not in compliance. Another State respondent said, a "letter can usually get rid of vending machines."

Ordinances that call for supervision or locking devices are not as easily enforced. Supervision of vending machines requires the same enforcement efforts as over the counter sales and are therefore, generally not being enforced. Additionally, a recent study in Minnesota concludes that "compliance with locking device laws is a problem." The study suggests that locking devices require additional enforcement to ensure compliance and may not be effective as vending machine bans. The author of the study also notes the importance of restricting vending machines, stating "it is hard to get over-the-counter merchants to take the age-of-sale laws seriously when they know that cigarettes are available in vending machines freely."[6]

Conclusion

Our finding that most States are not enforcing their laws limiting youth access to tobacco is a major concern given the requirements of Pub. L. 102–321. While we found that most States have laws that prohibit the sale of tobacco to minors, they must move quickly to enforce their laws to avoid the potential federal penalty on their FY 1994 ADAMHA Block Grant funds.

State Options

The models that exist at the State and local level present different successful options for enforcing youth access laws. Most often they include stings and vending machine restrictions. Each State must develop and implement its own enforcement program to reduce youth access and youth smoking. This report, however, describes several steps that can be taken by the States that can reasonably be expected to reduce tobacco usage by youth. The States can:

—Designate an enforcer
—Ban vending machines
—Enact provisions of the model law
—Educate communities and vendors
—Post signs
—Conduct stings

Federal Options

HHS has already taken steps to provide guidance to the States to assist them with their efforts to reduce the extent to which tobacco products are available to underage youth by developing and disseminating the Model law. However, as the Department implements the new law requiring that States ban the sale and distribution of tobacco products to anyone under the age of 18 and to enforce their laws, there may be other ways for the Department to provide leadership and direction to the States. The Department can:

—Provide technical assistance to the States
—Monitor States activities
—Conduct research on effective enforcement models
—Develop criteria
—Collect baseline data

Endnotes

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STATE LAW PROVISIONS*

[*See legend at end of matrix]

State	Age	Sale	Possession	Purchase	Licenses	Signs	Vending machines	Graduated penalties	Fines	Jail	Revocation	Enforcer	Preemption
AK	19	CV	Y		Y	Y	B		Y		Y		

STATE LAW PROVISIONS*

[*See legend at end of matrix]

State	Age	Sale	Possession	Purchase	Licenses	Signs	Vending machines	Graduated penalties	Fines	Jail	Revocation	Enforcer	Preemption
AL	19	CR			Y				Y	Y	Y		
AR	18	CR			Y	Y	B	Y	Y		Y		
AZ	18	CR	Y	Y	Y				Y				
CA	18	**				Y			Y				Y
CO	18	CR		Y		Y	B		Y				
CT	18	CV		Y	Y	Y	B	Y	Y				
DC	18	CR			Y	Y	P	Y	Y	Y	Y		
DE	18	CR	Y		Y				Y			Y	
FL	18	CR			Y	Y			Y	Y		Y	
GA	17	CR			Y	Y	S		Y		Y		
HI	18	CV	Y	Y		Y	P	Y	Y			Y	
IA	18	CR	Y	Y	Y		L		Y		Y	Y	Y
ID	18	CR	Y	Y	Y		S	Y	Y	Y			
IL	19	CR		Y		Y		Y	Y				
IN	18	CV	Y	Y		Y	P		Y				
KS	18	CR		Y	Y				Y	Y	Y		
KY	18	CR				Y		Y	Y				
LA	18	CR		Y		Y			Y				
MA	18	CR			Y	Y		Y	Y	Y			
MD	18	CV							Y	Y			
ME	18	CV		Y	Y	Y	S		Y				
MI	18	CR	Y	Y		Y			Y			Y	
MN	18	CR		Y	Y		B		Y	Y			
MO	18	CR				Y		Y	Y				
MS	18	CR							Y	Y			
MT	.....												
NC	18	CR							Y	Y			
ND	18	CR	Y		Y		S		Y	Y			
NE	18	CR	Y		Y		P		Y				
NH	18	CV	Y	Y	Y	Y		Y	Y				
NJ	18	CR			Y	Y			Y				
NM	18	CR		Y	Y	Y	P						Y
NV	18	CV			Y				Y		Y		
NY	18	CV			Y	Y	P	Y	Y		Y	Y	
OH	18	CR					B	Y	Y				
OK	18	CR	Y		Y				Y	Y			
OR	18	CV	Y	Y		Y	P		Y				
PA	18	CR		Y	Y			Y	Y	Y			
RI	18	CR	Y	Y	Y	Y		Y	Y		Y		
SC	18	CR							Y	Y			
SD	18	CR	Y	Y					Y				
TN	18	CR	Y		Y	Y		Y	Y	Y	Y		
TX	18	CR			Y	Y			Y				
UT	19	CR	Y	Y	Y		P	Y	Y	Y			
VA	18	CV	Y	Y		Y			Y				
VT	18	CV		Y	Y	Y	P	Y	Y		Y	Y	
WA	18	CR			Y				Y	Y	Y		
WI	18	CV	Y		Y	Y	B	Y	Y		Y	Y	Y
WV	18	CR	Y					Y	Y				
WY	18	CR	Y	Y		Y	P		Y				Y

Legend

State: The name of the State in abbreviation.
Age: The age at which a person may purchase tobacco products.
Sale: Type of sale law. CR indicates the law is criminal and CV indicates the law is civil. **indicates that the law may be enforced as a civil law or a criminal law.
Possession: Possession by a minor. Y indicates that it is illegal for a minor to possess tobacco products.
Purchase: Purchase by a minor. Y indicates that it is illegal for a minor to purchase tobacco products.
License: Licenses for vendors. Y indicates that vendors must have licenses to sell tobacco products.
Signs: Signs at the point of sale. Y indicates that a sign at the point of sale must be present.
Vending machines: Vending machine restrictions. S indicates that vending machines (vm) have to be supervised by an employee. P indicates that vm are restricted in placement (to areas where minors are not present). B indicates that vm have to be supervised and/or restricted in placement. L indicates that vm must have locking devices.
Graduated penalties: Y indicates that there is a set graduated scale of penalties for each offense.
Fines: Y indicates that fines may be a penalty for noncompliance.
Jail: Y indicates that jail time may be penalty for noncompliance.
Revocation: Revocation of license. Y indicates that the revocation of a vendor's license may be a penalty for noncompliance.
Enforcer: Enforcer of law. Y indicates that the enforcer is stated in the law.
Preemption: Preemption clause. Y indicates that there is a preemption clause not allowing localities to create stricter laws regarding youth access.

List of Subjects in 45 CFR Part 96

Alcohol abuse, Alcoholism, Confidentiality, Drug abuse, Health records.

For the reasons set out in the preamble, the Secretary proposes to amend part 96 of title 45 of the Code of Federal Regulations, as set forth below.

Dated: August 12, 1993.

Philip R. Lee,

Assistant Secretary for Health.

Dated: August 19, 1993.

Donna E. Shalala,

Secretary.

PART 96—BLOCK GRANTS

1. The authority citation for 45 CFR part 96, subpart L continues to read as follows:

Authority: 42 U.S.C. 300x–21 to 300x–35 and 300x–51 to 300x–64

§ 96.122 [Amended]

2. Subpart L is amended to add § 96.122(f)(6) to read as follows:

* * * * *

(f) * * *

(6) For the first applicable year for which the State is applying for a grant, a copy of the statute enacting the law as described in § 96.130(a), a description of the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought, and, if the State desires, a description of the activities undertaken during the previous fiscal year to enforce any law against the sale or distribution of tobacco products to minors that may have existed; and for subsequent fiscal years for which the State is applying for a grant, the annual report as required by § 96.130(d) and any amendment to the law described in § 96.130(a).

* * * * *

§ 96.123 [Amended]

3. Subpart L is amended to add § 96.123(a)(5) to read as follows:

(a) * * *

(5) the provisions of § 96.130 relating to the sale of tobacco products to minors are being carried out as prescribed by law;

* * * * *

4. Subpart L is amended to add § 96.130 as follows:

§ 96.130 State law regarding sale of tobacco products to individuals under age of 18.

(a) The Secretary may make a grant to a State only if the State has the following:

(1) Except as provided in paragraph (a)(2) of this section, the State shall for fiscal year 1994 and subsequent years, have in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under the age of 18 through any sales or distribution outlet.

(2) In the case of a State whose legislature does not convene a regular session in fiscal year 1993, and in the case of a State whose legislature does not convene a regular session in fiscal year 1994, the requirement described in paragraph (a)(1) of this section as a condition of a receipt of a Block Grant shall apply only for fiscal year 1995 and subsequent fiscal years.

(b) For purposes of this section, the term *first applicable fiscal year* means fiscal year 1995, in the case of any State described in paragraph (a)(2) of this section, and fiscal year 1994, in the case of any other State. The term "outlet" is any location which sells at retail or otherwise distributes tobacco products to consumers including (but not limited to) locations that sell such products over-the-counter or through vending machines.

(c) For the first applicable fiscal year and for subsequent fiscal years, the State (directly or through local governments or private entities) will, at a minimum, enforce the law described above as follows:

(1) The State shall conduct annual, random and targeted, unannounced inspections of both over-the-counter and vending machine outlets. The random inspections shall cover a range of outlets (not preselected on the basis of prior violations) to measure overall levels of compliance as well as to identify violations. Random, unannounced inspections shall be conducted annually and shall be conducted in such a way as to ensure a scientifically sound estimate of the success of enforcement actions being taken throughout the State. Thus, the State shall give due consideration to the methodological design of the inspection effort and the adequacy of the sample design. The sample shall reflect the distribution of the population of those under 18 throughout the State and the distribution of outlets throughout the State. The sample shall further reflect that, because of location (e.g. near schools) or other factors, some outlets are more likely to be used by minors. States are to ensure that the inspections occur at times when minors are likely to purchase tobacco products. Targeted inspections shall focus on outlets which have a history of prior violations.

(2) The State shall have in place other well-designed procedures for reducing the likelihood or prevalence of violations, such as, for example, a tobacco sales or distribution licensing system similar to that used for alcoholic sales, a graduated schedule of penalties for illegal sales or distribution culminating in loss of license, controls on tobacco vending machines in locations accessible to youth, publication of the names of outlets making illegal sales, or use of local enforcement to supplement central enforcement.

(d) The State shall annually submit to the Secretary with its application a report which shall include the following:

(1) A detailed description of the State's activities to enforce the law required in paragraph (a) of this section during the fiscal year preceding the fiscal year for which that State is seeking the grant;

(2) A detailed description regarding the overall success the State has achieved during the previous fiscal year in reducing the availability of tobacco products to individuals under the age of 18, including the results of the unannounced inspections as provided by paragraph (c)(1) of this section for which the results of over-the-counter and vending machine outlet inspections shall be reported separately;

(3) A detailed description of how the unannounced inspections were conducted and the methods used to identify outlets; and

(4) The strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought.

(e) The annual report required under paragraph (d) of this section shall be made public within the State and public comment shall be obtained and considered by the State prior to its submission to the Secretary.

(f) Before making a Block Grant to a State, the Secretary shall make a determination as to whether the State has maintained compliance with this section. In making this determination, the Secretary will consider the following factors:

(1) Except as provided by paragraph (f)(2) of this section, the State must demonstrate that its random, unannounced inspections were conducted in a scientifically sound manner and the results of the random, unannounced inspections submitted by the State in its annual report must show that the percentage of the sampled distributors that made illegal sales do not exceed:

(i) More than fifty (50) percent during the first applicable fiscal year;

(ii) More than forty (40) percent during the second applicable fiscal year;

(iii) More than thirty (30) percent during the third applicable fiscal year; and

(iv) More than twenty (20) percent during the fourth applicable year and subsequent fiscal years.

(2) If a State is not in substantial compliance with paragraph (f)(1) of this section, the Secretary, in extraordinary circumstances, may consider a number of factors, including scientifically sound survey data showing that the State is making significant progress toward reducing use of tobacco products by children and youth, data showing that the State has progressively decreased the availability of tobacco products to minors, the composition of the outlets inspected as to whether they were over-the-counter or vending machine outlets, and the State's plan for improving the enforcement of the law in the next fiscal year.

(g) If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with this section, the Secretary will reduce the amount of the allotment in such amounts as is required by section 1926 of the PHS Act.

(h) The State shall not expend the Block Grant program funds for enforcement activities under this section. However, the Block Grant funds which States are permitted to use for administrative purposes may be used for enforcement. Block Grant program funds may be used to provide technical assistance to communities to maximize procedures for enforcing the law regarding tobacco as provided in § 96.125(a)(6), including providing guidance on effective community approaches in enforcing the law.

[FR Doc. 93–20444 Filed 8–25–93; 8:45 am]

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Thursday
August 26, 1993

Part III

Department of Housing and Urban Development

Office of the Assistant Secretary for Public and Indian Housing

Notice of Fund Availability for the Indian CDBG Program for Fiscal Year 1993

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

[Docket No. N–93–3642; FR–3505–N–01]

Community Development Block Grant Program for Indian Tribes and Alaskan Native Villages; Notice of Fund Availability

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of Fund Availability for Fiscal Year 1993.

SUMMARY: This Notice of Fund Availability (NOFA) announces HUD's funding for the Community Development Block Grant Program for Indian tribes and Alaskan native villages for Fiscal Year 1993. In the body of this document is information concerning the following:

(a) The purpose of the NOFA, and information regarding eligibility, available amounts, and selection criteria;

(b) Application processing, including how to apply and how selections will be made; and

(c) A checklist of steps and exhibits involved in the application process.

DATES: Applications may be mailed to HUD, provided that they are postmarked no later than midnight on the deadline date: November 9, 1993. Applications that are physically delivered to HUD must be received by the appropriate HUD Field Office (FO) no later than 4:30 p.m. November 9, 1993. Application materials will be available from each field OIP.

FOR FURTHER INFORMATION CONTACT: Applicants should contact the HUD Field Office serving their geographic area.

Isaac Pimentel, Chicago Regional Office, Office of Indian Programs, Housing and Community Development Division, 77 West Jackson Blvd., Chicago, Illinois 60604. Telephone (312) 353–1683.

Jules Valdez, Oklahoma City Office, Indian Programs Division, CPD Branch, Murrah Federal Building, 200 NW 5th St., Oklahoma City, OK 73102–3202. Telephone (405) 231–5968.

Gloria Dale Lewis, Denver Regional Office, Office of Indian Programs, Housing and Community Development Division, Executive Tower Bldg., 1405 Curtis St., Denver, CO 80202–2349. Telephone (303) 844–6481.

Gerald Hammon, Office of Indian Programs, Region IX, CPD Division, Two Arizona Center, Suite 1650, 400 N. Fifth Street, Phoenix, Arizona 85004–2361. Telephone (602) 379–4197.

Robert Barth, Office of Indian Programs, CPD Division, Program Management Team, (San Francisco) Phillip Burton Federal Bldg. and U.S. Courthouse, 450 Golden Gate Ave., P.O. Box 36003, San Francisco, CA 94102–3448. Telephone (415) 556–9200.

Jeanne McArthur, Seattle Regional Office, Office of Indian Programs, CPD Division, Federal Office Building, 909 First Avenue, Suite 200 , Seattle, WA 98104–1000. Telephone (206) 553–0760.

Colleen Craig, Anchorage Office, CPD Division, 949 E. 36th Avenue, Suite 401, Anchorage, AK 99508–4135. Telephone (907) 271–4684.

With general program questions, contact Dom Nessi, Office of Native American Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, Room 4140, 451 Seventh Street SW, Washington, DC 20410. Telephone (202) 708–1015. The Telecommunications Device for the Deaf (TDD) number is (202) 708–2565. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION:

Paperwork Requirements

The information collection requirements contained in this notice have been approved by the Office of Management and Budget, under section 3504(h) of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3520), and have been assigned OMB control number 2506–0043.

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I. Purpose and Substantive Description:

A. Authority

Title I, Housing and Community Development Act of 1974, as amended (42 U.S.C. 5301 *et seq.*); sec. 7(d) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(d)); 24 CFR Part 571.

B. Funding

Amendments to Title I of the Housing and Community Development Act of 1974 have required that the allocation for Indian Tribes be on a competitive basis in accordance with selection criteria contained in a regulation promulgated by the Secretary after notice and public comment. The interim regulation containing the selection criteria was issued April 7, 1992.

The Department has determined that only quality Indian Community Development Block Grant (ICDBG) projects are to be funded. Section 571.100(b)(2) prohibits HUD field offices (FO) from funding applications that do not meet a serious need or which do not impact on the needs identified in the application. Accordingly, even if funds were available to fund a project based on its rating, if that project did not meet these criteria, it would not be funded. The funds would be used to fund the next highest ranking project or could be carried forward to the next funding cycle, if none of the lower ranking projects met a serious need or impacted on the needs identified in the application. All grant funds awarded in accordance with this NOFA are subject to the requirements of 24 CFR 571.

Documentation and Public Access Requirements; Applicant/Recipient disclosures: HUD Reform Act

Documentation and public access requirements. HUD will ensure that documentation and other information regarding each application submitted pursuant to this NOFA are sufficient to indicate the basis upon which assistance was provided or denied. This material, including any letters of support, will be made available for public inspection for a five-year period beginning not less than 30 days after the award of the assistance. Material will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. In addition, HUD will include the recipients of assistance pursuant to this NOFA in its quarterly **Federal Register** notice of all recipients of HUD assistance awarded on a competitive basis. (See 24 CFR 12.14(a) and 12.16(b), and the notice published in the **Federal Register** on January 16, 1992 (57 FR 1942), for further information on these documentation and public access requirements.)

Disclosures. HUD will make available to the public for five years all applicant disclosure reports (HUD Form 2880) submitted in connection with this NOFA. Update reports (also Form 2880) will be made available along with the applicant disclosure reports, but in no case for a period generally less than three years. All reports -- both applicant disclosures and updates --will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. (See 24 CFR subpart C, and the notice published in the **Federal Register** on January 16, 1992 (57 FR 1942), for further information on these disclosure requirements.)

1. *Allocations.* The requirements for allocating funds to field offices responsible for program administration are found at 24 CFR 571.101. Following these requirements, the allocation for FY 1993 is as follows:

Chicago	$ 2,965,000
Oklahoma	7,538,000
Denver	6,302,000
Phoenix	17,809,000
Seattle	2,182,000
Anchorage	3,204,000
Total	$40,000,000

2. *Grant Ceilings.* The authority to establish grant ceilings is found at 24 CFR 571.100(b). These grant ceilings are established for FY 1993 funding at the following levels:

Region/ Field Offices	Population	Ceiling
Region 5 (Chicago).	ALL	$300,000
Region 6 (OK City).	5,001+	500,000
	1,001–5,000	400,000
	1,000 or less	300,000
Region 8 (Denver).	ALL	800,000
Region 9 (Phoenix).	50,001+	5,000,000
	10,501–50,000	2,500,000
	9,001–10,500	2,000,000
	7,501–9,000	1,500,000
	6,001–7,500	1,000,000
	4,501–6,000	750,000
	3,001–4,500	650,000
	1,501–3,000	550,000
	1–1,500	450,000
Region 10 (Seattle).	ALL	270,000
Anchorage.	ALL	500,000

3. *Imminent Threats.* The criteria for grants to alleviate or remove imminent threats to health or safety that require immediate solution are described at Subpart E of Part 571. The following field offices are setting aside funds for imminent threats:

Region 9 (Phoenix) $400,000. These funds will be available until the Phoenix Office receives its FY 1994 ICDBG allocation.

Seattle $250,000. These funds will be available until Seattle completes the rating and ranking process for funds distributed under this NOFA.

Anchorage $500,000. These funds will be available until the Anchorage Office receives its FY 1994 ICDBG allocation.

C. Eligibility of Activities

Activities that are eligible for CDBG funds are identified at 24 CFR Part 570 Subpart C. Both the National Affordable Housing Act (NAHA) (P.L. 101–625) and the Housing and Community Development Act of 1992 (the 1992 Act) (P.L. 102–550) amended Title I of the Housing and Community Development Act of 1974 (HCD Act). Various amendments made by these two recent acts are applicable, as described below, to the funds made available under this NOFA.

1. *Program Income.* Section 804 of the 1992 Act deletes any consideration of

whether the grantee is still participating in the CDBG program in determining the applicability of CDBG requirements to the use of program income.

2. *Microenterprise and Small Business Development.* Section 807(c) of the 1992 Act defines a small business as one that meets the criteria set forth in section 3(a) of the Small Business Act (15 USC 632(a)) and defines a microenterprise as a commercial enterprise having five or fewer employees, one or more of whom owns the enterprise.

This section further directs HUD in the provision of assistance under § 570.203(b) to for-profit microenterprises and small businesses not to consider the use of CDBG funds for training, technical assistance, and other support costs provided to such entities to be planning or administrative costs.

The section also directs HUD not to consider CDBG funds to be for a planning or administrative activity when used to pay costs to develop the capacity of the grantee or a subrecipient to provide training, technical assistance or other support services to small businesses or microenterprises. Consequently, since these activities are not to be considered as planning or administrative activities, they are subject to compliance with the national objective requirements.

3. *Lump Sum Drawdowns.* The use of lump sum drawdowns for residential rehabilitation has been reauthorized by section 909 of the NAHA for CDBG funds appropriated after Fiscal Year 1992.

4. *Eligible Activities.*

a. *Changes Affecting Existing Categories*

(1) Assistance to For-profit Businesses. Section 806(b) of the 1992 Act amends Section 105(a) of the HCD Act so that CDBG assistance to for-profit businesses shall not be limited to activities for which no other forms of assistance are available, or to activities that could not be accomplished but for that assistance.

(2) Direct Homeownership Assistance. NAHA amended Section 105(a) of the HCD Act to add as an eligible activity direct assistance to facilitate and expand homeownership among persons of low- and moderate-income. Under this provision, CDBG funds may be used to: subsidize interest rates and mortgage principal amounts for low- and moderate-income homebuyers; finance the acquisition by low- and moderate-income homebuyers of housing that is occupied by homebuyers; acquire guarantees for mortgage financing obtained by low- and moderate-income homebuyers from private lenders (except that assistance under Title I of the HCD Act may not be used by recipients or subrecipients to directly guarantee such mortgage financing); provide up to 50 percent of the downpayment required from low-and moderate-income buyers; and pay reasonable closing costs normally associated with the purchase of a home incurred by a low- and moderate-income homebuyer. While this provision was set to expire on October 1, 1993, it has been extended to October 1, 1994, by section 807(b) of the 1992 Act.

(3) Code Enforcement. Section 807(e) of the 1992 Act adds private improvements or services undertaken in an area to the activities that may be considered together with code enforcement in order to determine whether CDBG funds may be used to pay for the code enforcement in that area.

(4) Loans to Subrecipients. Section 807(d) of the 1992 Act amends section 105(a)(14) of the HCD Act to authorize CDBG assistance to be provided for such activities in the form of loans, both interim and long-term, as well as grants.

(5) Neighborhood-based Nonprofit Organizations. Section 807(f) of the 1992 Act amends section 105(a)(15) of the HCD Act to add nonprofit organizations serving the development needs of communities in nonentitlement areas as eligible entities to carry out CDBG activities.

b. *New Categories of Eligibility*

(1) Nonprofit Capacity Building. Section 807(a)(4) of the Housing and Community Development Act of 1992 makes eligible the provision of technical assistance to public or nonprofit entities to increase the capacity of such entities to carry out eligible neighborhood revitalization or economic development activities, and makes clear that such use of funds is not to be considered as a planning or administrative cost of the program. Prior to the amendment, such a use of funds has only been eligible under § 570.205 and therefore subject to the cap on planning and administration at § 570.200(g). While nonprofit capacity building is now eligible under the new provision and not subject to a percentage limitation, it should be noted that any such use of funds under the new authority must be shown to meet one of the national objectives. This may be difficult in some cases since it appears that all activities carried out by the nonprofit using the added capacity will need to be considered for that purpose.

(2) Institutions of Higher Education. Section 807(a)(4) of the 1992 Act makes it eligible for the grantee to provide CDBG funds to institutions of higher education to carry out activities otherwise eligible for CDBG assistance, provided it can be determined that the institution has demonstrated capacity to carry out such activities.

(3) Acquisition by Tax Foreclosure. Section 807(a)(4) of the 1992 Act makes eligible the use of CDBG funds to make essential repairs and to pay operating expenses necessary to maintain the habitability of housing units acquired through tax foreclosure proceedings in order to prevent abandonment and deterioration of such housing in primarily low- and moderate-income neighborhoods.

(4) Microenterprises. Section 807(a)(4) of the 1992 Act establishes a new category of eligibility under which CDBG funds may be used to provide assistance to public and private organizations, agencies, and other entities (including nonprofit and for-profit entities) to enable such entities to facilitate economic development by:

- providing credit (including providing direct loans and loan guarantees, establishing revolving loan funds, and facilitating peer lending programs) for the establishment, stabilization, and expansion of microenterprises;
- providing technical assistance, advice, and business support services (including assistance, advice, and support relating to developing business plans, securing funding, conducting marketing, and otherwise engaging in microenterprise activities) to owners of microenterprises and persons developing microenterprises; and
- providing general support (such as peer support programs and counseling) to owners of microenterprises and persons developing microenterprises.

(5) Housing Services. Section 807(a)(4) of the 1992 Act establishes a new category of eligibility for housing services. Such activities include housing counseling, energy auditing, preparation of work specifications, loan processing, inspections, tenant selection, management of tenant-based rental assistance, and other services related to assisting owners, tenants, contractors, and other entities, participating or seeking to participate in housing activities authorized under the CDBG program or the HOME program. Activities that are carried out under this provision are to be subject to the 20 percent limitation on administrative expenses.

It is important to note that almost all of these activities are currently eligible in the CDBG program when carried out in conjunction with rehabilitation (see 24 CFR 570.202(b)(9)), and thereby not

subject to the administrative cap on expenditures.

(6) Lead-Based Paint Hazards. Section 1012 of the 1992 Act amends section 105(a) by stating that CDBG funds may be used for lead-based paint hazard evaluation and reduction, as defined in section 1004 of the Residential Lead-Based Paint Hazard Reduction Act of 1992. It should be noted that § 570.202(a)(iv) currently authorizes inspection and abatement of lead-based paint in conjunction with CDBG-assisted rehabilitation. Moreover, § 570.205 authorizes evaluation of lead-based paint hazards within the grantee's jurisdiction generally. Until the regulations are modified to incorporate this new provision, grantees may use the new authority to fund lead-based paint inspection of houses whether or not rehabilitation of the houses will be CDBG-funded. The new authority may also be used to fund large scale evaluation of lead based-paint hazards in the grantee's jurisdiction (assuming that it is an approved activity in the Indian Community Development Block Grant application), outside of the 20 percent limitation on planning and administration cost, if the grantee can demonstrate that the evaluation addresses a CDBG national objective.

c. *Changes Concerning National Objectives—Low/Mod Jobs Presumption.* Section 806(e) of the 1992 Act amends section 105(c) of the HCD Act by adding a subparagraph (4) which states that, for purposes of determining whether an activity involves the employment of persons the majority of whom are low- and moderate-income persons, a person may be presumed to be a low- or moderate-income person if they reside in a census tract where not less than 70 percent of the residents are low- and moderate-income persons.

D. Applicant Eligibility

To apply for funding in a given fiscal year, an applicant must be eligible as an Indian tribe or Alaskan native village, or as a tribal organization by the application submission date.

"Tribal organizations" are permitted to submit applications under 24 CFR 571.5(b) on behalf of eligible tribes or villages when one or more eligible tribe or village authorize the organization to do so under concurring resolutions. The Tribal organization must also be eligible under the Indian Self-Determination Act. If a tribe or tribal organization claims that it is a successor to an eligible entity, the FO must review the documentation to determine whether it is in fact the successor entity.

Due to the unique governmental structure of Alaskan Native Villages there is on occasion more than one group that could be recognized as the governing body of an eligible entity as set forth at 24 CFR 571.5.

On December 29, 1988, the Bureau of Indian Affairs (BIA) published a Federal Register Notice entitled "Indian Entities Recognized and Eligible to Receive Services From the United States Bureau of Indian Affairs". This Notice included an alphabetical listing of all Alaskan entities eligible to receive funding and services from the Bureau of Indian Affairs. Each entity listed qualified under one of the nine criteria set forth in the Notice. The Notice stated that an entity which qualified under criteria 1, 2, 3, 4, or 9 is also an "Indian tribe" under the definition of that term used for the purposes of the Indian Self-Determination Act. The criteria are:

1. "Tribes" as defined or established under the Indian Reorganization Act (IRA) as supplemented by the Alaska Native Act.

2. Alaska Native Villages defined in or established pursuant to the Alaska Native Claims Settlement Act (ANCSA).

3. Village corporations defined in or established pursuant to ANCSA.

4. Regional corporations defined in or established pursuant to ANCSA.

9. Tribes which have petitioned to be acknowledged and have been determined to exist as tribes pursuant to 25 CFR Part 83. (A BIA regulation)

The hierarchy for funding priority continues to be the IRA Village Council, then the Traditional Village Council, followed by the Village Corporation and the Regional Corporation. Since there may only be one application submitted for an ICDBG grant for each area within the jurisdiction of an entity eligible under 24 CFR 571.5, if a Village Corporation or Regional Corporation submits an application for an ICDBG grant for activities in the jurisdiction of one or more eligible tribes or villages, it must include a concurring resolution from each such tribe or village authorizing the submittal of the application. Each such resolution must also indicate that the tribe or village does not itself intend to submit a ICDBG application for that funding round.

If possible, questions regarding eligibility determinations and related documentation requirements should be referred to the Anchorage FO prior to the deadline for submitting an application. (See 24 CFR 571.5 for a complete description of eligible applicants.)

E. Selection Criteria/Rating Factors

1. Rating and Ranking System

Prior to the rating process, field offices will screen applications to ensure that they meet the acceptance criteria in 24 CFR 571.301(a). Field offices will review each application that passes the screening to ensure that each proposed project meets all of the requirements in 24 CFR 571.302(a), as implemented by this NOFA.

The field office will determine the proper category and component (e.g., Housing Rehabilitation) under which to rate each project. Each component is worth 100 points, which is the maximum that a project can receive.

All projects that meet the acceptance criteria and threshold requirements will be reviewed and rated by a field office rating team of at least three voting members. The rating team will normally consist of representatives from the Indian CDBG staff. Voting members may be selected from other HUD divisions, such as the non-CPD portion of the Office of Native American Programs, and non-Indian CPD. The rating panel may solicit technical advice from experts such as attorneys, economists and cost analysts. Experts may be voting or non-voting members.

After each of the applications has been rated, the projects will be ranked in order of the point totals they received, regardless of the rating category or component under which the points were awarded. Projects will be selected for funding based on their ranking, in accordance with the requirements of § § 571.100(b) and 571.302(c).

2. Thresholds

The ICDBG regulation (24 CFR Part 571) contains two types of general thresholds: those that relate to applicants, and those that address overall community development appropriateness. Project-specific definitions and thresholds will be addressed within the pertinent project selection criteria categories.

Applicant thresholds focus on the administrative capacity of the applicant to undertake the proposed project(s), and on its past performance in the ICDBG and Housing programs. An applicant that has participated in the ICDBG program previously must have performed adequately. In cases of previously documented deficient performance, the applicant must have taken appropriate corrective action to improve its performance prior to submitting an ICDBG application to HUD.

In order for the project(s) contained in applications that have passed the initial screening tests outlined in section 571.301 to be rated and ranked, field offices must determine that the proposed project(s) meets the

community development appropriateness thresholds and (a) has costs that are reasonable, (b) is appropriate for the intended use, and (c) will normally be completed within two years.

If an applicant fails to meet the applicant-specific thresholds, its application cannot be accepted for rating and ranking. Project(s) that do not meet the community development appropriateness or project-specific thresholds will not be considered for funding.

a. Applicant-Specific Thresholds—Capacity and Performance

(1) *Capacity.* The field office will assume, absent evidence to the contrary, that the applicant possesses, or can obtain the managerial, technical or administrative capability necessary to carry out the proposed project(s). The application should address who will administer the project(s) and how the applicant plans to handle the technical aspects of executing the project(s). If the field office determines, based on substantial evidence, that the applicant does not have or cannot obtain the capacity to undertake the proposed project(s), the project(s) will be rejected from further consideration.

(2) *Performance.* If an applicant has participated in the ICDBG Program previously, the field office shall determine whether the applicant has performed adequately in grant administration and management. Where an applicant was found to be performing inadequately, the field office shall determine whether the applicant is following a schedule to correct performance, to which the applicant and HUD have agreed. In cases of previously documented deficient performance, the field office must determine that the applicant has taken appropriate corrective action to improve its performance.

(a) *Community Development.* The applicant is presumed to be performing adequately unless the field office makes a performance determination to the contrary by monitoring.

(b) *Housing assistance.* The applicant is presumed not to have taken actions to impede the provision of housing assistance for low- and moderate-income members of the tribe or village. Any action that is known to HUD to prevent or obstruct the provision or operation of assisted housing for low and moderate income persons shall be evaluated in terms of whether it constitutes inadequate performance by the applicant.

In addition, tribes have certain responsibilities and obligations to Indian Housing Authorities (IHAs), outlined in Article VIII of HUD's Model Tribal Ordinance. In instances where a tribe has established or joined an IHA, and has obtained housing assistance from HUD, its compliance with the resolution set forth in Article VIII will be a performance consideration.

Applicants will not be held accountable for the poor performance of Indian Housing Authorities (IHAs). However, if inadequate performance is found to be a direct result of the applicant's action or inaction, the application will be rejected from further consideration. Applicants who are members of "umbrella" IHAs will be judged only on their individual performance and will not be held accountable for the poor performance of other tribes that are represented by the IHA.

In the case of tribes that have not established or are not members of housing authorities, HUD will consider in making its determination, whether the tribe received CDBG funds for the provision of new housing, and if so: (i) whether the proposed units were constructed; (ii) whether housing assistance was provided to the beneficiaries identified in the application, and if not, why not; (iii) whether the tribe followed the provisions of its housing plan and procedures; and (iv) whether there were sustained complaints from tribal members regarding provision and/or distribution of CDBG housing assistance.

(c) *Audits.* This threshold requires the applicant to meet the following performance criteria:

(i) The applicant cannot have an outstanding ICDBG obligation to HUD that is in arrears, or it must have agreed to a repayment schedule. An applicant that has an outstanding ICDBG obligation to HUD that is in arrears, or one that has not agreed to a repayment schedule, will be disqualified from the current competition and from subsequent competitions, until the obligations are current. If a grantee that was current at the time of application submission becomes delinquent during the review period, the application may be rejected.

(ii) The applicant cannot have an overdue or unsatisfactory response to an audit finding(s). If there is an overdue or unsatisfactory response to an audit finding(s), the applicant will be disqualified from current and subsequent competition until the applicant has taken final action necessary to close the audit finding(s). The field office director may provide exceptions to this disqualification in cases where the applicant has made a good faith effort to clear the audit finding(s). Only when a satisfactory arrangement for repayment of the debt has been made, and payments are current, will an exception be granted when funds are due HUD.

b. Community Development Appropriateness.

The following criteria must be met by all applicants:

(1) Costs are reasonable. The project(s) must be described in sufficient detail so that HUD can determine: (a) that costs are reasonable; and (b) that the funds requested from the CDBG program and all other sources are adequate to complete the proposed activity(ies) described in the application.

(2) The project(s) is appropriate for the intended use.

(3) The project(s) is usable or achievable in a timely manner, generally within a two-year period. The applicant must indicate its timetable for project implementation and completion. A period of more than two years is acceptable in certain circumstances, which are beyond the applicant's control. For example, a construction season may be limited by severe weather, or extra time may be required to coordinate different funding dates for other entities assisting the same project.

3. Tiebreakers

When rating results in a tie among projects, field offices shall approve projects that can be fully funded over those that cannot be fully funded. When that does not resolve the tie, the following factors should be used in the order listed to resolve the tie:

a. Chicago Office

(1) The application that benefits the highest percentage of low-and moderate-income persons.

(2) The application that benefits the most low-and moderate-income persons.

b. Oklahoma City Office

(1) The application that benefits the highest percentage of low-and moderate-income persons.

(2) The applicant with the fewest active grants.

(3) The application that benefits the most low-and moderate-income persons.

c. Denver Office

(1) The application that benefits the highest percentage of low-and moderate-income persons.

(2) The application that benefits the most low-and moderate-income persons.

d. Phoenix Office

(1) The applicant with the fewest active grants.

(2) The applicant that has not received a block grant over the longest period of time.

(3) The application that benefits the highest percentage of low-and moderate-income persons.

e. Seattle Office

(1) The applicant that has not received a block grant over the longest period of time.

(2) The applicant that has received the fewest CDBG dollars since the inception of the program.

(3) The application that benefits the highest percentage of low-and moderate-income persons.

f. Anchorage Office

(1) The applicant that has not received a block grant over the longest period of time.

(2) The application that benefits the highest percentage of low-and moderate-income persons.

(3) The application that benefits the most low-and moderate-income persons.

4. General Definitions

Adopt. To approve by formal tribal resolution, as defined at 24 CFR Part 571.4.

Assure. To comply with a specific NOFA requirement. The applicant should state its compliance or its intent to comply in its application.

Document. To supply supporting written information and/or data in the application, which satisfies the NOFA requirement.

Leverage. Resources the grantee can use in conjunction with CDBG funds to achieve the objectives of the project. Resources include, but are not limited to: tribal trust funds, loans from individuals or organizations, state or federal loans or guarantees, other grants, as well as noncash contributions and donated services. Funds from any source must be documented by a written commitment and may be contingent on approval of the CDBG award. Resources will be counted only if they are currently available or will be available within 3 months of grant notification. If delays in the Federal funding process preclude an agency from making a firm funding commitment, resources will be counted if the agency issues a written statement indicating that it is extremely likely that the applicant will be funded within 6 months of the date of grant notification. Donated services will be accepted, provided: (1) the costs are demonstrated and determined necessary and directly attributable to the actual development of the project; and (2) comparable costs and time estimates are submitted which support the donation.

Project Cost. Total cost to implement the project. Project cost includes both CDBG and non CDBG funds.

Tribe. Indian tribe, band, group or nation, including Alaskan Indians, Aleuts, Eskimos and Alaskan native villages.

5. Project Definitions, Thresholds and Selection Criteria

a. Housing

(1) *Definition—Section 8 standards.* Standards contained in the Section 8 Housing Assistance Payments Program–Existing Housing (24 CFR 882.109).

(2) *General Thresholds.* Households that have been evicted from HUD housing within the past five years may not be assisted, except in emergency situations, which will be reviewed by field offices on a case-by-case basis.

(3) *Rehabilitation*

(a) *Thresholds*

(i) All applicants for housing rehabilitation grants shall adopt rehabilitation standards and rehabilitation policies, prior to submitting an application.

(ii) Any units to be rehabilitated must be the permanent non-seasonal residence of the occupant(s). The resident(s) must live in the unit at least nine months per year.

(iii)) Housing units slated for eventual replacement may only receive repairs essential for health and safety.

(iv) The applicant shall provide an assurance that it will use project funds to rehabilitate HUD assisted units only where the tenant/homeowner's payments are current or the tenant/homeowner is current in a repayment agreement that is subject to approval by the field office. The field office may grant exceptions on a case-by-case basis, to the requirement that beneficiaries be current to permit housing rehabilitation in emergency situations.

(v) Houses that have received comprehensive rehabilitation assistance from any CDBG or federal grant within the past 8 years cannot receive CDBG funds to make the same repairs if the repairs are needed as a result of abuse or neglect.

(b) *Applicant Guidance.* The following requirements apply to all successful applicants for rehabilitation funds provided for under this NOFA. All single family units to be rehabilitated must be occupied by low-and moderate-income households. If a structure contains two units, at least one must be occupied by a low-or moderate-income household. If a structure contains more than 2 units, at least 51 percent of the units must be occupied by low-and moderate-income households. When two or more rental buildings being assisted are or will be located on the same or contiguous properties, and the buildings will be under common ownership and management, the grouped buildings may be considered a single structure for the purpose of calculating low- and moderate-income occupancy. Low- and moderate-income tenants occupying a rehabilitated dwelling shall pay no more than 30 percent of their household income in rent.

(c) *Grant limits.* Rehabilitation grant limits for each field office jurisdiction are as follows:

(i) Region 5 (Chicago)	$15,000
(ii) Region 6 (OK City)	15,000
(iii) Region 8 (Denver)	33,500
(iv) Region 9 (Phoenix)	25,000
(v) Region 10 (Seattle)	18,000
(vi) (Anchorage)	Lesser of $35/square feet or $25,000

(d) *Selection Criteria.* Applicants for housing rehabilitation projects will be rated based on the following:

(i) Project Need and Design (45 points)

(A) The percentage of CDBG funds committed to bring the housing up to standard condition as defined by the applicant. Standard condition is defined as adoption of standards at least as stringent as Section 8. Exceptions, which must be approved by the field office, may be made when local conditions make the use of Section 8 standards infeasible. For example, units may be too remote to make the provision of electricity and running water economically feasible, or Section 8 standards may not be met for historic preservation reasons. In all cases, to be considered in standard condition, a home must be in safe, sanitary, and physically sound condition with all systems performing their intended functions.

Administrative and technical assistance expenditures are excluded in computing the percentage of CDBG funds committed to bring housing up to standard condition. The percentage of CDBG funds not used to bring housing up to standard condition should be used for emergency repairs, demolition of substandard units, planning related to the particular project or another purpose closely related to the housing rehabilitation project.

Percentage of CDBG Funds Committed to bring housing up to standard condition	Points
1 91–100%	25
2 81–90%	10
3 80% and less	0

(B) The applicant's selection criteria give priority to the neediest households. "Neediest" is defined as households whose current residences are in the

greatest disrepair in the project area, or very low-income households.

1 YES (10 points)
2 NO (0 points)

(C) Documentation of project need with a housing survey of all of the units to be rehabilitated with CDBG funds. This survey should include standard housing data on each unit surveyed (e.g., age, size, type, rooms, type of heating). The survey should show the number of standard units, the number of substandard units suitable for rehabilitation with the deficiencies listed for each unit, and the number of substandard units unsuitable for rehabilitation. A definition of "suitable for rehabilitation" should be included. At a minimum, this definition should not include units that need only minor repairs, or units that need such major repairs that rehabilitation is structurally or financially infeasible.

Submission of acceptable survey of deficiencies.

1 YES (10 points)
2 NO (0 points)

(ii) Planning and Impiementation (45 points)

(A) Rehabilitation Policies including:

1 Adopted rehabilitation standards. Adopted rehabilitation standards should be at least equal to Section 8 standards except that the field office can approve lesser standards as provided in Paragraph I.E.5.a.(3)(d)(i). Tribes may submit their request for lesser standards prior to the application due date. If the request is submitted with the application, applicants should not assume automatic approval from the field office.

- YES (5 points)
- NO (0 points)

2 Rehabilitation selection criteria. Rehabilitation selection criteria include property selection standards, cost limits, type of financing (e.g., loan or grant), homeowner costs and responsibilities, procedures for selecting households to be assisted, and income verification procedures.

- MAXIMUM (11 points)

The application contains all the selection criteria listed above.

- MODERATE (5 points)

The application does not contain all the selection criteria listed above, but a sufficient number to enable the project to proceed effectively; OR the application contains all the selection criteria listed above, but in insufficient detail.

- UNSATISFACTORY (0 points)

The submission does not meet the MODERATE criteria.

3 Project planning documents and applicable policies and procedures. Project planning documents include surveys, time schedules, and work priorities. Policies and procedures include: inspections, contractor payment (an inspection to ensure the work is successfully completed before the contractor is paid), household involvement in the rehabilitation (e.g., helping select the contractor and signing off on inspections), contractor selection, contractor forms, complaints, contract or dispute resolution, and repayment provisions for early sale, (i.e., before 5 years).

- MAXIMUM (5 points)

The application contains all the policies and procedures listed above, and they will enable the project to be effectively implemented.

- MODERATE (3 points)

The application contains some but not all of the policies and procedures listed above, and they are sufficient for the project to proceed effectively.

- UNSATISFACTORY (0 points)

The submission does not meet the MODERATE criteria.

(B) Post rehabilitation maintenance policies, including counseling and training homeowners on maintenance.

1 MAXIMUM (7 points)

The policy contains a well-planned counseling and training program. Training will be provided for assisted households, and provision is made for households unable to do their own maintenance (e.g., elderly and handicapped). The policy includes follow-up inspections after rehabilitation is completed to ensure the unit is being maintained.

2 MODERATE (4 points)

The policy contains a well-planned homeownership maintenance training and counseling program.

3 UNSATISFACTORY (0 points)

The submission does not meet the MODERATE criteria.

(C) Quality of cost estimates. Cost estimates have been prepared by a qualified individual.

1 MAXIMUM (12 points)

Costs must be documented on a per unit basis and must be justified. Applicants must include work write-ups based on tribal specifications or estimates by a qualified individual. Work write-ups state what needs to be done to correct the deficiency (e.g., provide an oil heater to correct a deficiency of an inadequate heating system). The tribal specifications state the quality and the dimensions of the improvements (e.g., the heating unit must be capable of putting out x BTU's in order to heat the unit to a temperature of 70 degrees when the outside temperature is 0 degrees).

2 HIGH (8 points)

Cost estimates developed by a qualified individual have been prepared on each dwelling unit to be rehabilitated to determine the total rehabilitation cost. Costs to rehabilitate each house are documented by a deficiency list.

3 MODERATE (3 points)

A qualified individual has prepared cost estimates only for the project based on surveys, but not for individual units.

4 UNSATISFACTORY (0 points)

The submission does not meet the criteria in paragraph 3.

(D) Cost effectiveness of the rehabilitation program. This measures the efficiency of the expenditures that are made for housing rehabilitation, considering the needs of the unit. Projects should propose rehabilitation that is needed to bring units up to standard in the most efficient manner and at a reasonable cost. Cost savings may be realized through efforts such as energy conservation, or a partnership or affiliation with technical experts to develop an innovative approach.

1 Rehabilitation project is cost effective (5 points)

2 Rehabilitation project is not cost effective (0 points)

(iii) Leveraging (10 points)

Points under this component will be awarded based on the definition of "leverage" under General Definitions, and the following breakdown:

Non-CDBG % of Project Cost	Points
25 and over	10
20–24	8
15–19	6
10–14	4
5–9	2
0–4	0

(4) *Land to Support New Housing*

(a) *Thresholds*

(i) The net usable acres acquired must not exceed the amount of property needed to construct the proposed houses utilizing prudent site design.

(ii) Housing assistance needs must be clearly demonstrated, for example, with a survey or an IHA-approved waiting list.

(b) *Applicant Guidance*

The HUD FO may not enter into a contract with a successful applicant for funds provided under this NOFA if the following circumstances exist.

(i) There can be no outstanding reasons why the IHA cannot receive

housing units from HUD if units are to be provided by HUD Indian Housing.

(ii) Where a dwelling(s) currently exists on the land to be acquired, and the tribe plans to use that unit for housing for qualified households, the applicant must submit with the application a proposed plan that contains a method for selecting the recipient(s), housing maintenance and a description of the type of housing being acquired. If the unit(s) can be rehabilitated or can be occupied without rehabilitation, the unit(s) must meet tribal or Section 8 standards, whichever is higher.

(iii) If the CDBG funding cycle is before the Housing Development funding cycle (for housing projects proposed to be constructed with HUD Traditional Indian Housing Development funds), successful applicants in Land Acquisition for Housing will be issued a contract for the full amount of the grant. The contract will contain a condition that until the project receives Housing Development approval, CDBG funds may be expended only to secure an option. If the IHA is not selected for Housing Development Program funds, the balance of the CDBG grant will be canceled.

(iv) If it can be demonstrated that a commitment has been made by the Bureau of Indian Affairs (BIA) under the Home Improvement Program (HIP) for funding new housing construction, the 2-year time period for project completion may be extended to be consistent with the commitment identified. The commitment should indicate that the funds committed will be used to build housing on the land to be acquired.

(c) *Selection Criteria.*

Applications for land purchase will be selected based on the following:

(i) Project Need (40 Points)

(A) MAXIMUM (40 points)

The applicant has no suitable land to construct new housing and needed amenities (e.g., water and sewer) for new housing.

(B) HIGH (30 points)

The applicant has land suitable for housing construction and infrastructure, but the land is officially dedicated to another purpose.

(C) MODERATE (25 points)

The applicant will be acquiring land to construct new housing and to provide needed amenities (e.g., water and sewer) to both new housing and existing housing.

(D) LOW (15 points)

The applicant will be acquiring land to construct amenities (e.g., water and sewer) for existing housing.

(E) UNSATISFACTORY (0 points)

The submission does not meet the criteria in paragraph d.

(ii) Planning and Implementation (60 points)

(A) Suitability of land to be acquired. A preliminary investigation has been conducted by a qualified entity independent of the applicant (e.g., BIA or IHS). Based on the preliminary investigation, the land appears to meet all applicable requirements, soil conditions appear to be suitable for individual and/or community septic systems, if appropriate, and the land has adequate drainage and access to water, electricity and community sewer collection systems. Land has adequate access, and appears to comply with environmental requirements. Land is available at a reasonable price. Future land development costs are expected to be consistent with other area subdivision costs. (Subdivision costs include the cost of constructing each unit, plus the land, water and sewer service, electrical service and roads required to serve the subdivision.) The site complies with all applicable requirements.

1 YES (18 points)

2 NO (0 points)

(B) Housing resources are committed at the time of project application.

1 Conditional commitment or approvable application submitted. (5 points)

2 No Conditional commitment or approvable application submitted. (0 points)

(C) Availability/accessibility of supportive services and employment opportunities. Upon completion of construction, fire and police protection, road accessibility and utilities will be available to the site, and medical and social services, schools, employment opportunities, and shopping will be accessible from the site, i.e., according to the community's established norm.

1 YES (8 points)

2 NO (0 points)

(D) Commitment that families will move into the new housing.

1 Documented commitment from families that they will move into new housing. (5 points)

2 No documented commitment. (0 points)

(E) Land can be taken into trust or provisions have been made for taxes and fees. There must be a written assurance from the BIA that the land will be taken into trust within one year, or the applicant must be able to show the financial capability and commitment to pay the property taxes and fees on the land for the foreseeable future. This commitment should take the form of a resolution by the governing body indicating that the applicant will pay or guarantee that all taxes and fees on the land will be paid.

1 Documentation that land can be taken into trust or provisions made for taxes and fees. (4 points)

2 Inadequate or no documentation. (0 points)

(F) A plan for any infrastructure needed to support housing to be developed. This includes a conditional commitment for funds to develop necessary water, sewer, electricity and roads to support the housing to be developed.

1 Financial commitment provided or infrastructure is in place. (10 points)

2 A plan, but no financial commitment, is in place. (5 points)

3 No financial commitment or plan. (0 points)

(G) The extent to which the proposed site meets the applicant's housing needs. The application shows that the tribe has examined and assessed the appropriateness of alternative sites. The applicant submits comparable sales that show the cost is reasonable.

1 YES (10 points)

2 NO (0 points)

(5) *New Housing Construction/Direct Homeownership Assistance*

(a) *New Construction*

(i) Thresholds

(A) New housing construction can only be implemented through a nonprofit organization that is eligible under Section 571.202 or a nonprofit organization serving the development needs of the communities of nonentitlement areas or as otherwise eligible under Section 570.207(b)(3).

(B) All applicants for new housing construction grants must document the following in their application:

1 No other housing is available in the immediate reservation area that is suitable for the families to be assisted.

2 No other funding sources can meet the needs of the household(s) to be served.

3 Rehabilitation of the unit occupied by the family to be housed is not economically feasible, or the family to be housed is currently in an overcrowded unit (sharing unit with other household(s), or the family to be housed has no current residence.

(C) All applicants for housing construction grants shall adopt construction standards and construction policies, prior to submitting an application. Applicants must identify the building code they will use to construct the unit(s). The building code may be a locally adopted tribal building

code or a nationally recognized model code. If the code is a locally adopted code, it must regulate all of the areas and subareas identified in 24 CFR 200.925(b), and it must be reviewed and approved by the HUD field office. If the code is recognized nationally, it must be the latest edition of one of the codes incorporated by reference in 24 CFR 200.925(c).

(D) Any units to be constructed must be the permanent non-seasonal residences of the recipient. The residents must live in the unit at least nine months per year.

(E) The applicant shall assure that it will use project funds to construct units only where the tenant's/homeowner's payments are current or the tenant/homeowner is current in a repayment agreement that is subject to approval by the field office. The field office may grant exceptions, on a case-by-case basis, to the requirement that beneficiaries be current to permit new construction, in emergency situations.

(ii) Selection Criteria

(A) New construction under Section 248 of the National Housing Act will be rated under the Direct Homeownership Assistance Selection criteria. The New Construction thresholds will be used for Section 248 New Construction.

(B) Project Need and Design (45 points)

1 The applicant either is not a member of an IHA, or the umbrella IHA to which it belongs has not provided assistance to the applicant in a substantial period of time, or the IHA serving the applicant has not received HUD Public and Indian Housing new construction or modernization assistance in a substantial period of time, due to a lack of funds. The period of time during which the IHA serving the applicant does not receive funding for inadequate or poor performance by the applicant does not count towards the period of time that no assistance has been provided by HUD.

- No assistance from IHA for 10 years or longer. (15 points)
- No assistance from IHA for 6–9.9 years. (10 points)
- No assistance from IHA for 0–5.9 years. (0 points)

2 Adopted housing construction policies and plan. The plan should include a description of the proposed subrecipient and its relationship to the tribe. In addition, the policies and plan should include:

- A selection system that gives priority to the neediest households. Neediest shall be defined as households whose current residences are in the greatest disrepair, or very low-income households, or households without permanent housing.
- A system effectively addressing long-term maintenance of the constructed units.
- Estimated costs and identification of the responsible entity for paying utilities, fire hazard insurance and other normal maintenance costs.
- Policies governing ownership of the units, including the status of the land.
- Description of a comprehensive plan or approach being implemented by the tribe to meet the housing needs of its members.
- Policies governing disposition or conversion to non-dwelling uses of substandard units that will be vacated.

- Acceptable policies and plan. (20 points)

- Unacceptable policies and plan. (0 points)

3 Beneficiary identification (all beneficiaries are low- and moderate-income.)

- Beneficiaries to be housed are identified. (10 points)
- Beneficiaries are not identified. (0 points)

(C) Planning and Implementation (45 points)

1 Occupancy Standards. The proposed housing will be designed and built according to adopted reasonable standards that govern the size of the housing in relation to the size of the occupying family (minimum and maximum number of persons allowed for the number of sleeping rooms); the minimum and maximum square footage allowed for major living spaces (bedrooms, living room, kitchen and dining room).

- Applicant has adopted reasonable occupancy standards. (10 points)
- Applicant has no occupancy standards or standards are inappropriate. (0 points)

2 Site Acceptability. This includes consideration of land control, access, utilities, infrastructure, physical characteristics, and whether the site is held in trust.

The applicant has control of the land. The applicant has written assurance from the BIA that the land is (or will be) taken into trust within one year, or the applicant must be able to show the financial capability and commitment to pay the property taxes and fees on the land for the foreseeable future. This commitment should take the form of a resolution by the governing body within one year of the application deadline indicating that the applicant will pay or guarantee that all taxes and fees on the land will be paid.

A preliminary investigation has been conducted by a qualified entity independent of the applicant (e.g., BIA or IHS). Based on the preliminary investigation, the land appears to meet all applicable requirements, soil conditions appear to be suitable for individual and/or community septic systems, if appropriate, land has adequate drainage and accessibility to water, electricity and community sewer collection systems. Land has adequate access, and appears to comply with environmental requirements.

- YES (15 points)
- NO (0 points)

3 Energy Conservation Design. The project is designed so that energy consumption will meet or exceed state conservation standards for similar units in the same general area. Special design features and methodology should be described in detail.

- YES (5 points)
- NO (0 points)

4 Housing Survey. The survey should include all of the units in the service area for the new housing. The survey should include standard housing data on each unit surveyed (e.g., age, size, type, rooms, type of heating), as well as the components listed below.

i Total number of existing housing units in the community.

ii Number of occupied units.

iii Number of vacant units (line A minus line B).

iv The number of standard units.

v The number of substandard units suitable for rehabilitation with the deficiencies listed for each unit. A definition of "suitable for rehabilitation" should be included.

vi The number of substandard units unsuitable for rehabilitation.

vii Number of vacant units that are in standard condition available and affordable to low-and moderate- income families.

viii Number of Indian/native families living with other families resulting in overcrowded conditions.

ix Number of Indian/native families living in units which are below standard and that are not cost effective to rehabilitate.

x Number of homeless Indian/native families.

xi Number of families living in below standard conditions

(Lines *viii*, plus *ix*, plus *x* equal line *xi*.)

- Acceptable survey. (10 points)
- Unacceptable survey. (0 points)

5 Cost effectiveness of new housing construction. This measures the efficiency of the expenditures. Projects should provide new units in the most

efficient manner and at a reasonable cost. Cost savings may be realized through efforts such as the use of cost effective construction techniques, a partnership or affiliation with technical experts to develop an innovative approach, or a repayment provision.

- New Housing Construction is Cost Effective (5 points)
- New Housing Construction is not Cost Effective (0 points)

(D) Leveraging (10 points). Applicants must provide documentation of the amount and sources of additional funds. Sources may include private contributions including equity and loans, applicant and other non-CDBG governmental funding.

Non-CDBG % of Project Cost	Points
25 and over	10
20–24	8
15–19	6
10–14	4
5–9	2
0–4	0

(b) *Direct Homeownership Assistance*

(i) Thresholds

(A) No other funding sources can meet the needs of the household(s) to be served.

(B) The unit occupied by the family to be housed does not meet Section 8 standards, and rehabilitating the unit is not economically feasible, or the family to be housed currently is in an overcrowded unit (sharing unit with other household(s), or the family to be housed has no current residence.

(C) Any units to be occupied must be the permanent non-seasonal residences of the recipient. The residents must live in the unit at least nine months per year.

(D) The applicant shall assure that it will use project funds to provide direct homeownership assistance only where the tenant's payments are current or the tenant is current in a repayment agreement that is subject to approval by the field office. The field office may grant exceptions, on a case-by-case basis, to the requirement that beneficiaries be current to permit direct homeownership assistance in emergency situations.

(ii) Selection Criteria

(A) Project Need and Design (45 points)

1 Adopted housing policies and plan. The plan should include a description of the proposed subrecipient (if applicable) and its relationship to the tribe. In addition, the policies and plan should include:

- A selection system that gives priority to the neediest qualifiedhouseholds. Neediest may be defined as households whosecurrent residences are in the greatest disrepair, very low- income households, or households without permanent housing.
- Description of a comprehensive plan or approach being implementedby the tribe to meet the housing needs of its members.
- Policies governing disposition or conversion to non-dwelling uses of substandard units that will be vacated.
- A system effectively addressing long-term maintenance of theunits.
- Estimated costs of utilities, fire hazard insurance and other normal maintenance costs.
- Policies governing ownership of the units, including the status of the land.
- The units will meet Section 8 standards or another standard approved by the field office.

i The policies and plan are acceptable and contain all of the items listed above. (30 points)

ii The policies and plan contain only the first three items listed above, and they are acceptable. (20 points)

iii The policies and plan contain only the last four items listed above,and they are acceptable. (10 points)

iv The policies and plan do not meet the criteria of paragraphs *i, ii,* or *iii.* (0 points)

2 Beneficiary identification. (All beneficiaries are low and moderate income.)

- Beneficiaries are identified. (15 points)
- Beneficiaries are not identified. (0 points)

(B) Planning and Implementation (45 points)

1 Occupancy Standards. The housing units will meet adopted reasonable standards that govern the size of the housing in relation to the size of the occupying family (minimum and maximum number of persons allowed for the number of sleeping rooms); and the minimum and maximum square footage allowed for major living spaces (bedrooms, living room, kitchen and dining room).

- Applicant has appropriate occupancy standards. (13 points)
- Applicant has no occupancy standards or standards are inappropriate. (0 points)

2 Site Acceptability. This includes consideration of land control, access, utilities, infrastructure, physical characteristics, whether the site is held in trust, and available services, such as fire and police protection.

The applicant or prospective homeowner has control of the land. Applicant has a written assurance from the BIA that the land is (or will be) taken into trust within one year, or the applicant must be able to show the financial capability and commitment to pay the property taxes and fees on the land for the foreseeable future.

A preliminary investigation has been conducted by a qualified entity independent of the applicant (e.g., BIA or IHS). Based on the preliminary investigation, the land appears to meet all applicable requirements, soil conditions appear to be suitable for individual and/or community septic systems, if appropriate, land has adequate drainage and accessibility to water, electricity and community sewer collection systems. Land has adequate access, and appears to comply with environmental requirements.

- YES (20 points)
- NO (0 points)

3 Energy Conservation Design. The project is designed so that energy consumption will be no greater than that of similar units in the same general area. Special design features and methodology should be described in detail.

- YES (6 points)
- NO (0 points)

4 Cost effectiveness of program. This measures the efficiency of the expenditures that are made for direct homeownership. Cost savings may be realized through efforts such as the use of cost effective construction techniques, a partnership or affiliation with technical experts to develop an innovative approach, provision of the least amount of assistance necessary for each homeowner to acquire the unit, or a provision for the homeowner to repay the tribe.

- YES (6 points)
- NO (0 points)

(C) Leveraging (10 points). Points under this component will be awarded based on the definition of "leverage" under General Definitions, and the following breakdown:

Non-CDBG % of Project Cost	Points
70 and over	10
60–69	8
50–59	6
40–49	4
30–39	2
0–29	0

b. Community Facilities

(1) *General Thresholds.* The applicant shall describe the problem, the proposed project and the anticipated impact on the tribe/village if the problem is not solved immediately.

(2) *Infrastructure*

(a) *Applicant Guidance*

(i) For all projects which include provision of water, waste water treatment or solid waste disposal facilities, the applicant shall include with the application evidence that the project has been submitted to the Indian Health Service (IHS) for review and comment.

(ii) If the project consists of new or existing community water system improvements (defined as serving more than 25 persons or 15 households), the applicant must provide evidence that the project has been submitted to the Environmental Protection Agency (EPA) for review and comment. Community water systems serving fewer than 25 persons or 15 households are eligible for CDBG funding, but do not require EPA review.

(b) *Selection Criteria*

(i) Project Need and Design (60 points)

(A) Meets an essential community development need by addressing a basic need that is critical to the orderly development of the community and to the provision of basic human services. (Example: water/sewer, waste disposal)

1 Permanent solution. The project offers a long-term solution. (17 points)

2 Health and safety intermediate solution. The project responds to a health or safety problem by offering a solution which is not permanent (e.g., providing potable water from elsewhere). (15 points)

3 Intermediate solution. The project responds to a problem which is not related to health or safety by offering a solution which is not permanent (e.g., providing a gravel road to a reservation where no road exists). (12 points)

4 Inadequate solution. (0 points)

(B) Benefits the neediest segment of the population, as identified below. Applications must include tribal, BIA, IHS or other documentation that:

1 MAXIMUM (22 points)

90 percent or more of the beneficiaries are low and moderate income (80 percent of area income).

2 MODERATE (13 points)

75–89.9 percent of the beneficiaries are low and moderate income.

3 UNSATISFACTORY (0 points)

Less than 75 percent of the beneficiaries are low and moderate income.

(C) Provides infrastructure that does not currently exist for the area to be served OR replaces an existing facility that no longer functions adequately to meet the current needs OR eliminates or substantially reduces a health or safety problem. If the project addresses a health and safety problem, the applicant must provide documentation consisting of a signed study or letter from a reliable independent authority (e.g., state health officials, state fire marshals, BIA, IHS, EPA) verifying that: (1) a threat to health and safety exists which has caused or has the potential to cause serious illness, injury, disease or death; and (2) the threat can be substantially eliminated if the CDBG project is funded.

1 MAXIMUM (21 points)

The infrastructure does not exist or no longer functions, or does not meet health and safety standards. (Examples: there is no sewage treatment plant; paved roads do not exist or must be reconstructed due to severe deterioration.)

2 MODERATE (15 points)

The infrastructure no longer functions adequately or does not meet current needs. (Example: capacity of existing sewage treatment plant is insufficient to meet the demands of area residents.)

3 UNSATISFACTORY (0 points)

The infrastructure does not meet the criteria of *1* or *2*.

(ii) Planning and Implementation (30 points)

(A) A viable plan for maintenance and operation. The tribe must adopt a maintenance plan addressing maintenance, repair and replacement of items not covered by insurance, and operating resources, if applicable. The applicant must submit this plan. The plan must identify a funding source to assure that the facility will be properly maintained and operated. The resolution must identify the total annual dollar amount the tribe will commit, as well as the source and availability of funds, including evidence that funds will be available within sixty days of project completion. If an entity other than the Tribal Council commits to pay for maintenance and operation, that entity must submit a letter of commitment which identifies the responsibilities the entity will assume and the amount of funds that will be provided annually to the project. Points will only be awarded if the field office is able to determine that the entity is financially able to assume the costs of maintenance and operation.

1 YES (15 points)

2 NO (0 points)

(B) An appropriate and effective design, scale and cost. The applicant shows that it has proposed the most appropriate and cost effective approach to address its identified need(s). The applicant shows that it has considered initial construction and lifetime operation costs, as well as the use of existing facilities and resources, and alternatives, including method of implementation and cost. If only one approach is feasible, the applicant should explain why.

1 YES (15 points)

2 NO (0 points)

(iii) Leveraging (10 points). Points under this component will be awarded based on the definition of "leverage" under General Definitions, and the following breakdown:

Non-CDBG % of Project Cost	Points
a 25+	10
b 20–24	8
c 15–19	6
d 10–14	4
e 5–9	2
f 0–4	0

(3) *Buildings*

(a) *Thresholds.* Tribes proposing a facility which would provide health care services must assure the facility meets IHS requirements.

(b) *Selection Criteria.* Applications for Community Facilities will be evaluated based on the following:

(i) Project Need and Design (60 points)

(A) Benefits the neediest segment of the population, as identified below. Applications must include tribal, BIA, IHS or other documentation that:

1 MAXIMUM (28 points)

90 percent or more of the beneficiaries are low and moderate income (80 percent of area median).

2 MODERATE (18 points)

75–89.9 percent of the beneficiaries are low and moderate income.

3 UNSATISFACTORY (0 points)

Less than 75 percent of the beneficiaries are low and moderate income.

(B) Provides a building that serves a function that does not currently exist either within or outside (nearby) the community or reservation OR replaces an existing facility that no longer functions adequately to meet current needs. (Examples: health clinic; subsistence food processing facility, Alaska.)

1 MAXIMUM (15 points)

The building does not exist or does not meet health and safety standards.

2 MODERATE (12 points)

The building no longer functions adequately or does not meet current needs.

3 UNSATISFACTORY (0 points)

The building does not meet the criteria of *1* or *2*.

(C) Provides multiple uses or multiple benefits, or has services

available 24 hours a day. The application must show that the proposed facility will house more than one broad category of activity. "Broad category" means a single activity or group of activities which serves a particular group of beneficiaries (e.g., senior citizens) or meets a particular need (e.g., literacy). No one category of activity will occupy more than 75 percent of the available space for more than 75 percent of the time. The use of space must be actually committed and documented in writing. Multipurpose buildings do not automatically meet these criteria, nor do buildings that provide a variety of activities for one client group.

1 YES (3 points)
2 NO (0 points)

(D) Meets an essential community development need by addressing a basic need that is critical to the orderly development of the community and to the provision of basic human services; OR eliminates or substantially reduces a health or safety problem. If the project addresses a health or safety problem, the applicant must provide documentation consisting of a signed study or letter from a reliable independent authority (e.g., state health officials, state fire marshals, BIA, IHS, EPA) verifying that: (1) a threat to health and safety exists which has caused or has the potential to cause serious illness, injury, disease or death; and (2) the threat can be substantially eliminated if the CDBG project is funded.

1 YES (14 points)
2 NO (0 points)

(ii) Planning and Implementation (30 points)

(A) A viable plan for maintenance and operation. The tribe must adopt a maintenance plan addressing maintenance, repair and replacement of items not covered by insurance, and operating resources, if applicable. The applicant must submit this plan. The plan must show that adequate funds are available for future replacements and identify a funding source to assure that the facility will be properly maintained and operated. The adopted resolution must identify the total annual dollar amount the tribe will commit, as well as the source and availability of funds, including evidence that funds will be available within sixty days of project completion. If an entity other than the Tribal Council commits to pay for maintenance and operation, that entity must submit a letter of commitment which identifies the responsibilities the entity will assume and the amount of funds that will be provided annually to the project. Points will only be awarded if the field office is able to determine that the entity is financially able to assume the costs of maintenance and operation.

1 YES (15 points)
2 NO (0 points)

(B) An appropriate and effective design, scale and cost. The applicant documents that it has proposed an appropriate and cost effective approach to address its identified need(s). The applicant documents that it has considered initial construction and lifetime operation costs, as well as the use of existing facilities and resources, and alternatives including, method of implementation and cost. If only one approach is feasible, the applicant should explain why.

1 YES (15 points)
2 NO (0 points)

(iii) Leveraging (10 points). Points under this component will be awarded based on the definition of "leverage" under General Definitions, and the following breakdown:

Non-CDBG % of Project Cost	Points
a 25+	10
b 20–24	8
c 15–19	6
d 10–14	4
e 5–9	2
f 0–4	0

c. Public Services

(1) *Thresholds*

(a) Public services activities may comprise no more than 15 percent of the total grant award. Such projects must therefore be submitted with one or more other projects, which must comprise at least 85 percent of the total grant award. A public service project will be funded only if both the public service project itself *and* the other project(s) with which it is submitted rank high enough to be funded.

(2) *Selection Criteria.* Applications for Public Services will be evaluated based on the following:

(a) *Project Need and Design (45 points)*

(i) Meets an essential community development need by addressing a basic need that is critical to the orderly development of the community and to the provision of basic human services.

(A) YES (15 points)
(B) NO (0 points)

(ii) Benefits the neediest segment of the population, as identified below. Applications must include tribal, BIA, IHS or other documentation that:

(A) MAXIMUM (27 points)

90 percent or more of the beneficiaries are low and moderate income (80 percent of area median).

(B) MODERATE (16 points)

75–89.9 percent of the beneficiaries are low and moderate income.

(C) UNSATISFACTORY (0 points)

Less than 75 percent of the beneficiaries are low and moderate income.

(iii) Provides a service(s) that will eliminate or substantially reduce a health or safety problem. The applicant must provide documentation consisting of a signed study or letter from a reliable independent authority (e.g., state health officials, state fire marshals, BIA, IHS, EPA) verifying that: (1) a threat to health and safety exists which has caused or has the potential to cause serious illness, injury, disease or death; and (2) the threat can be substantially eliminated if the CDBG project is funded.

(A) YES (3 points)
(B) NO (0 points)

(b) *Planning and Implementation (45 points)*

(i) A viable plan for continuing provision of the service(s). The tribe must adopt a plan to address continuing provision of the service(s). The applicant must submit this plan. The plan must identify a funding source to assure that the public service(s) will be properly carried out. The resolution must identify the total annual dollar amount the tribe will commit, as well as the source and availability of funds, including evidence that funds will be available within sixty days of project completion.

(A) YES (15 points)
(B) NO (0 points)

(ii) An appropriate and effective design, scale and cost. The applicant shows that it has proposed an appropriate and cost effective approach to address its identified need(s). The applicant shows that it has considered initial and long-term costs, as well as the use of existing services and resources, or has submitted an analysis from a qualified authority addressing alternatives, method of implementation and cost. If only one approach is feasible, the applicant should explain why.

(A) YES (15 points)
(B) NO (0 points)

(iii) An innovative method of using the public service to resolve the problem (e.g., original treatment methods, program delivery system, or use of technology).

(A) YES (15 points)
(B) NO (0 points)

(c) *Leveraging (10 points).* Points under this component will be awarded based on the definition of "leverage" under General Definitions, and the following breakdown:

Non-CDBG % of Project Cost	Points
(i) 25+	10
(ii) 20–24	8
(iii) 15–19	6
(iv) 10–14	4
(v) 5–9	2
(vi) 0–4	0

D. Economic Development

(1) *Thresholds*

(a) Economic development assistance may be provided only when a financial analysis is done which shows public benefit commensurate with the assistance to the business can reasonably be expected to result from the assisted project, and the project has a reasonable chance of success. The applicant shall demonstrate the need for grant assistance by providing documentation to support a determination that the assistance is appropriate to implement an economic development project.

(b) All economic development projects must meet one of the national objectives. A general claim of cash flow or benefit to the tribe as a whole does *not* demonstrate low- and moderate-income benefit.

(2) *Applicant Guidance.* The applicant shall submit a project description. This description should include the following information:

(a) *The product or service:* what the enterprise will do or produce.

(b) *The location and physical facilities:* regional, local and site-specific location; description of existing and proposed facilities. If land is to be acquired for the specific economic development project, the applicant must either submit evidence that the land will be taken into trust, or demonstrate compliance with zoning and other local requirements, and show that the tribe or the entity operating the business, has the ability to pay all required taxes on that land.

(c) *Key production factors:* requirements relating to utilities, transportation access, special technical and/or equipment requirements, market, raw materials, and labor force.

(d) *Jobs/labor available:* justification that the number of permanent full time equivalent jobs proposed to be created or retained by the project (full and part-time) is realistic; evidence that the project can support job costs/salaries.

(e) *The developmental entity:* identification of entity to be used (e.g., local development corporation, tribe/village, private developer, joint venture).

(f) *Equipment:* projects that include the purchase of equipment must demonstrate the appropriateness and cost effectiveness of purchasing versus leasing. The use of lease financing is encouraged wherever possible to help contain development costs.

(g) *Financial information:* applicants shall submit a detailed cost summary, evidence of funding sources, and five year operating or cash flow financial projections. For existing businesses, financial statements for the most recent three year period shall be submitted. Financial statements include the balance sheet, income statement and statement of retained earnings. For new start-up businesses, current financial or net worth statements on the principal business owners or officers are needed unless the tribe or Alaskan Native Village will be the owner of the business.

(h) *Economic strategy and objectives:* the applicant shall demonstrate how the proposed project will meet the tribe's/village's economic development strategy and objectives (e.g., to create or retain permanent, private sector jobs or provide a product and service needed and affordable to native members).

(3) *Selection Criteria.* Applications for Economic Development projects will be evaluated based on the following:

(a) *Project Viability (55 points)*

The application will be rated on the adequacy and quality of the following subparts:

(i) Market analysis

(A) MAXIMUM (10 points)

An independent third party feasibility/market analysis, generally not older than two years, which identifies the market and demonstrates that the proposed activities are highly likely to capture a fair share of the market.

(B) MODERATE (6 points)

Feasibility/Market Analysis which identifies the market and demonstrates that the proposed activities are reasonably likely to capture a fair share of the market.

(C) LOW (0 points)

The submission does not meet the criteria in paragraph b.

(ii) Management capacity

(A) MAXIMUM (10 points)

A management team with qualifying *specialized* training or technical/managerial experience in the operation of a similar business has been identified. If the grant is approved, the business will hire the identified team or persons with similar training and experience. Applicants must submit job descriptions of key management positions as well as resumes showing qualifying specialized technical/managerial training or experience of the identified management team.

(B) MODERATE (6 points)

A management team with qualifying general business training or experience will be hired if the grant is approved. Applicants must submit job descriptions of key management positions.

(C) UNSATISFACTORY (0 points)

The submission does not meet the criteria in paragraph b.

(iii) Organization

(A) MAXIMUM (8 points)

1 The tribe or entity that will operate the business has anon-going successful business enterprise. The applicant mustdescribe this enterprise and provide documentation of itshealthy financial condition (e.g., audited financial statements for the past three years); and

2 The tribe or entity that operates the business has an acceptable business management system for project development and operation.

(B) MODERATE (5 points)

The tribe or entity that will develop and operate the business has an acceptable business management system for project development and operation.

(C) UNSATISFACTORY (0 points)

The submission does not meet the criteria in paragraph b.

(iv) Viability of the Business (excluding microenterprises). The viability of an economic development project will be determined by an analysis of financial and other project related information. Components of the financial analysis are: costs, sources of funds, cash flow projections and financial statements. The applicant must submit: a detailed cost summary, evidence of funding sources; five year operating or cash flow financial projections; and business financial statements for the most recent three year period. For start-up businesses, that are not owned by the grantee, current financial or net worth statements on principal business owners or officers are needed. Financial statements include the balance sheet, income statement and statement of retained earnings.

The information derived from the analysis will be reviewed and compared to local or national industry standards to assess reasonableness of development costs, financial need, profitability, and risk as factors in determining overall project viability. In determining whether a project is viable, the field office will also consider current and

projected market conditions and profitability measures such as cash flow return on equity, cash flow return on total assets and the ratio of net profit before taxes to total assets. Sources of industry standards include Marshall and Swift Publication Company, Robert Morris Associates, Dun and Bradstreet, the Chamber of Commerce, etc. Local standards may also be used.

(A) MAXIMUM (15 points)

Based on the analysis, the project has excellent prospect of achieving viability.

(B) MODERATE (7 points)

The project has an average prospect of achieving viability.

(C) LOW (0 points)

The project has a minimal prospect of achieving viability.

(v) Viability of the Microenterprise. Microenterprises employ five or fewer employees, including the entrepreneur. The viability of a microenterprise will be determined by an analysis of financial and other project related information. Components of the financial analysis are: costs, sources of funds, cash flow projections and financial statements. The applicant must submit: a detailed cost summary, evidence of funding sources; five year operating or cash flow financial projections and monthly projections until the cash flow is positive; and business financial statements for the most recent three year period. For start-up businesses, current financial or net worth statements on principal business owners or officers are needed. Financial statements include balance sheet, income statement and statement of retained earnings.

In determining whether a project is viable the field office will also consider current and projected market conditions and profitability measures such as net profit to total assets ratio, as well as other information that the field office has that will have an effect on the project's potential viability.

(A) MAXIMUM (15 points)

1 The project will generate income for the entrepreneur, over a minimum of five years, at or above 125 percent of the annual county average individual income; and

2 Based on the analysis, the project has excellent prospect of achieving viability.

(B) MODERATE (7 points)

1 The project will generate income for the entrepreneur at or above 100 percent of the annual county average individual income; and

2 The project has an average prospect of achieving viability.

(C) UNSATISFACTORY (0 points)

The submission does not meet the criteria in paragraph *(B)* above.

(vi) Leveraging. Points under this component will be awarded based on the definition of "leverage" under General Definitions, and the following breakdown:

Non-CDBG % of Total Project Cost	Points
30%+	12
20–29%	8
10–19%	4
less than 10%	0

(b) *Permanent Full-Time Equivalent Job Creation.* Provide total number of permanent full-time jobs expected to be created and/or retained as a result of the project. Provide a summary of job descriptions and skills required. Identify the number and kind(s) of jobs expected to be available to low-and moderate-income persons. (30 points)

(i) CDBG cost per job

(A) MAXIMUM (13 points)
$15,000 or less

(B) MODERATE (10 points)
$15,001–25,000

(C) LOW (7 points)
$25,001–35,000

(D) UNSATISFACTORY (0 points)
$35,001+

(ii) CDBG cost per job targeted to low-and moderate-income persons.

(A) MAXIMUM (13 points)
$15,000 or less

(B) MODERATE (10 points)
$15,001–25,000

(C) LOW (7 points)
$25,001–35,000

(D) UNSATISFACTORY (0 points)
$35,001+

(iii) Quality of jobs targeted to low-and moderate-income persons.

(A) The jobs offer wages and benefits comparable to area wages and benefits for similar jobs, provide opportunity for advancement, and teach a transferable skill; OR

(B) The employer commits to provide training opportunities (submit a description of planned training program).

1 YES (4 points)

2 NO (0 points)

(c) *Additional Considerations (15 points).* A project must meet three of the following criteria to receive 15 points. Maximum 15 points.

(i) Use, improve or expand members' special skills. Special skills are those that members have developed through education, training or traditional cultural experiences (e.g., technical expertise in electronic assembly; making traditional native crafts).

(A) YES (5 points)

(B) NO (0 points)

(ii) Provide spin-off benefits beyond the initial economic development benefits to employees or to the community (e.g., create new investment opportunities in the area; provide a consumer product or service not currently available on or near the reservation, or provide an available consumer product or service at a significant reduction in cost).

(A) YES (5 points)

(B) NO (0 points)

(iii) Provide special opportunities for residents of federally-assisted housing (e.g., employ residents for maintenance services).

(A) YES (5 points)

(B) NO (0 points)

(iv) Provide benefits to other businesses owned by Indians or Alaska natives (e.g., increase their sales).

(A) YES (5 points)

(B) NO (0 points)

(v) Loan Repayment/Reuse of CDBG funds. If the business is not tribally owned, at least 50% of the CDBG assistance to the business will be repaid to the grantee within a 10 year period. If the business is tribally owned, the tribe agrees within a 10 year period to use funds equal to 50% of the CDBG assistance for eligible activities that meet a national objective. These funds should come from the profits of the tribally owned business.

(A) YES (5 points)

(B) NO (0 points)

II. Application Process

A. An application package may be obtained from the HUD Field Offices of Indian Programs in the following geographic locations:

Region V.

Chicago Regional Office, Office of Indian Programs, Housing and Community Development Division, 77 West Jackson Blvd., Chicago, Illinois 60604. Telephone: (312) 353–1684 (all states east of the Mississippi River, plus Iowa and Minnesota)

Region VI.

Oklahoma City Office, Indian Programs Division, CPD Branch, Murrah Federal Bldg., 200 N.W. 5th Street, Oklahoma City, OK 73102–3202. Telephone: (405) 231–5968 (Louisiana, Kansas, Oklahoma, and Texas, except West Texas)

Region VIII.

Denver Regional Office, Office of Indian Programs, Housing and

Community Development Division, CPD Staff, Executive Tower Bldg., 1405 Curtis Street, Denver, CO 80202–2349. Telephone: (303) 844–6481 (Colorado, Montana, Nebraska, North Dakota, South Dakota, Utah and Wyoming)

Region IX.

Indian Programs Office, Region IX, CPD Division, Two Arizona Center, Suite 1650, 400 N. Fifth Street, Phoenix, Arizona 85004–2361. Telephone: (602) 379–4197 (Arizona, New Mexico, Southern California, West Texas)

Indian Programs Office, CPD Division, Program Management Team (San Francisco), Phillip Burton Federal Bldg. and U.S. Courthouse, 450 Golden Gate Ave., P.O. Box 36003, San Francisco, CA 94102–3448. Telephone: (415) 556–9200 (Northern California and Nevada)

Region X.

Seattle Regional Office, Office of Indian Programs, CPD Division, Federal Office Building, 909 First Avenue, Suite 200, Seattle, WA 98104–1000. Telephone: (206) 220–5271 (Idaho, Oregon, Washington)

Anchorage Office, CPD Division, 949 E. 36th Avenue, Suite 401, Anchorage, AK 99508–4135. Telephone: (907) 271–4684 (Alaska)

B. Completed applications should be submitted to the appropriate HUD Field Office, listed above, from which application information and packages were obtained.

C. Applications may be mailed to HUD, provided that they are postmarked no later than midnight on the deadline date: November 9, 1993. Applications that are physically delivered to HUD must be received by the appropriate HUD Field Office no later than 4:30 p.m. November 9, 1993.

III. Checklist of Pre-application and Application Submission Requirements

A. *Citizen participation.* Prior to submitting an application, the applicant shall certify, by an official tribal resolution, that it has:

1. Furnished residents with information concerning amounts of funds available and the range of activities to be undertaken;

2. Held one or more public meetings to obtain the views of residents;

3. Developed and published or posted a community development statement which gives affected residents an opportunity to review it and comment on it;

4. Given residents an opportunity to review and comment on the applicant's performance under any active community development block grant;

5. Considered public comments and, if the applicant deems it appropriate, modified the application accordingly; and

6. Made the modified application available to residents.

B. Applicants shall submit an application to the appropriate field office. In accordance with the requirements of Section 571.300(f) the application should include:

1. Standard Form 424;

2. Community Development Statement which includes:

a. Components that address the relevant selection criteria

b. A brief description or an updated description of community development needs;

c. A brief description of proposed projects to address needs, including scope, magnitude, and method of implementing the project.

d. A schedule for implementing the project (form HUD–4125);

e. Cost information by project, including specific activity costs, administration, planning, and technical assistance, total HUD share (form HUD–4123); and

3. A map showing project location, if appropriate;

4. If the proposed project will result in displacement or temporary relocation, include a statement that identifies (a) the number of persons (families, individuals, businesses and nonprofit organizations occupying the property on the date of the submission of the application (or date of initial site control, if later); (b) the number to be displaced or temporarily relocated; (c) the estimated cost of relocation payments and other services; (d) the source of funds for relocation; and (e) the organization that will carry out the relocation activities.

5. Citizen Participation. Certify, in the form of an official tribal resolution, that citizen participation requirements of section 571.604 have been met;

6. Form HUD–2880, Applicant/Recipient Disclosure/Update Report, as required under Subpart C of 24 CFR part 12, Accountability in the Provision of HUD Assistance.

IV. Corrections to Deficient Applications

HUD will not accept unsolicited information from the applicant regarding the application after the application deadline has passed.

HUD may advise applicants of technical deficiencies in applications and permit them to be corrected. A technical deficiency would be an error or oversight which, if corrected, would not alter, in either a positive or negative fashion, the review and rating of the application. Examples of curable technical deficiencies would be a failure to submit proper certifications or failure to submit an application containing an original signature by an authorized official. The field office also may, at its discretion, request information to resolve inconsistencies or ambiguities in the application.

HUD will notify applicants in writing of any curable technical deficiencies in applications. Applicants will have 14 calendar days from the date of HUD's correspondence to reply and correct the deficiency. If the deficiency is not corrected within this time period, HUD will reject the application as incomplete.

V. Other Matters

A. *Environmental Statement.* A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR Part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969. The Finding of No Significant Impact is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of the General Counsel, Department of Housing and Urban Development, Room 10276, 451 Seventh Street, S.W., Washington, D.C. 20410.

B. *Federalism Executive Order.* The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, *Federalism*, has determined that this NOFA will not have substantial, direct effects on states, on their political subdivisions, or on their relationship with the Federal Government, or on the distribution of power and responsibilities between them and other levels of government. While the NOFA will provide financial assistance to Indian tribes and Alaskan native villages, none of its provisions will have an effect on the relationship between the Federal Government and the states or their political subdivisions.

C. *Family Executive Order.* The General Counsel, as the Designated Official for Executive Order 12606, *The Family*, has determined that the policies announced in this NOFA would not have the potential for significant impact on family formation, maintenance and general well-being and thus is not subject to review under the Order.

D. *Registration of Consultants.* Section 13 of the Department of Housing and Urban Development Act contains two provisions dealing with efforts to influence HUD's decisions with respect to financial assistance. The first imposes

disclosure requirements on those who are typically involved in these efforts -- those who pay others to influence the award of assistance or the taking of a management action by the Department *and* those who are paid to provide the influence. The second restricts the payment of fees to those who are paid to influence the award of HUD assistance, if the fees are tied to the number of housing units received or are based on the amount of assistance received, or if they are contingent upon the receipt of assistance.

Section 13 was implemented by final rule published in the **Federal Register** on May 17, 1991 (56 FR 22912). If readers are involved in any efforts to influence the Department in these ways, they are urged to read the final rule, particularly the examples contained in Appendix A of the rule.

Any questions regarding the statute described above should be directed to the Director, Office of Ethics, Room 2158, Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, D.C. 20410. Telephone: (202) 708–3815; TDD/Voice. (This is not a toll-free number.) Forms necessary for compliance with the rule may be obtained from the local HUD office.

E. *Prohibition of Advance Disclosure of Funding Decisions.* HUD's regulation implementing section 103 of the Department of Housing and Urban Development Reform Act of 1989 was published May 13, 1991 (56 FR 22088) and became effective on June 12, 1991. That regulation, codified as 24 CFR Part 4, applies to the funding competition announced today. The requirements of the rule continue to apply until the announcement of the selection of successful applicants.

HUD employees involved in the review of the applications and in the making of funding decisions are restrained by Part 4 from providing advance information to any person (other than an authorized employee of HUD) concerning funding decisions, or from otherwise giving any applicant an unfair competitive advantage. Persons who apply for assistance in this competition should confine their inquiries to the subject areas permitted under 24 CFR part 4.

Applicants who have questions should contact the HUD Office of Ethics (202) 708–3815. (This is not a toll-free number.) The Office of Ethics can provide information of a general nature to HUD employees, as well. However, a HUD employee who has specific program questions, such as whether particular subject matter can be discussed with persons outside the Department, should contact his or her Regional or Field Office Counsel, or Headquarters counsel for the program to which the question pertains.

Authority: 42 U.S.C. 5301, *et seq.*; 42 U.S.C. 3535(d); 24 CFR part 571.

Dated: August 10, 1993.

Joseph Shuldiner,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 93–20655 Filed 8–25–93; 8:45 am]

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August 26, 1993

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 201

Warning Statements for Over-the-Counter Drugs Containing Water-Soluble Gums; Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 90N–0200]

RIN 0905–AA06

Warning Statements Required for Over-The-Counter Drugs Containing Water-Soluble Gums as Active Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule requiring specific warning and direction statements in the labeling of all over-the-counter (OTC) drug products containing as active ingredients water-soluble gums, hydrophilic gums, and hydrophilic mucilloids, including, but not limited to, agar, alginic acid, calcium polycarbophil, carboxymethylcellulose sodium, carrageenan, chondrus, glucomannan ((B-1,4 linked) polymannose acetate), guar gum, karaya gum, kelp, methylcellulose, plantago seed (psyllium), polycarbophil, tragacanth, and xanthan gum. The warning and direction statements will alert users of these products to consume adequate fluid and to avoid using such products if the person has previously experienced any difficulty in swallowing. FDA is issuing this final rule after evaluating reports of esophageal obstruction and asphyxiation involving OTC drug products containing water-soluble gums as active ingredients. Water-soluble gums as active ingredients have been used in OTC antidiarrheal, laxative, and weight control drug products. They are currently used primarily in OTC laxative drug products and are under review in the ongoing rulemaking for OTC laxative drug products as part of FDA's OTC drug review. FDA has determined that implementation of specific warning and direction statements for these ingredients should not await completion of the OTC drug review process. Therefore, the warning and direction statements will now be required to support the safe use of OTC drug products containing water-soluble gums as active ingredients. The warning and direction statements will be incorporated into the pertinent OTC drug monographs as the rulemakings for these drug products are completed.

EFFECTIVE DATE: February 28, 1994.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 30, 1990 (55 FR 45782), FDA proposed to amend 21 CFR part 201, subpart G, *Specific Labeling Requirements for Specific Drug Products*, to require a warning for all OTC drug products containing water-soluble gums as active ingredients. The agency proposed the following warning: (Select one of the following, as appropriate: "Take" or "Mix") "this product with at least 8 ounces (a full glass) of water or other fluid. Taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking. Do not take this product if you have ever had difficulty in swallowing or have any throat problems. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention." The agency considered this warning necessary because water-soluble gums used as active ingredients in certain orally-administered OTC drug products have been associated with esophageal obstruction and asphyxiation.

Water-soluble gums have primarily been used in OTC bulk laxative and weight control drug products. The ingredients involved are natural or semisynthetic hydrocolloid gums including, but not limited to, agar, alginic acid, calcium polycarbophil, carboxymethylcellulose sodium, carrageenan, glucomannan [1], guar gum, karaya gum, kelp [2], methylcellulose, plantago seed (psyllium) [3], polycarbophil, polycarbophil calcium, tragacanth, and xanthan gum. The ingredients polycarbophil and calcium polycarbophil are also used in OTC antidiarrheal drug products.

Because of the hydrophilic nature of water-soluble gums, when water is added to the gum it swells and increases in bulk. If inadequate water is added, a viscous, semi-solid mass forms. The rate and degree of swelling, as well as the viscosity and adhesiveness of the mass, vary from product to product depending on the amount of gum present. When orally-administered OTC drug products containing a high level of one of these gums are used by individuals who have difficulty in swallowing, or when such products are taken with an inadequate amount of water or other fluid, there is a risk that the product will swell and form a viscous adhesive mass that can block the throat or esophagus. The type and degree of adverse effects are influenced by the amount of fluid taken with the product.

As discussed in the proposed rule (55 FR 45782 at 45783 to 45784), esophageal obstruction and asphyxiation associated with the ingestion of water-soluble gums have been reported in the literature since the 1930's, although such reports were relatively rare. However, in recent years FDA has become aware of an increased number of reports. FDA is aware of at least 191 cases of esophageal obstruction and 8 cases of asphyxia associated with orally-administered OTC laxative and weight control products containing these ingredients between 1970 and May, 1992. Death occurred in 18 of these cases (Refs. 1 and 2).

As part of FDA's OTC drug review, water-soluble gums were reviewed as OTC bulk laxatives by the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products (Laxative Panel) and as OTC weight control drug products by the Advisory Review Panel on OTC Miscellaneous Internal Drug Products (Miscellaneous Internal Panel).

The Laxative Panel, in its report published in the **Federal Register** of March 21, 1975 (40 FR 12902), classified five water-soluble gums in Category I (safe and effective)—carboxymethylcellulose sodium, karaya gum, methylcellulose, polycarbophil, and psyllium. Three additional water-soluble gums were classified in Category III (insufficient effectiveness data)—agar, carrageenan, and guar gum. In its discussion of these bulk laxative ingredients, the Laxative Panel acknowledged the risk of esophageal obstruction from water-soluble gums (40 FR 12902 at 12907) and specifically noted with respect to psyllium:

> Esophageal, gastric, small intestinal and rectal obstruction due to the accumulation of mucilaginous derivatives of psyllium preparations have been described on several occasions. The common denominator in most cases has been insufficient water intake or underlying organic disease which resulted in

[1] Glucomannan is the commonly used name for the glucose/mannose polymer(B-1,4 linked) polymannose acetate.

[2] The panel that evaluated this ingredient as part of FDA's OTC drug review designated it "sea kelp." However, "kelp" is the official name for this ingredient in the "USAN and the USP dictionary of drug names, 1992."

[3] The panel that evaluated the ingredients "plantago ovata husks, plantago seeds, psyllium hemicellulose, psyllium hydrophilic mucilloid, psyllium seed, and psyllium seed husks" as part of FDA's OTC drug review designated these ingredients as "psyllium." However, "plantago seed" is the official name for these ingredients in the "USAN and the USP dictionary of drug names, 1992."

compromise of the intestinal lumen, (40 FR 12908).

The Laxative Panel recommended that labeling for bulk laxative ingredients stress the importance of adequate fluid intake, i.e., 8 ounces (oz) of liquid, with each dose.

After reviewing the recommendations of the Laxative Panel and considering public comments received following publication of its report, FDA published a tentative final monograph on OTC laxative drug products in the **Federal Register** of January 15, 1985 (50 FR 2124). The risk of esophageal obstruction from certain bulk laxative ingredients, including water-soluble gums, and the need for adequate fluid intake (8 oz) with each dose of these ingredients was again discussed in comments 36 and 37 of the tentative final monograph (50 FR 2124 at 2131 and 2132).

In an amendment to the tentative final monograph on OTC laxative drug products, published in the **Federal Register** of October 1, 1986 (51 FR 35136), FDA proposed that bulk laxative ingredients be administered in divided doses rather than a single daily dose. This action was taken because it was noted that: "* * * the maximum daily dose of some bulk laxatives is so large that it may pose a risk of esophageal obstruction if taken at one time," (51 FR 35136). In response to these proposals, a major manufacturer of psyllium-containing bulk laxatives commented in support of FDA's recommendation regarding adequate fluid intake (8 oz) with each dose of a bulk laxative. This manufacturer recommended that all bulk laxatives bear the following warning (Ref. 3):

> Bulk forming agents have the potential to block the esophagus, particularly in the presence of esophageal narrowing or when consumed with insufficient fluid. Patients with esophageal narrowing should not use this product. If you observe symptoms of esophageal blockage, including chest pain/pressure, regurgitation and difficulty swallowing, seek immediate medical attention.

In the **Federal Register** of November 7, 1990 (55 FR 46914), FDA published a final rule establishing that certain active ingredients in OTC drug products are not generally recognized as safe and effective or are misbranded. Among the ingredients listed in this final rule under active ingredients for bulk laxative drug products were agar, carrageenan (degraded), carrageenan (native), and guar gum. No substantive comments or new data had been submitted to support the reclassification of any of these ingredients to monograph status. The final rule stated that the listed active ingredients should be eliminated from OTC drug products by May 7, 1991, regardless of whether further testing was undertaken to justify future use, and regardless of whether the relevant OTC drug monographs had been finalized by that date. Therefore, on or after May 7, 1991, no OTC laxative drug product containing any of these four water-soluble gum active ingredients could be initially introduced or initially delivered for introduction into interstate commerce unless it was the subject of an approved application.

In its report on OTC weight control drug products, published in the **Federal Register** of February 26, 1982 (47 FR 8466), the Miscellaneous Internal Panel classified the water-soluble gums alginic acid, carboxymethylcellulose sodium, carrageenan, chondrus[4], guar gum, karaya gum, methylcellulose, psyllium, sea kelp, and xanthan gum in Category III. The Miscellaneous Internal Panel noted, with respect to carboxymethylcellulose sodium and methylcellulose, that occasional cases of esophageal obstruction have occurred when these ingredients are chewed or swallowed without liquid (47 FR 8466 at 8477 and 8478). While concluding that the water-soluble gums listed above are safe, the Miscellaneous Internal Panel recommended that directions for these products state: "Take a full glass of water (8 ounces) with each dose," (47 FR 8477 to 8479).

In the **Federal Register** of October 30, 1990 (55 FR 45788), the agency published a notice of proposed rulemaking stating that certain ingredients in OTC weight control drug products are not generally recognized as safe and effective and are misbranded. Among the ingredients proposed as nonmonograph were the water-soluble gums, alginic acid, carboxymethylcellulose sodium, carrageenan, chondrus, guar gum, karaya gum, kelp, methylcellulose, plantago seed, and xanthan gum. The agency determined that no substantive comments or additional data had been submitted to the OTC drug review to support any of these ingredients as being generally recognized as safe and effective in OTC weight control drug products.

In the **Federal Register** of March 6, 1991 (56 FR 9312), the agency issued a clarification of this October 30, 1990, notice of proposed rulemaking. The purpose of this clarification was to make clear that the addition of the proposed warning statement in product labeling was not a sufficient basis to permit the continued marketing of OTC weight control drug products containing guar gum.

In the **Federal Register** of August 8, 1991 (56 FR 37792), FDA issued a final rule establishing that certain active ingredients in OTC weight control drug products are not generally recognized as safe and effective or are misbranded. Among the ingredients subject to this final rulemaking are the water-soluble gums alginic acid, carboxymethylcellulose sodium, carrageenan, chondrus, guar gum, karaya gum, kelp, methylcellulose, plantago seed, and xanthan gum. On or after February 10, 1992, no OTC drug product containing any of these active ingredients for weight control use could be initially introduced or initially delivered for introduction into interstate commerce unless it was the subject of an approved application.

Although many drug products containing these water-soluble gums can no longer be initially introduced or initially delivered for introduction into interstate commerce, laxative drug products containing the water-soluble gums carboxymethylcellulose sodium, karaya gum, methylcellulose, polycarbophil, and psyllium may continue to be marketed. In addition, water-soluble gums may be present as active ingredients in other than laxative and weight control drug products, e.g., polycarbophil in antidiarrheal drug products. Accordingly, the agency is requiring these new warning and direction statements at this time, without waiting for the completion of any OTC drug review rulemakings related to such products.

In response to the proposed rule requiring a warning in the labeling of all OTC drug products containing water-soluble gums as active ingredients, nine manufacturers, one drug manufacturers' association, one individual, one health department, and six professional associations submitted comments. Copies of the comments received are on public display in the Dockets Management Branch, Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

[4] Chondrus was classified in Category III as a separate ingredient by the Miscellaneous Internal Panel; however, chondrus is but one of several sources of carrageenan.

References

(1) Department of Health and Human Services, FDA, Adverse Drug Reaction Reports for the years 1971 to 1992, in OTC

Volume 20 FR, Docket No. 90N–0200, Dockets Management Branch.

(2) Adverse Drug Reaction Reports, Reference No. 7 in OTC Volume 20 TFR, Docket No. 90N–0200, Dockets Management Branch.

(3) Comment No. C00100, Docket No. 78N–036L, Dockets Management Branch.

I. The Agency's Conclusions on The Comments

1. One comment supported the intent of the proposed warning for OTC drug products containing water-soluble gums, stating that there is sufficient evidence to mandate the inclusion of a warning for these products. Another comment stated that the warning requirement is appropriate and is preferable to FDA's October 30, 1990, proposal (55 FR 45788) to ban the use of guar gum in OTC weight control drug products. The comment added that the warning would allow consumers to continue using products they wish to use, while eliminating the potential for safety hazards in connection with such products.

The agency notes that this current rulemaking does not allow the use of guar gum in OTC weight control drug products even with the accompanying warning label. Since this comment was submitted, the agency published a clarification notice (March 6, 1991, 56 FR 9312) and a final rule for OTC weight control drug products (August 8, 1991, 56 FR 37792), in which it concluded that certain active ingredients, including guar gum, in OTC weight control drug products are not generally recognized as safe and effective and are misbranded. Accordingly, use of the warning and direction statements provided for in this final rule is not a basis for the continued use of guar gum or any other water-soluble gums as an active ingredient in OTC weight control drug products. As noted above, the warning and direction statements must appear on all OTC drug products containing a water-soluble gum as an active ingredient, including OTC bulk-forming laxative drug products containing carboxymethylcellulose sodium, karaya gum, methylcellulose, psyllium, or polycarbophil as an active ingredient.

2. Three comments stated that a warning is not necessary for water-soluble gum products because adverse reactions were reported by only a very small percentage of product users. Two comments suggested that the situation could be handled by manufacturers identifying the water-soluble gum ingredients on the product label so that the subpopulation of sensitive individuals can avoid these products. The comments stated that this approach is consistent with the FDA's long-term policy regarding the identification of ingredients as the primary means of notifying sensitive individuals who may react to certain ingredients. Two comments noted that even though many common foods (e.g., milk, eggs, nuts, shellfish) cause adverse reactions, which range from mild to life-threatening, in subgroups of the population, they are not required to have warning labels.

The agency agrees that listing ingredients on the product label is necessary and often sufficient to alert consumers who are sensitive to certain ingredients. In the present case, however, the problem presented is not one of the sensitivity of a subset of the population but of vulnerability to serious adverse outcomes in all members of the population who use the drugs incorrectly. The purpose of the warning for drug products containing water-soluble gums is to ensure that consumers know how to use the products safely, specifically, in a way that avoids esophageal obstruction. Merely identifying the water-soluble gum ingredient(s) on the product label would not alert consumers to the problem or to the remedy. Foods are discussed in comment 3.

3. One comment, which agreed with the need for a warning statement for OTC drug products containing water-soluble gums, recommended that the agency also address food products that contain approximately the same amount of these ingredients per serving as is used in a dose of certain OTC drug products. The comment mentioned a cereal product that contains 3.5 to 3.7 grams (g) of psyllium per serving, and an OTC laxative drug product containing 3.6 g of psyllium per dose. The comment was concerned that individuals taking both the OTC laxative drug product and one or more servings of such a cereal would increase their odds of having esophageal or bowel obstruction.

The agency is aware that there are many food products on the market containing water-soluble gums. The agency is concerned about the potential hazards of these ingredients, whether present in drug or food products, and has established standards for a number of water-soluble gums used as food additives. For example, the use of psyllium as an optional ingredient in certain frozen desserts at levels not exceeding 0.5 percent was provided for in a final rule establishing standards of identity for frozen desserts published by the agency in 1960 (25 FR 7126, July 27, 1960). Maximum usage levels also have been set for guar gum (21 CFR 184.1339), agar-agar (21 CFR 184.1115), karaya gum (21 CFR 184.1349), and gum tragacanth (21 CFR 184.1351). The percentage of water-soluble gums allowed in food products is generally low, and the agency has not seen any problems of esophageal obstruction or asphyxiation associated with the use of water-soluble gums at these levels in food products.

Although water-soluble gums used in food products are not included in this rulemaking, the agency will continue to evaluate and monitor these ingredients when they are used in any products marketed for human consumption. Appropriate warnings will be proposed if a need to do so is found to be necessary.

4. Several comments suggested that the proposed warning for OTC drug products containing water-soluble gums should apply only to products in a dry or unhydrated form. One comment mentioned that the cases of esophageal obstruction discussed in the proposed rule (55 FR 45782 at 45783) referred to gums in tablet form and agreed that the proposed warning is appropriate for this type of product. However, the comment contended that insufficient evidence exists to mandate the proposed warning for OTC drug products containing water-soluble gums in powder form which are dissolved in 8 oz of water prior to ingestion. The comment argued that little evidence exists that such water-based products, when taken according to the label directions by individuals without esophageal or throat problems, pose a risk of asphyxiation or esophageal obstruction.

The agency agrees that water-soluble, gum-containing products that are marketed in a fully hydrated form (e.g., in a solution) do not pose any significant risk of causing esophageal obstruction and that the warning statement is not necessary for those products. The problem with esophageal blockage associated with the use of water-soluble, gum-containing OTC drug products has been limited to those products marketed in the unhydrated form. Products that are marketed in a dry or incompletely hydrated state (intended to be dissolved in water by the consumer prior to ingesting, or taken with water or other liquid), whether in tablet (see comment 5), capsule, powder, or other form, have the potential for causing obstruction if the product is taken with inadequate fluid or if it is taken by individuals with swallowing or other throat problems. The agency acknowledges that the dosage forms involved in the cases of esophageal obstruction due to guar gum, which were discussed in the proposed

rule (55 FR 45782 at 45783), were tablets. However, a number of cases of esophageal obstruction due to other water-soluble gums have involved different dosage forms (e.g., powdered forms of psyllium, and granular forms of psyllium, karaya gum, and tragacanth) (see 55 FR 45783 and 45784: specifically references 7 through 10, 13, 15, and 16). Although dry forms of water-soluble gums could be hydrated according to label directions, prior to ingestion, and safely used by most consumers, the agency believes a warning will decrease the extent to which these products could be misused by some individuals with possible adverse consequences. Further, the agency does not have any data to show how much time is necessary to fully hydrate these products after mixing them with water. The agency therefore concludes that it is appropriate to require the warning for all dosage forms of OTC drug products containing water-soluble gums as active ingredients in dry or incompletely hydrated form, including those intended to be hydrated by the consumer (i.e., with label directions to dissolve the product in water). The agency has included this information in new § 201.319(b). Those OTC drug products marketed in a completely hydrated form will not require the warning.

5. One comment agreed that the proposed warning is appropriate for OTC drug products containing water-soluble gums in tablet form, but contended that the warning would be inaccurate for two-piece, hard-shell capsules that require significant exposure to fluid before dissolving. The comment claimed such an environment does not exist in the throat and therefore the risk is moot. The comment added that virtually all reports of esophageal blockage cited by the agency in the proposal (55 FR 45782 at 45783) involved tablets. The comment recommended that the warning be modified for water-soluble gums marketed in two-piece, hard-shell capsules to read as follows:

> Take this product with at least 8 ounces (a full glass) of water or other fluid. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention.

The comment concluded that this approach would encourage industry to adopt the safest known dosage forms and would minimize potential consumer confusion and loss of confidence in the safety of many other OTC drug products offered as capsules and tablets.

As discussed in comment 4, the agency is aware of numerous cases of esophageal obstruction due to various dosage forms of water-soluble gum OTC drug products (i.e., tablets, granules, powder). Although capsules may be a safer dosage form than tablets for administering water-soluble gums, the agency believes capsules could also be potentially hazardous if they are chewed or otherwise broken before or during ingestion. For instance, a consumer who has difficulty swallowing may chew the capsule to allow for greater ease in swallowing, thereby releasing the capsule contents in the throat or esophagus. Because of the small size of the released particles, greater hydration and greater swelling could occur from the broken capsule than from a tablet. Therefore, because esophageal obstruction could occur when capsules are broken, the agency believes that safer consumer use would result by having the same warnings for capsules as other dosage forms containing water-soluble gums. Accordingly, the warning in § 201.319(b) is being required for all dosage forms (e.g., capsules, granules, powders, tablets, wafers) of unhydrated water-soluble gums when used as active ingredients in OTC drug products. However, the agency will consider exempting a water-soluble gum product from the warning statements on the basis of data demonstrating that no swelling occurs for that particular ingredient in a specific dosage form or formulation. Such requests for exemption from the warning should be submitted in the form of a citizen petition as provided in § 10.30 (21 CFR 10.30). However, the mere submission of a citizen petition does not allow an exemption from the required warning while the citizen petition is being evaluated.

6. Four comments objected to the proposed warning statements being applicable to psyllium, calcium polycarbophil, and methylcellulose dry powder. Two comments contended that the proposed warnings should not apply to psyllium on the basis of a 1982 evaluation by the Select Committee of GRAS Substances (a group of leading food experts). This Committee reviewed 60 years of data on psyllium and stated (Ref. 1):

> There is no evidence in the available information on psyllium seed husk gum that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when it is used at levels that are now current or that might reasonably be expected in the future.

One comment stated that calcium polycarbophil is not a soluble fiber and does not swell appreciably in the upper gastrointestinal tract. The comment contended that, based on the drug's chemical characteristics and reported adverse drug reactions, esophageal obstruction due to swelling of the product is not an adverse reaction associated with calcium polycarbophil. Another comment contended that the proposed warnings are not appropriate for the methylcellulose dry powder formulation used in its product because there is no evidence that this formulation causes esophageal obstruction. The comment submitted results of some simple in-vitro comparison tests carried out by mixing methylcellulose-based formulations and ground psyllium-based formulations with grossly underrecommended quantities of water and observing the resulting properties of the mixtures. The comment argued that, even when dispersed in inadequate amounts of water, its methylcellulose formulation does not form a gel that could cause esophageal obstruction. The comment requested a hearing on this issue.

The comments' arguments that the proposed warnings should not apply to specific water-soluble gums are not persuasive. Because ingestion of water-soluble gums with inadequate amounts of fluid or by individuals with difficulty in swallowing could potentially cause esophageal obstruction, the agency believes that the warning statements are necessary to ensure the safe use of these drug products. Swelling and increased bulk are known results of adding water to a water-soluble gum. Even though different formulations and types of gums vary in their swelling volume, the degree of swelling remains uncertain. Although the in-vitro tests indicated a difference in the viscosities of methylcellulose-based formulations and ground psyllium-based products, no data were submitted to indicate how these results would apply to the in-vivo situation, where variables such as individual body temperature, additional food intake, or esophageal motility might affect the ingredients. The agency concludes that it cannot accept contentions of no evidence of a hazard as a basis for exempting specific water-soluble gum ingredients from the warning requirement. As noted in comment 5, the agency will consider an exemption from the required warning. The agency concludes that, without adequate data at this time, insufficient justification exists to grant a hearing.

Reference

(1) "Evaluation of the Health Aspects of Oat Gum, Okra Gum, Quince Seed Gum, and Psyllium Seed Husk Gum as Food Ingredients," Report of the Select Committee on GRAS Substances, Life Sciences Research

Office, Federation of American Societies for Experimental Biology, Bethesda, MD, 1982.

7. Several comments contended that proposed § 201.319(b) is too broadly worded in that it requires the warning statement on any drug products containing water-soluble gums. The comments suggested that the warning be revised to clarify its application only to those drug products containing water-soluble gums as active ingredients. The comments stated that the warning was not necessary on drug products that contain water-soluble gums in small quantities as inactive ingredients because such products do not pose a risk of esophageal obstruction. Several comments mentioned that water-soluble gums are used as suspending agents in many liquid drug products for both prescription and OTC use, and claimed there is no risk of esophageal obstruction associated with those products. One comment added that certain water-soluble gums have been used as a tablet disintegrant for more than 25 years with no known adverse incidents.

The agency concurs that the warning should be clarified to state its application only to those OTC drug products containing water-soluble gums as active ingredients. Many currently marketed products contain water-soluble gums as inactive ingredients used as suspending agents, binders, tablet disintegrants, etc. The agency is not aware of any reports showing that the amount of a water-soluble gum used as an inactive ingredient produces the potential for esophageal obstruction and thus poses a threat to consumer safety. Accordingly, the agency is revising the language in the heading in § 201.319 to read: § 201.319 *Water-soluble gums, hydrophilic gums, and hydrophilic mucilloids (including * * *) as active ingredients; required warnings and directions*, and paragraph (b) of § 201.319 to read: "Any drug products for human use containing a water-soluble gum, hydrophilic gum, or hydrophilic mucilloid as an active ingredient in an oral dosage form when marketed in a dry or incompletely hydrated form as described in paragraph (a) of this section are misbranded within the meaning of section 502 of the Federal Food, Drug, and Cosmetic Act unless their labeling bears the following warnings and directions in bold print and capital letters: * * *."

8. Three comments contended that the concerns raised by the proposed warning statements for OTC drugs containing water-soluble gums could be adequately addressed under "Directions for Use." One comment mentioned that the first statement of the proposed warning currently exists under "Directions for Use" for OTC bulk-forming laxatives. Another comment stated that the directions for use found on its product label (both descriptive and pictorial) adequately convey appropriate product use, which is supported by actual consumer experience. The comment mentioned the very low incidence rate of serious esophageal blockage reports for its products, which are mixed with liquid prior to ingestion. The comment requested an oral hearing if the agency disagrees with its position and maintains that the warning is warranted (for its product).

Two comments suggested adding the following sentence to the "Directions for Use": "Taking this product without enough liquid may cause choking." One of the comments stated that the term "choking" encompasses several of the other proposed consequence terms of the warning and thus would eliminate the need for the part of the proposed warning that states: "If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention." The comment recommended that the proposed warning appear under the "Directions for Use" as follows:

(Select one of the following, as appropriate: "Take" or "Mix") "this product with at least8 ounces (a full glass) of liquid. Taking this product without enough liquid may cause choking."

Three comments suggested an alternative to the proposed warning in the form of an "instructive warning," which states: "*VERY IMPORTANT*—Take (or mix) this product with at least 8 ounces (a full glass) of water or other fluid."

The agency has considered the comments' recommendations and agrees that information conveying the proper use of OTC water-soluble, gum-containing drug products should be included under the "Directions" section of the product's labeling (see also comment 9). Therefore, the agency is establishing a "Directions" section in § 201.319 that states: "(Select one of the following as appropriate: 'TAKE' or 'MIX') 'THIS PRODUCT (CHILD OR ADULT DOSE) WITH AT LEAST 8 OUNCES (A FULL GLASS) OF WATER OR OTHER FLUID. TAKING THIS PRODUCT WITHOUT ENOUGH LIQUID MAY CAUSE CHOKING. SEE WARNINGS." This new direction statement will be required in the labeling of OTC water-soluble, gum-containing drug products upon the effective date of this final rule. At a later date, when the final rules for OTC laxative and antidiarrheal drug products are published, the warnings and directions included under § 201.319 will be incorporated into the labeling of bulk laxative drug products in § 334.52 and antidiarrheal drug products in § 335.50, respectively.

The agency concludes that critical information alerting the consumer about the possible consequences of not taking these products correctly should be appropriately placed in both the "Warnings" and the "Directions" sections of the products' labeling. The agency believes that the significance of the information will be emphasized if it appears in both sections of the labeling. Further, because of possible adverse reactions that can occur if the product is not taken correctly, the agency considers it very important that consumers' attention also be directed to the warning information. Therefore, to help draw attention to the warning statement, the agency is also adding the phrase "SEE WARNINGS" at the end of the "Directions" in § 201.319, to read: "(Select one of the following as appropriate: 'TAKE' or 'MIX') 'THIS PRODUCT (CHILD OR ADULT DOSE) WITH AT LEAST 8 OUNCES (A FULL GLASS) OF WATER OR OTHER FLUID. TAKING THIS PRODUCT WITHOUT ENOUGH LIQUID MAY CAUSE CHOKING. SEE WARNINGS."

The agency denies one comment's request for a hearing at this time because of a lack of adequate data showing that the warning is not warranted for a specific product. However, as noted in comment 5, the agency will consider requests for an exemption from the warning, submitted in the form of a citizen petition as provided in § 10.30. Interested parties must provide documentation of the safety and low incidence rate of esophageal blockage for their specific product(s) in the citizen petition.

9. One comment contended that the proposed warning is inaccurate, overly broad in scope, and would not serve properly to warn consumers. The comment pointed out that the requirement to state "at least 8 ounces (a full glass) of water or other fluid" does not take into account the lower recommended dosages for some of these ingredients for children ages 6 to under 12. The comment stated that lesser amounts of liquid are appropriate for those users, and the warning should be modified to recognize the different dosages for these products.

The purpose of the warning is to ensure safe and effective use by both adults and children of OTC drug products containing water-soluble gums

as active ingredients; specifically, to prevent esophageal blockage that could result from taking or mixing these drugs with inadequate amounts of water or from use by individuals with swallowing difficulties. Although the maximum single dose of water-soluble gums for children (ages 6 to under 12) generally equals one-half the maximum single dose for adults, the minimum single dose for children is frequently the same as that for adults. For instance, in the tentative final monograph for OTC laxative drug products, the agency proposed that the minimum single dose of psyllium as a bulk forming laxative for both adults and children (ages 6 to under 12) is 2.5 g (51 FR 35136 at 35137). Similarly, for methylcellulose and sodium carboxymethylcellulose the proposed minimum single dose for adults and children is 0.45 g. Thus, because a child (age 6 to under 12) would take the same minimum single dose as an adult, the child would need to consume the same amount of fluid to avoid swelling and possible blockage problems. Therefore, the directions statement included in this final rule state that the same amount of fluid (at least 8 oz) should be taken with both children's and adult's doses of water-soluble gum products.

10. A number of comments suggested revising the third and fourth sentences of the proposed warning, which state:

DO NOT TAKE THIS PRODUCT IF YOU HAVE EVER HAD DIFFICULTY IN SWALLOWING OR HAVE ANY THROAT PROBLEMS. IF YOU EXPERIENCE CHEST PAIN, VOMITING, OR DIFFICULTY IN SWALLOWING OR BREATHING AFTER TAKING THIS PRODUCT, SEEK IMMEDIATE MEDICAL ATTENTION.

The comments described these statements as "unduly alarming," "without sufficient justification," "not easily understood," "too strongly worded," "too broad and too vague," and "ambiguous." Several of the comments contended that the phrase "if you have ever had difficulty in swallowing or have any throat problems" could apply to almost all consumers because nearly everyone at some time has had a sore throat (from a cold, cough, minor irritation, or smoking) that resulted in difficulty in swallowing. Several comments expressed concern that if people take the warning literally, the market for water-soluble, gum-containing OTC drug products would be severely damaged. The comments mentioned that many of the water-soluble gums are already generally recognized as safe as food ingredients, and that these products are currently being used safely by millions of people.

Two comments argued that the statement about difficulty in swallowing or throat problems should be eliminated or, if retained, modified to refer only to persons with diagnosed swallowing problems or a history of throat problems. Another comment suggested modifying the statement to read: "Do not take this product if you have esophageal narrowing or dysfunction."

Two comments suggested revising the proposed warning statement to direct individuals with throat problems to seek the advice of a doctor prior to using the product. One comment suggested the following: "If you have been diagnosed with a condition that causes difficulty in swallowing, consult a doctor before using this product." The other comment suggested different wording, as follows: "If you have been diagnosed with esophageal narrowing or have difficulty swallowing, consult a doctor before taking this product."

The agency agrees that the third sentence of the proposed warning could be revised to make the statement more specific. Individuals who have had swallowing difficulties in the past due to minor sore throat, colds, or coughs need not be excluded from taking water-soluble gum drug products; however, individuals with medically-related swallowing problems must be warned to avoid these products. The agency does not believe a statement advising consumers with swallowing difficulties to seek the advice of a doctor before taking this type of product is appropriate because water-soluble, gum-containing products should not be taken by those individuals. Further, the agency does not believe that the terms "esophageal narrowing" or "esophageal dysfunction" should be used in the warning because they are too technical. The agency believes that the term "difficulty in swallowing" is better understood by consumers. The agency also is not including the term "diagnosed" in the warning statement because individuals could have throat problems without the problems having been diagnosed by a physician. None of the comments requested a specific revision in the fourth sentence of the warning. If chest pain, vomiting, or difficulty in swallowing occur after taking a water-soluble gum-containing drug product the agency finds it appropriate to alert consumers to seek immediate medical attention. Accordingly, in this final rule, the third sentence of the warning statement is revised and the fourth sentence remains as proposed, to read:

DO NOT TAKE THIS PRODUCT IF YOU HAVE DIFFICULTY IN SWALLOWING. IF YOU EXPERIENCE CHEST PAIN, VOMITING, OR DIFFICULTY IN SWALLOWING OR BREATHING AFTER TAKING THIS PRODUCT, SEEK IMMEDIATE MEDICAL ATTENTION.

11. One comment stated that if this final rule becomes effective before the monographs for OTC laxative and weight control drug products, it must provide adequate time for manufacturers to develop and implement new labeling. The comment recommended that the effective date of any final rule be at least 12 months after the date of publication in the **Federal Register**, and that consideration be given to requests for limited extensions based on extenuating circumstances.

A final rule on OTC weight control drug products containing water-soluble gum active ingredients was published in the **Federal Register** of August 8, 1991 (56 FR 37792). All water-soluble gum active ingredients were found to be not generally recognized as safe and effective for this use. A final rule for OTC laxative and for OTC antidiarrheal drug products will not be published until after this final rule for water-soluble gums becomes effective. The final rules for OTC laxative and antidiarrheal drug products may include several water-soluble gum active ingredients. Drug products containing these active ingredients will need to be relabeled to bear the directions and warning statements required by this final rule (21 CFR 201.319) before the final monographs for OTC laxative and antidiarrheal drug products become effective. Normally, when a monograph is published, the agency provides a 12-month period for any necessary reformulation, relabeling, and stability testing that needs to be done. In the current situation, no reformulation or stability testing needs to be done. The only required action is relabeling to add several additional statements. The agency recognizes that in order for manufacturers to comply with this final rule for OTC drug products containing water-soluble gums, new labels will have to be written, ordered, received, and incorporated into the manufacturing process. However, this required relabeling relates to a safety problem, for which the agency has determined that a shorter deadline than the customary 12 months should be established. Therefore, this final rule will be effective 6 months after the date of publication in the **Federal Register**. The agency believes that 6 months is sufficient time for most manufacturers to bring their products into compliance with this final rule, which affects only the labeling of the product. Therefore, any OTC drug product that is subject to

this rule that is initially introduced or initially delivered for introduction into interstate commerce, or that is repackaged or relabeled, after the effective date of the rule must be in compliance with the rule regardless of the date the product was manufactured, initially introduced, or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with this rule at the earliest possible date. Requests for a limited extension of time will be considered by the agency only if extenuating circumstances are adequately documented. Any such requests should be sent to the Food and Drug Administration, Division of Drug Labeling Compliance (HFD–310), 7520 Standish Pl., Rockville, MD 20855.

II. Summary of Significant Changes From The Proposed Rule

1. The agency has clarified § 201.319 to state that the warning and direction statements apply only to OTC drug products containing a water–soluble gum as an active ingredient. (See comment 7.)

2. The agency has revised § 201.319(b) to indicate that the warning and direction statements are required only for water-soluble gum products marketed in a dry or incompletely hydrated form. (See comments 4 and 5.)

3. The agency is deleting the first sentence of the warning proposed in § 201.319(b) and is, instead, adding "Directions" in § 201.319(b) that state: (Select one of the following, as appropriate: "TAKE" or "MIX") "THIS PRODUCT (CHILD OR ADULT DOSE) WITH AT LEAST 8 OUNCES (A FULL GLASS) OF WATER OR OTHER FLUID. TAKING THIS PRODUCT WITHOUT ENOUGH LIQUID MAY CAUSE CHOKING. SEE WARNINGS." (See comment 8.) These directions indicate that the same amount of fluid (at least 8 ounces) should be mixed or taken with the product by an adult as well as a child. (See comment 9.)

4. The agency is revising the third sentence of the warning statement proposed in § 201.319 to read: "DO NOT TAKE THIS PRODUCT IF YOU HAVE DIFFICULTY IN SWALLOWING." (See comment 10.)

III. The Agency's Final Conclusions on The Safety of Water-Soluble Gums in Orally-Administered OTC Drug Products

Based on available evidence, the agency is issuing a final rule requiring specific warning and direction statements in the labeling of all OTC drug products for human use containing a water-soluble gum, hydrophilic gum, or hydrophilic mucilloid as an active ingredient when marketed in a dry or incompletely hydrated form to include, but not limited to, the following dosage forms: capsules, granules, powders, tablets, and wafers. Esophageal obstruction and asphyxiation due to orally-administered OTC drug products containing water-soluble gums, hydrophilic gums, and hydrophilic mucilloids as active ingredients are significant health risks when these products are taken without adequate fluid or when they are used by individuals with esophageal narrowing or dysfunction, or with difficulty swallowing. Therefore, the agency is requiring specific warning and direction statements for all OTC drug products containing water-soluble gums as active ingredients prior to the completion of rulemakings for certain classes of OTC drug products that contain these ingredients. These ingredients include, but are not limited to, agar, alginic acid, calcium polycarbophil, carboxymethylcellulose sodium, carrageenan, chondrus, glucomannan ((B-1,4 linked) polymannose acetate), guar gum, karaya gum, kelp, methylcellulose, plantago seed (psyllium), polycarbophil, tragacanth, and xanthan gum. (NOTE: Although some of these ingredient names are no longer official, they do appear in the labeling of some products. Therefore, the agency is including all ingredient names, whether official or not, in this final regulation.)

Because of the potential serious health risk involved, the warning and direction statements must appear in bold print and in capital letters. The required statements are as follows:

"*WARNINGS*: TAKING THIS PRODUCT WITHOUT ADEQUATE FLUID MAY CAUSE IT TO SWELL AND BLOCK YOUR THROAT OR ESOPHAGUS AND MAY CAUSE CHOKING. DO NOT TAKE THIS PRODUCT IF YOU HAVE DIFFICULTY IN SWALLOWING. IF YOU EXPERIENCE CHEST PAIN, VOMITING, OR DIFFICULTY IN SWALLOWING OR BREATHING AFTER TAKING THIS PRODUCT, SEEK IMMEDIATE MEDICAL ATTENTION."

DIRECTIONS: (Select one of the following, as appropriate: "TAKE" or "MIX") "THIS PRODUCT (CHILD OR ADULT DOSE) WITH AT LEAST 8 OUNCES (A FULL GLASS) OF WATER OR OTHER FLUID. TAKING THIS PRODUCT WITHOUT ENOUGH LIQUID MAY CAUSE CHOKING. SEE WARNINGS."

The warning and direction statements in § 201.319 will be incorporated into the labeling contained in the monographs for OTC laxative and antidiarrheal drug products, or any other applicable monograph, as the monographs are finalized. The agency concludes that it would be an unacceptable health risk to delay implementation of these warning and direction statements until these rulemakings are completed. Manufacturers are encouraged to comply with this final rule at the earliest possible date.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (55 FR 45782 at 45784). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for specific warning and direction statements for OTC drug products containing water-soluble gums as active ingredients, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC drugs containing water-soluble gums as active ingredients is not expected to pose such an impact on small businesses. The final rule will impose direct one- time costs associated with changing product labels, but that cost is estimated to total less than $1 million. Manufacturers will have 6 months in which to implement this relabeling. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 201 is amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 is revised to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 510, 512, 530–542, 701, 704, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360, 360b, 360gg–360ss, 371, 374, 379e); secs. 215, 301, 351, 361 of the Public Health Service Act (42 U.S.C. 216, 241, 262, 264).

2. Section 201.319 is added to subpart G to read as follows:

§ 201.319 Water-soluble gums, hydrophilic gums, and hydrophilic mucilloids (including, but not limited to agar, alginic acid, calcium polycarbophil, carboxymethylcellulose sodium, carrageenan, chondrus, glucomannan ((B-1,4 linked) polymannose acetate), guar gum, karaya gum, kelp, methylcellulose, plantago seed (psyllium), polycarbophil tragacanth, and xanthan gum) as active ingredients; required warnings and directions.

(a) Reports in the medical literature and data accumulated by the Food and Drug Administration indicate that esophageal obstruction and asphyxiation have been associated with the ingestion of water-soluble gums, hydrophilic gums, and hydrophilic mucilloids including, but not limited to, agar, alginic acid, calcium polycarbophil, carboxymethylcellulose sodium, carrageenan, chondrus, glucomannan ((B-1,4 linked) polymannose acetate), guar gum, karaya gum, kelp, methylcellulose, plantago seed (psyllium), polycarbophil, tragacanth, and xanthan gum. Esophageal obstruction and asphyxiation due to orally-administered drug products containing water-soluble gums, hydrophilic gums, and hydrophylic mucilloids as active ingredients are significant health risks when these products are taken without adequate fluid or when they are used by individuals with esophageal narrowing or dysfunction, or with difficulty in swallowing. Additional labeling is needed for the safe and effective use of any OTC drug product for human use containing a water-soluble gum, hydrophilic gum, or hydrophilic mucilloid as an active ingredient when marketed in a dry or incompletely hydrated form to include, but not limited to, the following dosage forms: capsules, granules, powders, tablets, and wafers.

(b) Any drug products for human use containing a water-soluble gum, hydrophilic gum, or hydrophilic mucilloid as an active ingredient in an oral dosage form when marketed in a dry or incompletely hydrated form as described in paragraph (a) of this section are misbranded within the meaning of section 502 of the Federal Food, Drug, and Cosmetic Act unless their labeling bears the following warnings and directions in bold print and capital letters:

"*WARNINGS*: TAKING THIS PRODUCT WITHOUT ADEQUATE FLUID MAY CAUSE IT TO SWELL AND BLOCK YOUR THROAT OR ESOPHAGUS AND MAY CAUSE CHOKING. DO NOT TAKE THIS PRODUCT IF YOU HAVE DIFFICULTY IN SWALLOWING. IF YOU EXPERIENCE CHEST PAIN, VOMITING, OR DIFFICULTY IN SWALLOWING OR BREATHING AFTER TAKING THIS PRODUCT, SEEK IMMEDIATE MEDICAL ATTENTION."

"*DIRECTIONS*:" (Select one of the following, as appropriate: "TAKE" or "MIX") "THIS PRODUCT (CHILD OR ADULT DOSE) WITH AT LEAST 8 OUNCES (A FULL GLASS) OF WATER OR OTHER FLUID. TAKING THIS PRODUCT WITHOUT ENOUGH LIQUID MAY CAUSE CHOKING. SEE WARNINGS."

(c) After February 28, 1994, any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce, or any such drug product that is repackaged or relabeled after this date regardless of the date the product was manufactured, initially introduced, or initially delivered for introduction into interstate commerce, that is not in compliance with this section is subject to regulatory action.

Dated: August 19, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–20695 Filed 8–25–93; 8:45 am]

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federal register

Thursday
August 26, 1993

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 331
Antacid Drug Products; Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 331

[Docket No. 85N–0049]

RIN 0905–AA06

Antacid Drug Products For Over-the-Counter Human Use; Amendment Of Antacid Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to amend the final monograph for over-the-counter (OTC) antacid drug products to require that all antacid drug products contain the statement: "Drug Interaction Precaution: Antacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your physician or other health professional." FDA is issuing this final rule after considering public comments on the agency's proposed regulation and all new data and information that have come to the agency's attention. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: August 26, 1994.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 4, 1974 (39 FR 19862), FDA issued a final monograph for OTC antacid drug products that established conditions under which these products are generally recognized as safe and effective and not misbranded. Section 331.30(d)(1) (21 CFR 331.30(d)(1)) of the monograph currently requires that the labeling of OTC aluminum-containing antacid drug products include the following drug interaction precaution: "Do not take this product if you are presently taking a prescription antibiotic drug containing any form of tetracycline." In the Federal Register of October 19, 1979 (44 FR 60328), the agency proposed to amend the antacid monograph to require that this drug interaction precaution also be included on the labeling of antacid drug products containing calcium or magnesium. The proposed amendment also would have required the following additional statement as part of the drug interaction precaution: "If you are not sure whether or not you are taking a tetracycline product, contact your physician or pharmacist." Interested persons were invited to file written comments to the proposed amendment on or before December 18, 1979.

On November 15, 1982, FDA received a petition (Docket No. 82P–0360/CP) requesting, among other things, that the labeling of OTC antacid drug products include a precaution concerning the interaction between antacids and the prescription drug digoxin. After evaluating the comments to the proposed amendment (44 FR 60328), the petition, and data in the literature indicating that antacids interact with a number of other drugs, in the Federal Register of July 30, 1986 (51 FR 27342), FDA proposed that a different drug interaction precaution be included in the labeling of all OTC antacid drug products, as follows: "Antacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your physician." Interested persons were invited to file written comments or objections by September 29, 1986.

In response to this notice of proposed rulemaking, seven professional associations, three manufacturers, three academic institutions, two pharmaceutical trade organizations, two pharmaceutical publications, and one individual submitted comments. Copies of the comments are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch.

I. The Agency's Conclusions on the Comments

1. Many comments requested that the wording of the proposed warning be revised to include the "pharmacist" as another health professional that consumers could check with about possible drug interactions. The comments mentioned several reasons for including pharmacists as a source of information and advice: their professional knowledge, ready availability, and willingness to provide advice without charging expensive professional fees. The comments contended that pharmacists have access to the patients' full medical profile and consumers are likely to purchase antacids from pharmacies. Two comments added that FDA has used similar language in the past.

The agency agrees that pharmacists' professional knowledge, ready availability, and willingness to provide advice make them an excellent source of information, particularly relating to drug interactions, for consumers taking both an OTC antacid and a prescription drug. In some cases, the pharmacist may have access to the consumer's complete medical profile and be able to offer medication counseling when a questionable situation arises.

The agency believes, however, that other health professionals, such as nurses and physician assistants, can also help consumers determine whether the prescription drug they are taking interacts with an antacid. Information about such interactions appears in references, such as the "Physicians' Desk Reference," that are available to these health professionals. In developing warning and drug interaction precaution statements for other OTC drug products, the agency has previously considered the most appropriate wording to designate who could provide consumers with information concerning OTC drugs. The agency determined that "health professional" is the preferred term, because this term does not restrict consumers from other available sources of information. (See, for example, the pregnancy-nursing warning for OTC drugs in 21 CFR 201.63 and the proposed drug interaction precaution for monoamine oxidase inhibitor drugs (57 FR 27658, 27662, and 27666 (June 19, 1992)).

Accordingly, in this final rule, the agency is revising the drug interaction precaution statement in § 331.30(d) to read as follows: "Antacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your physician or other health professional."

2. Two comments contended that physicians and their staffs would be overburdened by patient inquiries regarding possible OTC antacid-prescription drug interactions, many of which may be "trivial, clinically insignificant, or nonexistent." Another comment stated that the warning language is so broad that it fails to distinguish between known interactions and merely conjectural ones. The comment considered the warning to be a public service message to remind patients to keep physicians apprised of all medications being consumed. The comment concluded that while this is a laudable goal, it is not a proper use of limited OTC drug labeling space.

The agency has determined that an antacid drug interaction precaution is necessary due to the large number of interactions that could occur between antacids and prescription drugs. Antacids can alter the rate of absorption, bioavailability, and/or renal elimination of a number of drugs (see discussion in comment 5). While the language in the precaution could be considered overly broad, the agency's goal is to alert consumers without resorting to a confusing and burdensome list of all known interactions.

The agency does not believe that physicians and their staffs will be overburdened as a result of the new precaution. Information regarding interactions of prescription drugs with other drugs (prescription or OTC) should be provided as part of the physician-patient consultation when prescription drugs are prescribed. However, in some instances, patients may not be taking an OTC antacid at the time a prescription drug is prescribed. Later, the patient may have a need for an OTC antacid. In these instances, the drug interaction precaution is intended to alert patients to check with their physician before taking the antacid. The agency believes that this process is an essential part of good health care, and that most physicians and their staffs would not consider such inquiries to be burdensome.

3. Four comments contended that if a drug interaction merits a warning, then the proper vehicle for the warning would be the approved labeling for the prescription drug in question. The comments argued that the information is best provided when the medication is prescribed by the physician as part of the physician-patient consultation. Two of the comments mentioned that information about possible drug interactions is also provided by the pharmacist at the time the prescription is filled.

The agency agrees that when clinically significant drug interactions occur, the labeling of the prescription drug in question is an appropriate place to state that information. However, the prescription labeling is not the only appropriate place where such information can be provided. Also, having this information in the OTC drug product labeling serves to remind patients who may have forgotten their physicians' or pharmacists' instructions and is intended to help prevent unnecessary drug interactions from occurring.

The agency's general policy is that when an interaction between a prescription drug and an OTC drug is significant enough to be included in the approved labeling of the prescription drug product, a similar corresponding warning should be included in the labeling of the OTC drug product. This policy may not apply when the known prescription-OTC drug interaction cited in the prescription drug labeling affects only a limited portion of the total population taking the prescription drug. However, in those cases where known drug interactions are not limited to specific drugs and involve numerous drugs or entire drug categories, the agency states the interaction information in terms of general drug categories. For example, if a significant number of prescription drugs are known to interact with an OTC drug, the drug interaction warning may need to be a general "prescription drug" warning rather than listing all of the possible prescription drugs likely to cause interactions.

In the case of antacid drug products, the interaction between aluminum, calcium, or magnesium antacids and tetracycline is the most frequently reported. However, as discussed in comment 5, data in the literature indicate that drugs in the entire class of antacids, due to pH-related and other mechanisms, interact with a number of other drugs (Refs. 1 through 8). Because it would be impossible to list every prescription drug that could possibly cause an interaction in the antacid product's labeling, the agency finds a general warning statement to be most appropriate for this situation.

References

(1) D'Arcy, P. F., and J. C. McElnay, "Drug-Antacid Interactions: Assessment of Clinical Importance," *Drug Intelligence and Clinical Pharmacy*, 21:607–617, 1987.

(2) "USP DI, Volume I, Drug Information for the Health Care Professional," 13th ed., United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 195–197, 1993.

(3) Hansten, P. D., and J. R. Horn, "Drug Interactions," 6th ed., Lea and Febiger, Philadelphia, pp. 225, 229, 250, and 348, 1987.

(4) "Drug Evaluations," 6th ed., American Medical Association, Chicago, p. 947, 1986.

(5) Garnett, W. R., "Antacid Products" in "Handbook of Nonprescription Drugs," 9th ed., American Pharmaceutical Association, Washington, pp. 270–274, 1990.

(6) Clark, W. G., D. C. Brater, and A. R. Johnson, "Goth's Medical Pharmacology," 12th ed., The C. V. Mosby Co., St. Louis, pp. 748–750, 1988.

(7) Brunton, L. L., "Agents for Control of Gastric Acidity and Treatment of Peptic Ulcers" in "The Pharmacological Basis of Therapeutics," 8th ed., edited by L. S. Goodman, and A. G. Gilman, Pergamon Press Co., Inc., New York, pp. 904–909, 1990.

(8) Shinn, A. F., and R. P. Shrewbury, "Evaluations of Drug Interactions," 3d ed., The C. V. Mosby Co., St. Louis, p. 399, 1985.

4. Two comments contended that the proposed warning is contrary to the statutory definition of OTC drugs in section 503(b)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(b)(1)(B) the intent of that definition which, according to one comment, "mandates nonprescription status for drug products which are deemed as safe for use without the supervision of a physician." These comments argued that a general drug interaction statement, as proposed, would "seek to impose a requirement of physician intervention before use if the patient is taking any concurrent prescription therapy."

The agency considers the drug interaction precaution statement to be consistent with section 503(b)(1)(B) of the act. That section states that certain drugs shall be dispensed only by prescription when certain conditions exist and the drug is not safe except when used under the supervision of a practitioner licensed by law to administer such drug. This section of the statute does not prohibit warnings and drug interaction precaution statements for OTC drug products. These warnings and precaution statements do not impose a requirement of physician intervention for all consumers, but serve to alert certain users of the product to consult a physician or other health professional for advice when certain situations exist (e.g., when taking a prescription drug product concurrently). Thus, the requirements are not at odds with the statute.

In other OTC drug rulemakings, the agency has included similar drug interaction precautions in the OTC drug products' labeling to alert consumers to consult a doctor before taking certain drugs concurrently. For example, the precaution, "Do not use this product if you are presently taking a prescription drug for high blood pressure or depression without first consulting your doctor," is currently required for OTC bronchodilator drug products (see 21 CFR 341.76(c)(4)) and OTC anorectal drug products (see 21 CFR 346.50(c)(7)(ii)). On June 19, 1992 (57 FR 27662), the agency proposed to revise the wording for the precaution for OTC bronchodilator drug products. Other examples include the warning, "Do not give this product to children who have a chronic pulmonary disease, shortness of breath, or who are taking other drugs unless directed by a doctor," for OTC antitussive drug products containing codeine labeled for children under 12 years of age (see 21 CFR 341.74(c)(4)(iii)) and the warning, "Avoid alcoholic beverages while taking

this product. Do not take this product if you are taking sedatives or tranquilizer, without first consulting your doctor," for OTC nighttime sleep-aid drug products containing diphenhydramine hydrochloride or diphenhydramine monocitrate (see 21 CFR 338.50(c)(4)).

5. Two comments contended that the proposed drug interaction warning is not supported by the medical/scientific literature. One comment stated that the articles referenced in the agency's proposal provide questionable support for the agency's position because they are largely review articles with citations to papers that are often anecdotal and out of date. The comment added that the articles contain broad generalizations about drug interactions without adequate discussion of clinical significance.The comment argued that unnecessary warnings dilute the significance and impact of such warnings that are needed for the safe use of the product by the consumer. The comment concluded that the warning is unnecessary.

The agency disagrees with the comments. The medical/scientific literature reviewed by the agency shows that the entire class of antacids can cause numerous drug interactions. In 1982, D'Arcy and McElnay identified the hazards of interactions with antacids as being largely confined to a relatively small group of drugs: tetracycline, phenytoin, digoxin, and chloroquine (Ref. 1). In 1987, the same authors reported newer evidence showing that additional interactions occurred between antacids and cimetidine, quinidine, nonsteroidal antiinflammatory drugs, and beta-adrenergic blocking drugs (Ref. 2). Other references published after the agency's proposal in 1986 include more reports of antacid interactions. For example, the "United States Pharmacopeial Dispensing Information" currently contains extensive interaction data, listing 35 specific interactions between antacids containing aluminum, calcium, magaldrate, magnesium, or sodium bicarbonate and frequently prescribed medications selected on the basis of their potential clinical significance (Ref. 3).

These reports in the literature show that antacids can interact with a wide range of primary drugs, and can adversely affect the efficacy of the primary medication. Interactions can occur by a number of mechanisms, some of which act concomitantly: for example, by altering gastric pH (giving rise to altered dissolution rate of drug formulation, changed drug ionization, and modified absorption patterns), by adsorption of drug onto the surface of the interactant, or through the formation of poorly soluble salts or complexes. Interactions with antacids may also involve kinetic changes, including changed gastric emptying rate and/or gastric motility.

Antacids may alter the rate of dissolution, absorption, biovailability, and renal elimination of a number of drugs. Numerous authors report that, through a combination of factors, many antacids decrease the bioavailability of cimetidine, ranitidine, nitrofurantoin, digoxin, ethambutol, some indomethacin, phenytoin, vitamin A, fluoride, and phosphate (Refs. 2 and 4 through 8). It has also been reported that antacids considerably reduce ketoconazole concentrations (Ref. 4). Antacids decrease the bioavailability of atenolol and propranolol and increase the bioavailability of metoprolol. Antacids also increase the dissolution and absorption of the acidic forms of sulfonamides and the rate of absorption of levodopa (Ref. 8). Concurrent antacid therapy with ferrous sulfate, isoniazid, or tetracycline has frequently been reported to decrease the bioavailability of these drugs in actual patients (Refs. 2, 3, and 9).

Concurrent administration of tetracycline with antacid products containing aluminum hydroxide or divalent ions (magnesium or calcium) significantly decreases the gastrointestinal absorption of the antibiotic, thereby lessening its therapeutic effect. Demeclocycline, methacycline, chlortetracycline, and oxytetracycline are other forms of tetracycline that, administered concurrently with an aluminum hydroxide antacid product, also form insoluble chelates (Ref. 9).

Aluminum hydroxide has been shown to interfere with the absorption or excretion of warfarin, while aluminum hydroxide in combination with magnesium hydroxide can increase the absorption of dicumarol (Refs. 5 and 6). Thiazide diuretics cause retention of calcium and may exacerbate hypercalcemia when calcium carbonate antacids are taken concurrently (Ref. 8).

Alkalinization of the urine affects renal clearance of drugs that are weak acids or bases. Concurrent antacid therapy increases the rate of elimination of salicylates and phenobarbital and decreases the elimination of amphetamine, ephedrine, mecamylamine, pseudoephedrine, and quinidine (Refs. 5 and 8).

Antacids containing aluminum delay gastric emptying, tending to slow the entry of drugs to the absorptive surface of the small intestine, thus resulting in a delayed absorption rate. In combination products, compounds that contain magnesium can partially block the effect of aluminum on gastric motility; therefore, the combination product's absorption rate will be less delayed as compared to that of an aluminum compound's. Magnesium trisilicate and aluminum compounds are notable for their ability to absorb drugs and to form insoluble complexes that are not absorbed (Ref. 8).

Based on information in the medical/scientific literature, the agency concludes that the drug interaction precaution statement is necessary not only for antacid drug products containing aluminum, but for all OTC antacid drug products. Section 331.30(d) of the antacid monograph is revised accordingly.

References

(1) D'Arcy, P. F., and J. C. McElnay, "Drug-Metal Ion Interactions in the Gut," in Sigel H., "Metal Ions in Biological Systems, Vol. 14," in "Inorganic Drugs in Deficiency and Disease," Marcel Dekker, New York, 1982:1–35.

(2) D'Arcy, P. F., and J. C. McElnay, "Drug-Antacid Interactions: Assessment of Clinical Importance," Drug Intelligence and Clinical Pharmacy, 21:607–617, 1987.

(3) "USP DI, Volume I, Drug Information for the Health Care Professional," 13th ed., United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 195–197, 1993.

(4) Hansten, P. D., and J. R. Horn, "Drug Interactions," 6th ed., Lea and Febiger, Philadelphia, pp. 225, 229, 250, and 348, 1987.

(5) "Drug Evaluations," 6th ed., American Medical Association, Chicago, p. 947, 1986.

(6) Garnett, W. R., "Antacid Products" in "Handbook of Nonprescription Drugs," 9th ed., American Pharmaceutical Association, Washington, pp. 270–274, 1990.

(7) Clark, W. G., D. C. Brater, and A. R. Johnson, "Goth's Medical Pharmacology," 12th ed., The C. V. Mosby Co., St. Louis, pp. 748–750, 1988.

(8) Brunton, L. L., "Agents for Control of Gastric Acidity and Treatment of Peptic Ulcers" in "The Pharmacological Basis of Therapeutics," 8th ed., edited by L. S. Goodman, and A. G. Gilman, Pergamon Press Co., Inc., New York, pp. 904–909, 1990.

(9) Shinn, A. F., and R. P. Shrewbury, "Evaluations of Drug Interactions," 3d ed., The C. V. Mosby Co., St. Louis, p. 399, 1985.

6. Two comments stated that this proposal for a general warning may be setting a precedent that could affect the labeling of many OTC drug products in other drug classes. One comment contended that such action after a rulemaking process has been completed represents a major deviation from the scope of a final monograph and usurps the dedicated efforts of many people who participated in that process. The other comment argued that, because the proposed change is of such a sweeping

nature, it should be made subject to a formal rulemaking proceeding in order to provide meaningful notice to all interested parties with opportunity for comment. The comment concluded that if the policy is not abandoned, it must be published as a freestanding proposed rule.

The agency does not consider this antacid drug interaction precaution to be a precedent setting matter that could affect the labeling of many other classes of OTC drug products. This particular drug interaction is a problem specific to OTC antacid drug products. While FDA has used general warnings that affect more than one class of OTC drugs, such as the general pregnancy and nursing warning in 21 CFR 201.63, this usage has been rather limited and there currently are no plans to expand the usage of general warnings on a broad basis. The agency will consider the need for such general warnings as circumstances arise.

In the current situation, the drug interaction precaution for OTC antacid drug products was initiated by a citizen petition (Ref. 1) after the rulemaking for OTC antacid drug products had been completed. Agency regulations in 21 CFR 330.10(a)(12) provide for the amendment of monographs in this manner. Further, the proposed change has been the subject of a proposed rule in a notice and comment rulemaking proceeding, and interested parties have had the opportunity to comment.

Reference

(1) CP, Docket No. 82P–0360, Dockets Management Branch.

7. One comment strongly urged the agency to finalize the proposed rule to amend the labeling requirements for OTC antacid drug products. The comment mentioned personal experience relating to an adverse interaction that occurred between an OTC antacid and a prescription drug. The comment stated that "physicians can not be relied upon to inform their patients of possible negative reactions to a combination of a prescription drug and OTC antacid drug," and "the general public has no other way of ascertaining the information easily."

This comment supports the need for having the drug interaction precaution statement in the labeling of OTC antacid drug products. The warning provides the general public guidance on how to seek information when a question arises as to drug use and should specifically benefit consumers who did not receive adequate instructions initially, who may have forgotten the original instructions regarding their prescription products, or who need to take an antacid after a prescription medication has been prescribed by a doctor. In the event that adequate information was not given initially, the warning alerts consumers to check with their physician or other health professional when taking an OTC antacid drug product with their prescription medication(s) and should result in specific guidance being given at the time of the subsequent inquiry.

II. Summary of Changes in the Final Monograph

After considering the comments received and warnings used for other OTC drug products (see comment 1), the agency has added the words or "other health professional" to the second sentence of the drug interaction precaution so that it now reads: "Antacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your physician or other health professional." In addition, the agency is now requiring that this drug interaction precaution appear in the labeling of all OTC antacid drug products, not just antacid drug products containing aluminum. (See comment 5.) Section 331.30(d) of the antacid monograph is revised accordingly.

The agency is also adding new § 331.30(h) to provide that the word doctor may be substituted for the word physician in any of the labeling statements in § 331.30. No comments were received in response to this part of the proposal. This addition makes the antacid monograph consistent with other recently published monographs.

III. The Agency's Final Conclusions on a Revised Drug Interaction Precaution Statement for OTC Antacid Drug Products

The agency has determined that a drug interaction precaution is needed in the labeling of all OTC antacid drug products (not just those containing aluminum) because the medical/scientific literature identifies a number of interactions that can occur between OTC antacids and prescription drugs. The agency believes that this information represents good health care and will serve as a reminder to consumers who are using antacids to contact their physicians or other health professionals for medication counseling if they are taking a prescription drug.

As discussed in the proposal (51 FR 27342 at 27343), the agency advised that any final rule resulting from the proposal would be effective 12 months after its date of publication in the **Federal Register**. Therefore, on or after August 26, 1994, any OTC antacid drug product that is not in compliance with the final rule may not be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC antacid drug product subject to the rule that is repackaged or relabeled after the effective date of the rule must be in compliance with the rule regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the rule at the earliest possible date.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (51 FR 27342 at 27343). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules including amendment of the monograph for OTC antacid drug products is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking amending the final monograph for OTC antacid drug products is not expected to pose such an impact on small businesses. This final rule will require minor relabeling of one statement in the labeling for all OTC antacid drug products. Manufacturers will have 1 year to implement this relabeling, and almost all manufacturers normally reorder labeling during that time span. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

The agency has determined under 21 CFR 25.24(c)(6) that this actions is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,

neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 331

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 331 is amended as follows:

PART 331—ANTACID PRODUCTS FOR OVER–THE–COUNTER (OTC) HUMAN USE

1. The authority citation for 21 CFR part 331 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 331.30 is amended by revising paragraph (d) introductory text and by adding paragraph (h) to read as follows:

§ 331.30 Labeling of antacid products.

* * * * *

(d) Drug interaction precaution. The labeling of the product contains the following statements under the heading "Drug Interaction Precaution": "Antacids may interact with certain prescription drugs. If you are presently taking a prescription drug, do not take this product without checking with your physician or other health professional."

* * * * *

(h) The word "doctor" may be substituted for the word "physician" in any of the labeling statements in this section.

Dated: August 19, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–20698 Filed 8–25–93; 8:45 am]

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federal register

Thursday
August 26, 1993

Part VI

Department of Education

34 CFR Part 776
Library Education and Human Resource Development Program; Final Rule

DEPARTMENT OF EDUCATION

34 CFR Part 776

RIN 1850–AA48

Library Education and Human Resource Development Program

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the regulations governing the Library Education and Human Resource Development Program (formerly the Library Career Training Program). These amendments are needed to implement the Higher Education Amendments of 1992 (1992 Amendments), to reflect changes in the Education Department General Administrative Regulations (EDGAR), and to clarify and restructure certain provisions in the existing regulations governing the program.

EFFECTIVE DATE: These regulations take effect either 45 days after publication in the **Federal Register** or later if the Congress takes certain adjournments. If you want to know the effective date of these regulations, call or write the Department of Education contact person. A document announcing the effective date will be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Louise V. Sutherland or Frank A. Stevens. Telephone: (202) 219–1315. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Library Education and Human Resource Development Program, is authorized by section 222 of title II, part B of the Higher Education Act of 1965, as amended (HEA). Section 222 was amended by the Higher Education Amendments of 1992 (1992 Amendments) (Pub. L. 102–325), which were enacted on July 23, 1992. These final regulations revise the existing regulations to implement the 1992 Amendments, to reflect changes in the Education Department General Administrative Regulations (EDGAR), and to clarify and restructure certain provisions in the existing regulations governing the program.

On June 11, 1993, the Secretary published a notice of proposed rulemaking (NPRM) for this program in the **Federal Register** (58 FR 32828). The major issues addressed by the regulations are discussed in the preamble to the NPRM.

The Secretary notes that the preamble of the NPRM incorrectly stated that § 776.7 of the regulations would be revised to replace the word "training" in the definition of "institute" with the term "staff development." The proposed regulations did not incorporate this change, and the Secretary has determined that this change is unnecessary. Institute grants have been and continue to be available for training projects, including staff development projects.

Public Comment

In the NPRM the Secretary invited comments on the proposed regulations. The Secretary did not receive any substantive comments. There are no differences between the NPRM and these final regulations.

Executive Order 12291

These regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. The objective of the Executive order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for these programs.

Assessment of Educational Impact

In the NPRM, the Secretary requested comments on whether the proposed regulations would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the proposed rules and on its own review, the Department has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 776

Education, Government contracts, Grant programs—education, Libraries.

(Catalog of Federal Domestic Assistance Number: 84–036B—Library Education and Human Resource Development Program)

Dated: August 23, 1993.

Richard W. Riley,

Secretary of Education.

The Secretary amends title 34 of the Code of Federal Regulations by revising part 776 to read as follows:

PART 776—LIBRARY EDUCATION AND HUMAN RESOURCE DEVELOPMENT PROGRAM

Subpart A—General

Sec.

776.1 What is the Library Education and Human Resource Development Program?
776.2 Who is eligible for a grant?
776.3 Who is eligible to participate in a project?
776.4 What types of projects may the Secretary fund?
776.5 What priorities may the Secretary establish?
776.6 What regulations apply?
776.7 What definitions apply?
776.8 What is the duration of a project?

Subpart B—What Are the Application Requirements?

776.10 How does one apply for a grant?
776.11 What assurance must an applicant for a fellowship project provide?

Subpart C—How Does the Secretary Make an Award?

776.20 How does the Secretary evaluate an application?
776.21 How does the Secretary evaluate an application for a fellowship project?
776.22 What selection criteria does the Secretary use to evaluate an application for an institute project?
776.23 What selection criteria does the Secretary use to evaluate an application for a traineeship project?

Subpart D—What Conditions Must be Met After an Award?

776.30 How may a grantee use grant funds?
776.31 What are the restrictions on costs for participants?
776.32 What are the allowances for assistance under other Federal programs?
776.33 What requirements govern the removal, withdrawal, and substitution of participants?
776.34 What agencies must be informed of activities funded under this program?

Authority: 20 U.S.C. 1021, 1031, 1032, unless otherwise noted.

Subpart A—General

§ 776.1 What is the Library Education and Human Resource Development Program?

The Secretary awards grants under the Library Education and Human Resource Development Program to—

(a) Educate and train persons in library and information science through fellowships, institutes, or traineeships, particularly in areas of critical needs; and

(b) Establish, develop, and expand programs of library and information

science, including new techniques of information transfer and communication technology.

(Authority: 20 U.S.C. 1021, 1032)

§ 776.2 Who is eligible for a grant?

Eligible applicants are—

(a) Institutions of higher education;

(b) Library organizations; or

(c) Library agencies.

(Authority: 20 U.S.C. 1032)

§ 776.3 Who is eligible to participate in a project?

In order to be selected by a grantee as a participant in a project, an individual must—

(a)(1) Be a United States citizen or national;

(2) Provide evidence from the United States Immigration and Naturalization Service that he or she—

(i) Is a permanent resident of the United States; or

(ii) Is in the United States for other than a temporary purpose with the intention of becoming a citizen or permanent resident; or

(3) Be a permanent resident of the Republic of Palau (until the Compact of Free Association with Palau takes effect);

(b) Be engaged in or preparing to engage in a profession or other occupation involving library or information science; and

(c) Meet the selection criteria of the grantee.

(Authority: 20 U.S.C. 1032)

§ 776.4 What types of projects may the Secretary fund?

A grantee may conduct one or more fellowship projects, institute projects, and traineeship projects with funds under this program.

(Authority: 20 U.S.C. 1032)

§ 776.5 What priorities may the Secretary establish?

(a) The Secretary may give priority to applications that address one or more of the following critical needs:

(1) To educate, train or retrain library personnel in areas of library specialization where there are currently shortages, such as school media, children's services, young adult services, science reference, and cataloging.

(2) To educate, train or retrain library personnel in new techniques of information acquisition, transfer, and communication technology.

(3) To educate, train or retrain library personnel to serve the information needs of the elderly, the illiterate, the disadvantaged, or residents of rural America.

(4) To increase excellence in library leadership through advanced training in library management.

(5) To increase excellence in library education by encouraging study in library and information science and related fields at the doctoral level.

(6) To provide advanced training in the development, structure, and management of new library organizational formats, such as networks, consortia, and information utilities.

(7) To recruit, educate, train, retrain and retain minorities in library and information science.

(b) The Secretary establishes priorities by publishing a notice in the **Federal Register**, in accordance with 34 CFR 75.105.

(Authority: 20 U.S.C. 1032)

§ 776.6 What regulations apply?

The following regulations apply to this program:

(a) The Education Department General Administrative Regulations (EDGAR) as follows:

(1) 34 CFR part 74 (Administration of Grants to Institutions of Higher Education, Hospitals, and Nonprofit Organizations).

(2) 34 CFR part 75 (Direct Grant Programs).

(3) 34 CFR part 77 (Definitions that Apply to Department Regulations).

(4) 34 CFR part 79 (Intergovernmental Review of Department of Education Programs and Activities).

(5) 34 CFR part 82 (New Restrictions on Lobbying).

(6) 34 CFR part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(7) 34 CFR part 86 (Drug-Free Schools and Campuses).

(b) The regulations in this part 776.

(Authority: 20 U.S.C. 1021)

§ 776.7 What definitions apply?

(a) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR 77.1:

Applicant
Application
Award
Contract (includes definition of Subcontract)
Department
EDGAR
Grant
Grantee
Private
Project
Project period
Public
Secretary

(b) *Other definitions.* The following definitions also apply to this part:

Act means the Higher Education Act of 1965, as amended.

Disadvantaged means those persons whose socio-economic or educational deprivation or whose cultural isolation from the general community may preclude them from benefiting from library services to the same extent as the general community benefits from these services.

Fellowship means an award of financial assistance for tuition to an individual who has been accepted for admission to an institution of higher education and who is or will be enrolled full-time in a graduate program of library and information science, working toward or completing the requirements for a specific degree in some aspect of library and information science.

Financial need means the fellow's financial need as determined under title IV, part F, of the Act for the period of the fellow's enrollment in the graduate program for the specific degree in library and information science for which the fellowship was awarded.

Institute means a specialized long-term or short-term group training project in library and information science that—

(i) Is separate from the regular academic program of the applicant;

(ii) Has an innovative curriculum; and

(iii) Either provides persons with the skills needed to enter the library and information science field or provides library and information science personnel—including library educators—an opportunity to strengthen or increase their knowledge and skills.

Institution of higher education means an institution of higher education as defined in section 1201 of the Act.

Library and information science means the study of recordable information and knowledge and the services and technologies to facilitate their management and use. The term encompasses information and knowledge creation, communication, identification, selection, acquisition, organization, description, storage, retrieval, preservation, analysis, interpretation, evaluation, synthesis, dissemination, and management.

Library organization or agency means a public or private organization or agency that provides library services or programs.

Participant means a person who is enrolled in a project funded under this part.

Participation costs means the costs associated with participation in a

traineeship or institute, including the costs of travel and subsistence, for which the grantee pays directly or reimburses the trainee or institute participant.

State agency means the State agency designated under section 1203 of the Act.

Stipend means an award of money from a grantee to a fellow, the amount of which is determined on the basis of the fellow's demonstrated financial need.

Traineeship means a training project in library and information science that—

(i) Is separate from the regular academic program of the applicant;

(ii) Is designed to meet the individual needs of mid-level library and information science professionals; and

(iii) Provides individualized instruction, usually through an internship.

(Authority: 20 U.S.C. 1021, 1032)

§ 776.8 What is the duration of a project?

(a) A fellowship must provide at least one academic year of training.

(b) A long-term institute project must provide at least one academic year but no more than 12 months of training.

(c) A short-term institute project must provide at least one week but no more than six weeks of training.

(d) A traineeship project may not exceed 12 months.

(Authority: 20 U.S.C. 1021, 1032)

Subpart B—What Are the Application Requirements?

§ 776.10 How does one apply for a grant?

(a) An applicant must submit separate applications for fellowship, institute, and traineeship projects.

(b) An applicant must submit separate applications for fellowship projects at the master's, post-master's, and doctoral levels, limited to one application per level for new fellowships.

(c) An applicant must include all of its requests for new fellowships at a particular level within the single application for that level.

(Authority: 20 U.S.C. 1021, 1032)

§ 776.11 What assurance must an applicant for a fellowship project provide?

An applicant for a fellowship project must provide an assurance that in the event funds made available to a participant under this program are insufficient to provide the assistance due a participant under the commitment entered into between the applicant and the participant, the applicant will endeavor, from any funds available to it, to fulfill the commitment to the participant.

(Authority: 20 U.S.C. 1032)

Subpart C—How Does the Secretary Make an Award?

§ 776.20 How does the Secretary evaluate an application?

(a) The Secretary evaluates an application for a fellowship project on the basis of the provisions in § 776.21 and awards up to 110 possible points for these criteria.

(b) The Secretary evaluates an application for an institute project on the basis of the criteria in § 776.22 and awards up to 100 possible points for these criteria.

(c) The Secretary evaluates an application for a traineeship project on the basis of the criteria in § 776.23 and awards up to 100 possible points for these criteria.

(d) The maximum score for each criterion is indicated in parentheses.

(Approved by the Office of Management and Budget under control number 1850–0022.)

(Authority: 20 U.S.C. 1032)

§ 776.21 How does the Secretary evaluate an application for a fellowship project?

(a) *Continuation awards.* Before considering applications to support new fellowships, the Secretary provides funds to continue support for qualified students who were awarded fellowships under this program in the previous two years and who are maintaining satisfactory progress as determined by the institution.

(b) *Selection criteria for new fellowship projects.* The Secretary evaluates an application for a new fellowship project based on the following selection criteria:

(1) *Project description* (20 points). The Secretary reviews each application to determine the quality of the applicant's project, including the extent to which—

(i) The project addresses one or more of the critical needs announced by the Secretary as a priority or priorities under § 776.5(a);

(ii) The project objectives are clearly stated, realistic, and satisfy a current training need;

(iii) The required courses meet standards that are recognized by the library and information science profession; and

(iv) The student field experience component (if included) is well designed.

(2) *Plan of operation* (20 points). The Secretary reviews each application to determine the quality of the plan of operation for the project, including—

(i) The quality of the design of the project;

(ii) The extent to which the plan of management is effective and ensures proper and efficient administration of the project;

(iii) How well the objectives of the project relate to the purpose of the program; and

(iv) The quality of the applicant's plans to use its resources and personnel to achieve each objective.

(3) *Quality of key personnel.* (10 points)

(i) The Secretary reviews each application to determine the quality of the key personnel the applicant plans to use on the project, including—

(A) The qualifications of the project director (if one is to be used);

(B) The qualifications of each of the other key personnel to be used in the project; and

(C) The time that these key personnel will commit to the project.

(ii) To determine the qualifications of these key personnel the Secretary considers—

(A) Experience, training, and professional productivity in fields related to the objectives of the project; and

(B) Any other qualifications that pertain to the quality of the project.

(4) *Selection of fellows* (15 points). The Secretary reviews each application to determine the effectiveness of the applicant's method of selecting fellows including—

(i) Conformance with program priorities in § 776.5(a); and

(ii) Evidence that admissions standards for fellows are comparable to those for other students admitted to the library and information science education program.

(5) *Applicant characteristics* (20 points). The Secretary reviews each application to determine the applicant's commitment to library and information science education, including—

(i) The adequacy of the description in the applicant's catalog of the specific library education program in which participants will be enrolled;

(ii) The extent to which the amount the applicant spends per student for education in library and information science is comparable to that of other education programs;

(iii) The extent to which the ratio of degrees awarded to total enrollment in the applicant's library education program is comparable to that of other library education programs;

(iv) The extent to which the ratio of requested fellowships to other fellowships and scholarships in library and information science supported by the applicant is comparable to that of other library education programs; and

(v) The extent to which the academic level of the project is appropriate to the applicant's capabilities or experience.

(6) *Budget and cost effectiveness* (5 points). The Secretary reviews each application to determine the extent to which—

(i) The budget is adequate to support the project; and

(ii) Costs are reasonable in relation to the objectives of the project.

(7) *Evaluation plan* (5 points). The Secretary reviews each application to determine the quality of the evaluation plan for the project, including the extent to which the applicant's methods of evaluation are—

(i) Appropriate to the project;

(ii) Objective; and

(iii) Designed to produce data that are quantifiable.

Cross-Reference: See 34 CFR 75.590 Evaluation by the grantee.

(8) *Adequacy of resources* (5 points). The Secretary reviews each application to determine the adequacy of the resources that the applicant plans to devote to the project, including facilities, equipment, and supplies.

(9) *Project impact* (10 points). The Secretary reviews each application to determine the extent to which the project will expand and strengthen the applicant's library and information science degree programs.

(c) *Other considerations.* The Secretary may give priority among applications for new fellowship projects that are of substantially the same quality to applications that will contribute to an appropriate balance of fellowships among the priorities announced under § 776.5.

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(Authority: 20 U.S.C. 1021, 1032)

§ 776.22 What selection criteria does the Secretary use to evaluate an application for an institute project?

(a) *Project description* (20 points). The Secretary reviews each application to determine the quality of the applicant's project, including the extent to which—

(1) The project addresses one or more of the critical needs announced by the Secretary as a priority or priorities under § 776.5(a);

(2) The subject matter of the project is significant, timely, well-described, appropriate for an institute, and is not duplicated in the applicant's regular curriculum;

(3) The project duration is appropriate for presenting the subject matter;

(4) The project content satisfies rigorous educational standards;

(5) The blend of theoretical and practical training is suitable to the subject matter and the needs of the participants; and

(6) The training methods are innovative and imaginative.

(b) *Plan of operation* (20 points). The Secretary reviews each application to determine the quality of the plan of operation for the project, including—

(1) The quality of the design of the project;

(2) The extent to which the plan of management is effective and ensures proper and efficient administration of the project;

(3) How well the objectives of the project relate to the purpose of the program; and

(4) The quality of the applicant's plan to use its resources and personnel to achieve each objective.

(c) *Quality of key personnel.* (15 points)

(1) The Secretary reviews each application to determine the quality of the key personnel the applicant plans to use on the project, including—

(i) The qualifications of the project director (if one is to be used);

(ii) The qualifications of each of the other key personnel to be used in the project; and

(iii) The time that these key personnel will commit to the project.

(2) To determine the qualifications of these key personnel, the Secretary considers—

(i) Experience, training, and professional productivity in fields related to the objectives of the project; and

(ii) Any other qualifications that pertain to the quality of the project.

(d) *Selection of institute participants* (15 points). The Secretary reviews each application to determine the effectiveness of the method of participant selection, including the extent to which—

(1) Participants will be selected according to their ability, experience, current responsibilities, and training needs; and

(2) The number of participants is appropriate to the training methods and project resources.

(e) *Budget and cost effectiveness* (5 points). The Secretary reviews each application to determine the extent to which—

(1) The budget is adequate to support the project; and

(2) Costs are reasonable in relation to the objectives of the project.

(f) *Evaluation plan* (8 points). The Secretary reviews each application to determine the quality of the evaluation plan for the project, including the extent to which the applicant's methods of evaluation are—

(1) Appropriate to the project;

(2) Objective; and

(3) Designed to produce data that are quantifiable.

Cross-Reference: See 34 CFR 75.590 Evaluation by the grantee.

(g) *Adequacy of resources* (7 points). The Secretary reviews each application to determine the adequacy of the resources that the applicant plans to devote to the project, including facilities, equipment, and supplies.

(h) *Project effectiveness* (10 points). The Secretary reviews each application to determine the effectiveness of the project, including the extent to which—

(1) The project will increase the number of librarians with specialized skills; and

(2) The project includes plans for disseminating promising results and high quality materials to other institutions or agencies.

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(Authority: 20 U.S.C. 1032)

§ 776.23 What selection criteria does the Secretary use to evaluate an application for a traineeship project?

(a) *Project description* (15 points). The Secretary reviews each application to determine the quality of the applicant's project, including the extent to which—

(1) The project addresses one or more of the critical needs announced by the Secretary as a priority or priorities under § 776.5(a);

(2) The training needs to be met by the project are significant, of current interest to the library and information science community, and well-described;

(3) Project activities are designed to meet the individual needs of each participant; and

(4) Other library agencies or institutions will cooperate with the applicant in providing appropriate and high quality internship opportunities.

(b) *Plan of operation* (20 points). The Secretary reviews each application to determine the quality of the plan of operation for the project, including—

(1) The quality of the design of the project;

(2) The extent to which the plan of management is effective and ensures proper and efficient administration of the project;

(3) How well the objectives of the project relate to the purpose of the program; and

(4) The quality of the applicant's plans to use its resources and personnel to achieve each objective.

(c) *Quality of key personnel.* (15 points)

(1) The Secretary reviews each application to determine the quality of

key personnel the applicant plans to use on the project, including—

(i) The qualifications of the project director (if one is to be used);

(ii) The qualifications of each of the other key personnel to be used in the project; and

(iii) The time that these key personnel plan to commit to the project.

(2) To determine the qualifications of these key personnel, the Secretary considers—

(i) Experience, training, and professional productivity in fields related to the objectives of the project; and

(ii) Any other qualifications that pertain to the quality of the project.

(d) *Selection of trainees* (15 points). The Secretary reviews each application to determine the effectiveness of the applicant's method of trainee selection, including the extent to which trainees will be selected on the basis of their stated career goals and on their potential for high level advancement and continued professional growth within the field of library and information science.

(e) *Budget and cost effectiveness* (10 points). The Secretary reviews each application to determine the extent to which—

(1) The budget is adequate to support the project; and

(2) Costs are reasonable in relation to the objectives of the project.

(f) *Evaluation plan* (10 points). The Secretary reviews each application to determine the quality of the evaluation plan for the project, including the extent to which the applicant's methods of evaluation are—

(1) Appropriate for the project;

(2) Objective; and

(3) Are designed to produce data that are quantifiable.

Cross-Reference: See 34 CFR 75.590 Evaluation by the grantee.

(g) *Adequacy of resources* (15 points). The Secretary reviews each application to determine the adequacy of the resources that the applicant plans to devote to the project, including facilities, equipment, and supplies.

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(Authority: 20 U.S.C. 1021, 1032)

Subpart D—What Conditions Must Be Met After an Award?

§ 776.30 How may a grantee use grant funds?

(a)(1) A grantee may use grant funds in the following amounts to cover the cost of providing fellowship training:

(i) For each fellowship awarded at the master's level—$6,400 for an academic year plus $1,600 for a summer session.

(ii) For each fellowship awarded at postmaster's and doctoral levels—$8,000 for an academic year plus $2,000 for a summer session.

(2) A grantee shall use grant funds to pay stipends to fellows, based on the amount of demonstrated financial need up to a maximum of $14,000 a year.

(b)(1) A grantee may use grant funds to cover the costs of providing institute training.

(2) A grantee may use grant funds to assist in covering the participation costs of institute training.

(c)(1) A grantee may use grant funds to cover the costs of providing traineeship training.

(2) A grantee may use grant funds to assist in covering the participation costs of traineeship training.

(Authority: 20 U.S.C. 1032)

§ 776.31 What are the restrictions on costs for participants?

A grantee may not charge tuition or fees to a participant in a project funded under this program.

(Authority: 20. U.S.C. 1032)

§ 776.32 What are the allowances for assistance under other Federal programs?

(a) Any amount paid a participant from any other Federal grant program for educational purposes (except veterans', war orphans', and widows' educational assistance under title 38, United States Code) must be deducted from the amount that participant would receive under this part.

(b) If a participant receives a federally assisted educational loan, the amount of the loan and any interest paid may not be deducted from the amount received by the participant under this part.

(Authority: 20 U.S.C. 1021, 1032 and 38 U.S.C. 1700)

§ 776.33 What requirements govern the removal, withdrawal, and substitution of participants?

(a) A grantee shall remove a participant from a project if the grantee determines that the participant has ceased to maintain academic proficiency.

(b) If a grantee removes the participant or if a participant withdraws, the grantee—

(1) May replace the participant if the new participant can successfully complete the fellowship, traineeship, or institute at no additional cost to the Department; and

(2) Must notify the Secretary in writing—

(i) Within 30 days of the removal or withdrawal; or

(ii) Within 30 days of a substitution if the grantee substitutes another participant.

(c) The date of removal or withdrawal is—

(1) The date the grantee determined that the participant had ceased to maintain academic proficiency; or

(2) The last date the participant attended class.

(d)(1) If a grantee removes a fellowship participant or if a fellowship participant withdraws, the grantee shall prorate the participant's stipend, according to the number of weeks the participant has completed in the project.

(2) For purposes of paragraph (d)(1) of this section, the grantee shall count attendance in any part of a week as a full week.

(e) If a grantee does not substitute a participant for the participant who has been removed or who has withdrawn from a fellowship, traineeship, or institute, the grantee shall return to the Federal Government the unused portion of the stipend and any participation costs.

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(Authority: 20 U.S.C. 1032)

§ 776.34 What agencies must be informed of activities funded under this program?

Each institution of higher education that receives a grant under this part shall annually inform the agency designated under section 1203 of the Act of its project activities.

(Authority: 20 U.S.C. 1022)

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