

(e) The evidence necessary to prove the claim cannot be produced or the necessary witnesses are unavailable and efforts to induce voluntary payment have failed.

Subpart G—Referrals

§ 13.33 Referrals to the Department of Justice.

(a) *Prompt referral.* The Administrator refers to DOJ for litigation all claims on which aggressive collection actions have

been taken but which could not be collected, compromised, suspended or terminated. Referrals are made as early as possible, consistent with aggressive agency collection action, and within the period for bringing a timely suit against the debtor.

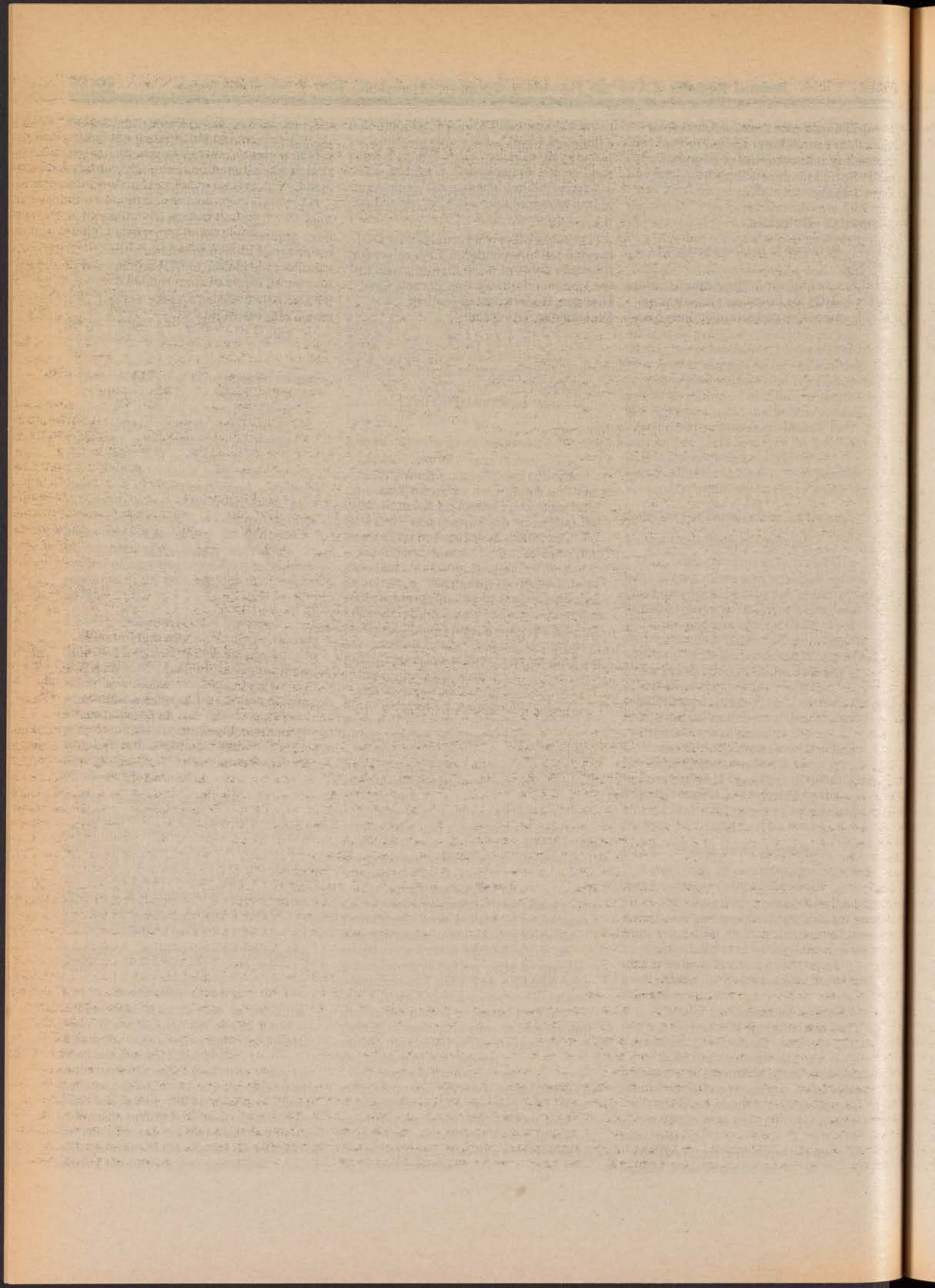
(1) Unless otherwise provided by DOJ regulations or procedures, EPA refers for litigation debts of more than \$100,000 to the Commercial Litigation Branch, Civil Division, Department of Justice, Washington, DC 20530.

(2) Unless otherwise provided by DOJ regulations or procedures, EPA refers for litigation debts of \$100,000 or less to the United States Attorney in whose judicial district the debtor can be found.

(b) *Claims Collection Litigation Report (CCLR).* Unless an exception has been granted by DOJ, the CCLR is used for referrals of all administratively uncollectible claims to DOJ and is used to refer all offers of compromise.

[FR Doc. 87-19186 Filed 8-24-87; 8:45 am]

BILLING CODE 6560-50-M



Federal Register

**Tuesday
August 25, 1987**

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 874

Ear, Nose, and Throat Devices; Exemptions From Premarket Notification; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. 86N-0010]

Ear, Nose, and Throat Devices; Exemptions From Premarket Notification

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is exempting from the requirement of premarket notification, with limitations, certain ear, nose, and throat devices. These actions are being taken under the Medical Device Amendments of 1976 and are a step in implementing one of the goals in FDA's plan for action.

EFFECTIVE DATE: September 24, 1987.

FOR FURTHER INFORMATION CONTACT:

David A. Segerson, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-8185.

SUPPLEMENTARY INFORMATION: The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: Class I, general controls; class II, performance standards; and class III, premarket approval.

Section 513(d)(2)(A) of the act (21 U.S.C. 360c(d)(2)(A)) authorizes FDA to exempt, by regulation, a generic type of class I device from the requirement of, among other things, premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR Part 807, Subpart E. Such an exemption allows manufacturers to introduce into commercial distribution devices of the generic type exempted without first submitting to FDA a premarket notification. When FDA was publishing its proposed classification regulations for preamendments devices, the agency did not routinely evaluate whether it should grant to manufacturers of such devices placed in class I an exemption from the requirement of premarket notification in section 510(k) of the act and 21 CFR Part 807, Subpart E.

Generally, FDA considered such exemptions only when the advisory panels recommended the exemptions.

Recently, FDA developed criteria for exempting certain class I devices from the requirement of premarket notification, to reduce the number of premarket notifications on relatively innocuous devices and free agency resources for the review of more complex notifications.

The development of these criteria and the issuance of proposed and final rules exempting appropriate devices from the requirement of premarket notification in section 510(k) of the act will help implement a goal in FDA's May 1987 "A Plan for Action Phase II" (Ref. 1).

On November 6, 1986 (51 FR 40394), FDA proposed to exempt from premarket notification requirements four ear, nose, and throat devices. Interested persons were given until January 5, 1987, to comment. No comments were received. Therefore, FDA is adopting the regulation as proposed.

Criteria for 510(k) Exemptions

FDA is exempting generic types of class I devices from the requirement of premarket notification with the limitations described below, if FDA determines that premarket notification is not necessary for the protection of the public health. FDA may grant an exemption if both of the following criteria are met:

1. FDA has determined that the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device such as device design or materials. When making these determinations, FDA may consider the frequency, persistence, cause, or seriousness of such claims or risks, or other factors.

2. FDA has determined that: (a) Characteristics of the device necessary for its safe and effective performance are well established; (b) anticipated changes in the device that are of the type that could affect safety and effectiveness will (1) be readily detectable by users by visual examination or other means, such as routine testing, e.g., testing of a clinical laboratory reagent with positive and negative controls, before causing harm, or (2) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (c) any changes in the device will not be likely to result in a change in the device's classification.

FDA will make the determination above based on its knowledge of the device, including past experience with premarket notification and publicly available reports or studies on device

performance. Based on the above criteria, FDA will place the exempted device into the same class as the class I device to which it would be substantially equivalent.

FDA may, if it has concerns only about certain types of changes in a class I device, grant a limited exemption from premarket notification for the generic type of device. A limited exemption will specify what types of changes manufacturers must continue to report to FDA. For example, FDA may exempt a device except when a manufacturer intends to use a different material.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic of a device that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

Reference

The following information has been placed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Food and Drug Administration—A Plan for Action Phase 11," Public Health Service, Department of Health and Human Services, May 1987, p. 9.

Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) 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.

Economic Impact

FDA has carefully analyzed the economic effects of this final rule and has determined that the final rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this final rule has been carefully analyzed and it has been determined that the final rule does not constitute a major rule as defined in section 1(b) of the Executive Order.

The devices subject to this final rule are now subject only to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j), with certain exemptions.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 874 is amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

1. The authority citation for 21 CFR Part 874 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794-795 as amended, 90 Stat. 540-546, 552-559, 565-574, 576-577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

2. Part 874 is amended by adding new § 874.9 to read as follows:

§ 874.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

3. In § 874.1100 by revising paragraph (b) to read as follows:

§ 874.1100 Earphone cushion for audiometric testing.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials

that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807.

4. In § 874.3540 by revising paragraph (b) to read as follows:

§ 874.3540 Prosthesis modification instrument for ossicular replacement surgery.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

5. In § 874.4420 by revising paragraph (b) to read as follows:

§ 874.4420 Ear, nose, and throat manual surgical instrument.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807.

6. In § 874.5800 by revising paragraph (b) to read as follows:

§ 874.5800 External nasal splint.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807.

Dated: July 1, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-19396 Filed 8-24-87; 8:45 am]

BILLING CODE 4160-01-M

Statistical Report

Tuesday
August 25, 1987

Part IV

Office of Management and Budget

Review of the "Dress Rehearsal" for the
1990 Census of Population and Housing;
Notice

OFFICE OF MANAGEMENT AND BUDGET

Review of the "Dress Rehearsal" for the 1990 Census of Population and Housing

AGENCY: Office of Management and Budget.

ACTION: Notice containing information on the status of the review under the Paperwork Reduction Act of the 1990 Census Dress Rehearsal.

SUMMARY: The Office of Management and Budget (OMB) is currently reviewing, under the Paperwork Reduction Act, the "Dress Rehearsal" for the 1990 Census of Population and Housing. Since the review period began on June 17, 1987, OMB has received several hundred letters from members of the public concerning the review and the content of the 1990 Census. Both in response to the large number of people who have submitted comments already and to assist others who may wish to do so before the end of the review period, OMB is publishing the following information about the review process and the current status of the Dress Rehearsal review.

DATES: The review period for the 1990 Census Dress Rehearsal will end September 15, 1987. Public comments on the Dress Rehearsal will be welcomed up to that date.

ADDRESS: Comments on the 1990 Census Dress Rehearsal should be made in writing and sent to: Donald R. Arbuckle, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Donald R. Arbuckle or Francine Picoult, Office of Information and Regulatory Affairs, Office of Management and Budget. Telephone number: (202) 395-3740.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) is currently reviewing, under the Paperwork Reduction Act of 1980, the "Dress Rehearsal" for the 1990 Census of Population and Housing, a prototype of the questionnaires and design to be used in the 1990 Census. In recent weeks, OMB has received several hundred letters concerning the census. All the letters have been read and will become part of the public record of the Dress Rehearsal review.

Under the Paperwork Reduction Act of 1980, all collections of information from 10 or more people must be reviewed by OMB to assure that the information to be collected and published will be as useful as possible

to the government and the public and that the burden of respondents is held to the minimum practical level. OMB is also responsible under the Paperwork Reduction Act for overseeing and establishing standards for Federal statistical programs, to maintain and improve the quality of government statistics. OMB's information collection reviews for statistical surveys such as the decennial census focus not only on burden but also on quality issues.

OMB may take up to 90 days for its reviews, and during the review period the public is invited to comment on any aspect of the information collection under review. In the case of the Dress Rehearsal for the 1990 Census, the OMB review period began on June 17th and will end on September 15th. OMB will welcome public comments until the end of the review period. *OMB has as yet made no decisions or recommendations concerning the Dress Rehearsal, nor will any final decisions be made until mid-September.*

In reviewing all proposed information collections, OMB is responsible for assuring that the agency sponsoring the collection has provided adequate demonstration that the data to be collected have substantial, practical uses and that no more burden than necessary is placed on those who must provide the data, be they individuals, businesses, or State and local governments. For statistical data collections, OMB is further responsible for assuring that the data collected and published are sufficiently reliable to meet the major requirements of government and public users. To fulfill these responsibilities, OMB frequently must ask sponsor agencies—such as the Bureau of the Census, in the case of the 1990 Census Dress Rehearsal—for additional justification of their data collection plans. In the role of reviewer, it is OMB's responsibility to ask questions and make sure that there are adequate answers for the public record.

Some Questions OMB is Raising in its Review of the 1990 Census Dress Rehearsal

The 1990 Census Dress Rehearsal, which OMB is currently reviewing, is a prototype of the forms and design to be used in the 1990 Census. The Bureau of the Census is proposing to administer a "short form" questionnaire containing 17 questions to every household in the country (about 96 million households) and to ask an additional 44 questions, on a "long form," of a nationwide sample of 1 in 6 (about 16 million) households.

Having reviewed the materials submitted by the Bureau of the Census

to justify the proposal, OMB has raised a number of questions about the content and design, to determine that the data to be collected in the census will be reliable and of the greatest possible use and that respondent burden has been reduced to the minimum level practicable and appropriate. OMB would particularly welcome public comments directed to these questions.

1. Are there substantial uses for all the data to be collected?

There are some items on the questionnaire for which OMB has asked for more information concerning substantial use. For example,

- Question H20—How many bedrooms do you have?

The justification states that this information, to be collected on the long form, "provides an important assessment of the amount of available living and sleeping space" and that it is used in calculations of "fair market rentals." However, question H3 asks total number of rooms. OMB is inquiring whether both items are needed in the census.

- Question H7—Do you have a telephone in this house or apartment? (if yes,) enter phone number.

This question is being proposed for the short form. OMB has questioned the need to ask every household whether it has a telephone, but has particularly questioned the need for, and propriety of, requiring people, under penalty of law, to give their home telephone number. If the Bureau of the Census wishes to use telephone numbers for follow-up, could respondents be asked to provide that information on the back of the forms (where they are asked to give the name and address of the person who filled out the form)?

2. Is the decennial census the best source of certain data?

In certain cases, OMB has asked for a stronger demonstration that the decennial census is an appropriate vehicle for collecting reliable, analytically-useful information. For example,

- The long form proposed for the census contains seven questions concerning energy use and costs:

H15—Which fuel is used most for heating this house or apartment?

H16—What kind of heating equipment is used most to heat this house or apartment?

H17—What fuel is used most for heating the water in this house or apartment?

H18a-d—What are the yearly costs of utilities and fuels for this house or apartment? If you have been here less than 1 year, estimate the yearly cost.

(Four-part question, asked separately for electricity, gas, water, and "oil, coal, kerosene, wood, etc.")

The Energy Information Administration (EIA) has a statistical program dealing with residential energy use and costs. When the EIA program began in the late 1970s, cost questions such as those proposed for the 1990 Census were rejected as unreliable. This judgment was based in part on the experience in an earlier census where such questions produced results that were 25 to 50 percent higher than actual energy costs. This kind of reporting bias cannot be reduced by increasing sample size—the error persists in a complete census or a sample of any size and is so large that it dwarfs the effect of sampling error, even in a sample covering only a fraction of 1 percent of all households.

EIA dealt with this problem by getting the permission of randomly selected households to go directly to their energy suppliers for accurate records of energy use and costs. EIA also found that more specific questions were needed to describe energy consumption—to identify electric heaters used to supplement an oil furnace, for example. Based on its experience, EIA reported that the only 1990 Census question necessary for this use was question H15 ("Which fuel is used most for heating this house or apartment?"), to be used for benchmarking the more complete and accurate sample surveys conducted by EIA to measure energy consumption and costs. In the past, for a modest charge, EIA has augmented its surveys to meet the needs of other agencies for accurate energy information.

• The proposed 1990 Census long form contains two questions on water source and sewage disposal:

H12—Do you get your water from—
A public system such as a city water department or private company?
An individual drilled well?
An individual dug well?
Some other source such as a spring, creek, river, cistern, etc.?

H13—Is this building connected with a public sewer?

The Census Bureau's supporting statement indicates that the principal uses of this information are in planning various rural development and assistance programs. Inasmuch as the coverage of public water and sewer systems is known from other sources than the census (local government and utility company records, which might be able to serve local planning needs), and the principal use of census data is to determine the circumstances of households that are *not* served by public systems, OMB is asking whether a

survey targeted at rural areas might be a better vehicle for collecting these data.

3. *Is it necessary to ask some of the questions of such large numbers of households (96 million for the short-form questions, 16 million for the long form)?*

In 1975, Congress inserted into Title 13 (the Census Code) a new section (Section 195) specifically authorizing the Census Bureau to use statistical sampling whenever *feasible* in all areas of the census except the actual count of the population. OMB would like to make sure that optimum use is made of sampling, both so that respondent burden is minimized and so that, for any given burden, a greater amount of useful information can be gathered in the census.

• *Short-form housing questions.* The proposed short form includes 10 housing questions. In 1986, GAO studied the uses of these 100-percent data, questioned the need for collecting them from all households (rather than a sample), and recommended that the Census Bureau test a short form that included only four housing questions.

OMB too is questioning the need for asking the following housing questions on the 100-percent (short) form:

H3—How many rooms do you have in this house or apartment?

H4—Do you have complete plumbing facilities in this house or apartment?

H5—Is this house or apartment part of a condominium?

H6—Is this house on ten or more acres? Is there a business or a medical office on this property?

H7—Do you have a telephone in this house or apartment?

H8—Is this house or apartment—
Owned with a mortgage or loan?
Owned free and clear?

Rented for cash rent?
Occupied without payment of cash rent?

H9—(For owners) What is the value of this property; that is, how much do you think this house and lot or condominium unit would sell for if it were for sale?

H10—(For renters) What is the monthly rent? Does the monthly rent include any meals?

In the case of the last two questions (H9 and H10), which are to be answered by checking ranges representing approximate dollar values, a 100-percent count has no advantage in accuracy over a much smaller sample.

• *Sample size for the long form.* OMB is concerned that the proposed 16 million-household sample may be larger than necessary for collecting much of the long-form data.

Some of the questions to be used in the 1990 Census are known to produce

large errors because households cannot accurately estimate, or do not wish to report, the answer. In these cases, the bias dwarfs any error introduced by sampling, even at very modest sample sizes. The error is inherent in the question and is not reduced by asking the question of millions of additional households. Questions calling for estimates of dollar values or specific costs are likely to provide no more accuracy averaged across 16 million households than over a sample of 100,000 or less.

The principal justification given for many of the 1 in 6 sample questions is that data are needed for very small areas for planning purposes. However, there are some cases where similar data are available locally. OMB is questioning whether these data could not adequately serve planning purposes. For example, information on real estate transactions, including the price for which houses have recently sold, is available from locally-available records, as is information on real estate tax assessments (question H23 on the proposed long form).

For some other long-form questions, OMB is asking for more information indicating that data for small areas are actually needed and used. Examples of such questions are:

H24—What was the annual payment for fire, hazard, and flood insurance on this property?

H25a—Do you have a mortgage, deed of trust, contract to purchase, or similar debt on this property?

H25b—How much is your regular monthly mortgage payment on this property?

H25c—Does your regular monthly mortgage payment include payments for real estate taxes on this property?

H25d—Does your regular monthly mortgage payment include payments for fire, hazard, or flood insurance on this property?

H26a—Do you have a second or junior mortgage or a home equity loan on this property?

H26b—How much is your regular monthly payment on all second or junior mortgages and all home equity loans?

H27—(For condominium owners) What is the monthly condominium fee?

H28—(For mobile home owners) What was the total cost for personal property taxes, site rent, registration fees, and license fees on this mobile home and its site last year? Exclude real estate taxes.

4. *Is the response burden of the census fairly distributed?*

The proposed long form with 61 questions (as compared with the short form's 17) imposes a lopsided burden on

those households that receive the long form. OMB has asked the Census Bureau to consider the possibility of dividing the long-form questions into two or more questionnaires, so as to distribute the burden more equitably.

5. *Is the length of the proposed questionnaires, particularly the long form, likely to have any adverse effect on the quality of response?*

OMB's concern about questionnaire length and content relates not just to burden but, even more important, to the

accuracy of the census count and the reliability of the demographic data that are collected in the census. The high rates of "failed edits" in the 1970 and 1980 censuses (the percentage of returned forms that did not meet the Census Bureau's edit criteria and therefore had to be followed up) suggest that in the recent past respondents have experienced substantial problems filling out forms completely and accurately. For example, in 1980 45 percent of the long forms that were mailed back were

so incomplete or otherwise deficient that a follow-up was required. Before approving plans for the 1990 census, OMB would like to be sure that careful attention has been paid to all aspects of data collection that could affect the quality of response.

Authority: 44 U.S.C. 3504.

Wendy L. Gramm,

Administrator for Information and Regulatory Affairs.

[FR Doc. 87-19574 Filed 8-24-87; 8:45 am]

BILLING CODE 3110-01-M