to the public interest to grant such exemption.

Issued in Washington, DC on August 4, 1987, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 87-18046 Filed 8-7-87; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 131

[Docket No. 81N-204C]

Milk, Lowfat Milk, and Skim Milk, Pasteurization Requirements for Fluid Milk Products for Consumer Use

AGENCY: Food and Drug Administration.

ACTION: Final rule; termination of stay.

SUMAMRY: The Food and Drug Administration (FDA) is announcing that the stay of that portion of the standard of identity for milk, lowfat milk, and skim milk products that concern the requirement that certified fluid milk products for consumer use be pasteurized is terminated. Elsewhere in this issue of the **Federal Register** under 21 CFR Part 1240—Control of Communicable Diseases, FDA is taking action to require that milk and milk products, certified and noncertified, in final package form for human consumption in interstate commerce be pasteurized.

EFFECTIVE DATE: September 9, 1987.

FOR FURTHER INFORMARTION CONTACT: Robert J. Lahan, Center for Food Safety and Applied Nutrition (HFF-302), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0162.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 9, 1972 (37 FR 18392), FDA, under section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341), proposed to revise existing standards of identity and to establish new standards of identity for certain milk and cream products. This notice included an FDA proposal to require that each of the listed milk and cream products be pasteurized.

In the **Federal Register** of October 10, 1973 (38 FR 27924), FDA published a final rule which included the requirement that milk products moving in interstate commerce be pasteurized. In deciding upon the pasteurization requirement, FDA reasoned that pasteurization was the only way to assure the destruction of pathogenic microorganisms that might be present.

Following publication of the final rule, FDA received one request for a hearing and an accompanying set of objections on the pasteurization requirement for certified raw milk. The procedures used in producing certified raw milk are significantly different from those used in producing raw milk in general in that they must comport with the methods and standards established by the American Association of Medical Milk Commissions, a private organization that provides to its members guidelines for the production of certified raw milk. Only dairies that employ the Association's techniques have the right to use the term "certified" on their products. The objections, which pertained only to certified raw milk, were based on two premises: (1) Certified raw milk is a safe product, and (2) section 401 of the Act (21 U.S.C. 341) does not provide authority to establish a standard of identity solely for health reasons.

In the preamble of the **Federal Register** of December 5, 1974, (39 FR 42351), FDA announced that the objections raised a substantial issue of fact with regard to whether pasteurization is needed for certified raw milk and that a hearing would be conducted. Accordingly, FDA stayed this requirement for certified raw milk.

This stayed requirement for certified raw milk has been rendered moot by the agency's issuance elsewhere in this issue of the **Federal Register** of a final rule requiring that all milk and milk products, certified and noncertified, in final package form for human consumption in interstate commerce be pasteurized. This fianl rule was issued in response to a decision by the United States District Court for the District of Columbia ordering "that the Food and Drug Administration and the Secretary of Health and Human Services publish in the **Federal Register**, a proposed rule banning the interstate sale of all raw milk and raw milk products, both certified and non-certified, pursuant to the provisions of 5 U.S.C. section 553 and complete all rulemaking proceedings in accordance with this Court's opinion within one hundred eighty (180) days." *Public Citizen* v. *Heckler*, 653 F. Supp. 1229, 1242 (D.D.C. 1986). The proposal was published in the **Federal Register** of June 11, 1987 (52 FR 22340).

Therefore, consistent with the court decision, the agency is announcing that the stay of that portion of the standards of identity for milk, lowfat milk, and skim milk products that concern the requirement that certified fluid milk products for consumer use be pasteurized is hereby terminated.

List of Subjects in 21 CFR Part 131

Cream, Food standards, Milk, Yogurt.

PART 131—MILK AND CREAM

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10); *It is ordered* that the stay announced in the preamble of the **Federal Register** of December 5, 1974 (39 FR 42351) is terminated.

Dated: August 5, 1987.

Ronald G. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-18191 Filed 8-6-87; 3:14 pm]

BILLING CODE 4160-01-M

21 CFR Part 1240

[Docket No. 81N-204C]

Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final regulation requiring that milk and milk products in final package form for human consumption in interstate commerce be pasteurized. The final regulation does not apply to the interstate transportation of raw (unpasteurized) milk to dairy processing plants for pasteurization or to raw milk products in intrastate commerce. The final regulation also does not apply to milk and milk products for which an alternative to pasteurization is established in a standard of identity regulation.

EFFECTIVE DATE: September 9, 1987.

FOR FURTHER INFORMATION CONTACT: Robert J. Lenahan, Center for Food Safety and Applied Nutrition (HFF-302), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0162.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 11, 1987 (52 FR 22340), FDA issued a notice of proposed rulemaking in response to a decision by the United States District Court for the District of Columbia ordering "that the Food and Drug Administration and the Secretary of Health and Human Services publish in the **Federal Register**, a

proposed rule banning the interstate sale of all raw milk and raw milk products, both certified and non-certified, pursuant to the provisions of 5 U.S.C. section 553 and complete all rulemaking proceedings in accordance with this Court's opinion within one hundred eighty (180) days." *Public Citizen* v. *Heckler*, 653 F. Supp. 1229, 1242 (D.D.C. 1986). The notice proposed a pasteurization requirement for all milk and milk products in final package form in interstate commerce. The proposed requirement did not apply to the interstate shipment of raw milk to dairy plants for pasteurization or to products for which procedures are provided by regulation (such as in 21 CFR Part 133, which pertains to the curing of certain varieties of cheese).

The agency invited public comment on the proposal. Because of the time constraint imposed upon the agency by the Court in ordering the completion of "all rulemaking proceedings," FDA limited the comment period to 30 days. In this notice, the agency is issuing a final rule based on the proposal.

The provisions of the Public Health Service Act that relate to communicable disease (42 U.S.C. 216, 243, 264, and 271) form the legal basis for the final rule. The Public Health Service Act authorizes the Department of Health and Human Services (HHS) to make and enforce such regulations as "are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States * * * or from one State * * * into any other State" (42 U.S.C. 264(a)). Five regulations banning the distribution of products have been published under this section: § 1240.60 *Shellfish* (21 CFR 1240.60); § 1240.62 *Turtles, intrastate and interstate* (21 CFR 1240.62); § 1240.65 *Psittacine birds* (21 CFR 1240.65); § 1240.70 *Lather brushes* (21 CFR 1240.70); and § 1240.75 *Garbage* (21 CFR 1240.75). Additional support for the final rule is found in sections 402(a) (1), (3), and (4) and 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 342(a) (1), (3), and (4) and 371(a)). Under these sections, FDA is authorized to promulgate regulations for preventing adulterated or contaminated food, such as unpasteurized milk containing harmful microorganisms, from entering interstate commerce.

I. Background

A. Standard of Identity Proceedings

Over the years, FDA regulation of milk and milk products, in conjunction with State and local dairy associations, has been pervasive. A brief history of this proceeding reveals that the final rule is consistent with past agency action and will not have a burdensome impact on milk producers.

In the **Federal Register** of September 9, 1972 (37 FR 18392), FDA, under section 401 of the act (21 U.S.C. 341), proposed to revise existing standards of identity and to establish new standards of identity for certain milk and cream products. This notice included an FDA proposal to require that each of the listed milk and cream products be pasteurized.

In the **Federal Register** of October 10, 1973 (38 FR 27924), FDA published a final rule which included the requirement that fluid milk products moving in interstate commerce be pasteurized. In deciding upon the pasteurization requirement, FDA reasoned that pasteurization was the only way to assure the destruction of pathogenic microorganisms that might be present.

Following publication of the final rule, FDA received one request for a hearing and an accompanying set of objections on the pasteurization requirement for certified raw milk. The procedures used in producing certified raw milk are significantly different from those used in producing raw milk in general in that they must comport with the methods and standards established by the American Association of Medical Milk Commissions, a private organization that provides to its members guidelines for the production of certified raw milk. Only dairies that employ the Association's techniques have the right to use the term "certified" on their products. The objections, which pertained only to certified raw milk, were based on two premises: (1) Certified raw milk is a safe product, and (2) section 401 of the act (21 U.S.C. 341) does not provide authority to establish a standard of identity solely for health reasons.

In the **Federal Register** of December 5, 1974 (39 FR 42351), FDA announced that the objections raised a substantial issue of fact with regard to whether pasteurization is needed for certified raw milk and that a hearing would be conducted. Accordingly, FDA stayed this requirement for certified raw milk. Elsewhere in this issue of the **Federal Register**, the agency is announcing that the stay of December 5, 1974 (39 FR 42351), concerning certified raw milk, is terminated.

The requirement for pasteurization for all other milk and milk products covered by the new standards of identity was made final in the December 5, 1974, final rule. Therefore, since December 1974 any such milk product that is in final package form for human consumption moving in interstate commerce, but that is not pasteurized, is misbranded. See section 403(g) of the act (21 U.S.C. 343(g)). Most milk and milk prouducts in final package form for human consumption in intrastate commerce are also required by various State laws to be pasteurized.

B. Citizen Petition

On April 10, 1984, the Health Research Group (HRG) of Public Citizen, a privately-funded advocacy organization, petitioned the Secretary of HHS to "promulgate a regulation banning all sales, interstate and intrastate,of raw (unpasteurized) milk and raw milk products in the United States."

C. Public Hearing (October 11 and 12, 1984)

In the **Federal Register** of August 3, 1984 (49 FR 31065), FDA announced a public hearing to receive information on whether milk and milk products sold for human consumption should be pasteurized. The notice, published in part in response to the citizen petition, encouraged interested persons to present information, data, and views on the following issues:

1. Whether the consumption of raw milk, including certified raw milk and raw milk products, is of public health concern; and

2. If the answer to issue 1 is yes, whether requiring pasteurization of raw milk, including certified raw milk and raw milk products, is the most reasonable regulatory option.

The notice of hearing stressed that the purpose of the hearing was to develop an administrative record upon which sound agency action could be based. The hearing resulted in a 330-page transcript and well over 300 comments totaling approximately 4,000 pages.

Over 30 witnesses either submitted written testimony or testified at the public hearing. Most of the witnesses testifying against any Federal regulation of raw milk and raw milk products acknowledged that associations between the consumption of raw milk and the onset of disease have been reported, but pointed out that many other foods, against which no similar Federal action is contemplated, also present sources of exposure to harmful microorganisms. Other witnesses asserted that the "relative risk" of contracting communicable disease from raw milk, in particular certified raw milk, is low when compared to other potential sources of infection.

Several witnesses testified that, in the absence of a definitive case-control study, there is no way to determine whether the apparent association between drinking raw milk and being infected by harmful microorganisms is causal, and encouraged HHS to sponsor such a study rather than ban raw milk.

Many witnesses testified in favor of some form of ban on raw milk. These witnesses argued that the risks associated with the consumption of raw milk, including certified raw milk, outweigh any benefits from its consumption.

D. Court Related Developments

On September 19, 1984, after FDA had announced the public hearing, but before the hearing was held, HRG filed suit in Federal district court to compel HHS to promulgate a regulation banning all sales, interstate and intrastate, of raw milk and raw milk products in the United States.

On January 14, 1985, in *Public Citizen* v. *Heckler*, 602 F. Supp. 611 (D.D.C. 1985), the Court held that there had been unreasonable delay in deciding whether there should be additional Federal regulation of raw milk as requested in the April 10, 1984, HRG petition and ordered HHS to respond to the petition.

By letter dated March 15, 1985, the Commissioner of Food and Drugs denied the petition, stating that the agency would not ban either interstate or intrastate sales of raw milk (Ref. 18). The letter acknowledged that "raw milk, including certified raw milk, is a vehicle for the transmission and spread of communicable diseases," but concluded that a Federal ban on the interstate shipment of raw milk would not be the most appropriate means of dealing with the health problems posed by unpasteurized milk and milk products, and would have minimal public health benefit, given the current patterns of distribution and sale of these products. The letter further explained that FDA's authority to prohibit the intrastate sale of raw milk was at least questionable and that, in any case, State and local authorities were fully able to take action to ban the product should they consider it appropriate to do so.

Following FDA's denial of its citizens' petition, HRG again filed suit in the Federal district court, this time seeking judicial review of the agency action. HRG asked the Federal district court to compel HHS to initiate a new rulemaking proceeding banning both interstate and intrastate sales of raw milk.

In *Public Citizen* v. *Heckler*, 653 F. Supp. 1229 (D.D.C. 1986), the Court ruled that the agency's denial of the HRG petition was arbitrary and capricious in light of the record compiled in the proceeding before the agency. The Court concluded that the record presents "overwhelming evidence of the risks associated with the consumption of raw milk, both certified and otherwise * * *" and is "replete with credible evidence of the danger of raw milk consumption, and the support of various organizations, both within and without the Government, for a federally imposed interstate ban," (653 F. Supp. at 1238). The Court went on to state that the evidence FDA has accumulated concerning raw milk "conclusively" shows that raw and certified raw milk are unsafe (653 F. Supp. at 1232, 1241). According to the Court, "There is no longer any question of fact as to whether the consumption of raw milk is unsafe." (653 F.2d at 1241). The Court ruled that FDA should propose a rule "banning the interstate sale of all raw milk and raw milk products, both certified and noncertified * * *." (653 F. Supp. at 1242). The Court also found that there was no indication that a rule banning the intrastate shipment of raw milk would be necessary to carry out an interstate ban.

II. Comments on the Proposed Regulation

A. Overview

Numerous comments were received on the agency's proposed regulation. Three comments opposed the requirement that raw milk be pasteurized. All the remaining comments favored the proposed rule on the basis that the risks associated with consuming raw milk, including certified raw milk, outweigh any benefits from its consumption. Comments favoring the proposed rule include the American Academy of Pediatrics, the National Milk Producers, the National Association of State Departments of Agriculture, the Centers for Disease Control, and numerous State departments of health.

In its comments opposing a final rule, Stueve's Natural (Stueve) (formerly Alta-Dena Dairy) urged FDA not to ban certified raw milk because it is safe and has never been shown to cause illness. Stueve also suggested that individuals have the right to freely choose whether the benefits of raw milk outweigh its potential risks. Moreover, Stueve contended that raw milk, in particular certified raw milk, is being singled out for unwarrranted, selective attention by FDA and other public health authorities because other ready-to-consume foods are, naturally or by viture of cross-contamination, major sources of disease and are not subject to strict Government regulation. Similarly, Stueve argued that contaminated or improperly pasteurized milk represents a far more serious health hazard than does raw milk. Stueve also questioned whether pasteurization would kill *Salmonella dublin* (*S. dublin*) microorganisms and whether a requirement for pasteurization of milk would have any significant impact on the public health. Stueve submitted data and information in support of its contentions.

Congressman William E. Dannemeyer also filed comments opposing a final rule. In addition to identifying the same issues Stueve raised, the Congressman stressed the nutritional and immunologic benefits of raw milk.

Based on its review and evaluation of all data and information submitted, FDA has concluded that these contentions are unconvincing when considered in light of the known, documented health risks associate with the consumption of raw milk, as discussed below.

B. The Association Between Raw Milk and the Outbreak of Disease

The administrative record compiled as a result of the hearing and rulemaking process demonstrates that there is an association between the consumption of raw milk and the outbreak of disease (Refs. 1 through 12 and 14 through 16). The record also demonstrates an association between the consumption of certified raw milk and the outbreak of disease, particularly among consumers who are young, elderly, or infirm (Refs. 1 through 12 and 16).

In its comments, however, Stueve argued that raw milk and certified raw milk have never been shown to "cause" disease. The argument is based on the fact that the data and information that associate the consumption of raw milk with the outbreak of disease are not the result of blinded, prospective case-control studies but rather the result of epidemiological, retrospective evaluations of case studies. Epidemiological investigations are not designed to establish causation per se but rather to test the strength of an "association" between an event and a possible cause.

The record of this proceeding reveals that on the basis of epidemiological evidence "the role of unpasteurized dairy products, including raw and certified raw milk, in the transmission of disease has been established repeatedly" (Ref. 4; see also Refs. 1 through 3, 5 through 12, and 14 through 16). For example, the California Department of Health Services (CDHS) has reported that 50 percent of all the *S.*

dublin infection cases reported in California in 1984 invovled the use of certified raw milk. According to CDHS, no other risk factor has been prevalent among cases. For example, even though *S. dublin* is host adapted to cattle, only a small percent (15 percent or less) of cases report use of either lightly cooked or uncooked beef or beef products. CDHS concluded that the relative risk of contracting *S. dublin* is 158 times greater for those Californians who consume certified raw milk than for those who do not drink any form of raw milk (Refs. 3 and 12). CDHS considered this relative risk "extremely large and among the largest obtained in any epidemiologic investigation." (CDHS' observations are consistent with those discussed in the preamble to the proposed rule (52 FR 22342 and 22343). Under these circumstances, to conduct the type of studies Stueve would seem to be calling for would appear not only unnecessary but also ethically questionable.

C. Selective Enforcement

In an October 1984 survey, CDC addressed the type of selective enforcement issues raised by Stueve (Ref. 4). CDC pointed out that other ready-to-consume foods of domestic animal origin are subjected to processing procedures designed to render them safe for consumption and are microbiologically monitored for adequacy of processing. Raw foods of animal origin, such as chicken, may also be contaminated with microorganisms such as *Salmonella* and *Campylobacter*, but are normally cooked before consumption. CDC noted that extensive efforts are routinely made by public health agencies to inform the public of the hazards and the proper cooking procedures for these products. For other foods, like oysters, that are often consumed raw, CDC noted that practical measures to eliminate the contamination are not available. A practical measure—pasteurization—is available for milk and milk products. Under these circumstances, the agency finds no merit in any argument that raw milk in interstate commerce is wrongly being singled out for regulation.

D. Certification

Raw milk, no matter how carefully produced, may be unsafe. Accordingly, raw milk products may be unsafe. Examinations of cattle and of milk handlers can be done only at intervals. Consequently, pathogenic organisms may enter the milk during these intervals and be transmitted to humans before the presence of the organisms or the existence of a disease condition in cattle or handlers is discovered.

Moreover, it has not been shown to be feasible to perform routine bacteriological tests on the raw milk itself to determine the presence or absence of all pathogens and thereby ensure that it is free from infectious organisms.

In the past, supporters of certified raw milk pointed to standards such as total bacterial counts as proof of safety, but the high incidence of disease associated with certified raw milk is strong evidence that these standards are unreliable indexes of safety. In addition, the American Association of Medical Milk Commissions, the entity that "certifies" raw milk, recently deleted any mention of *Salmonella*, a known pathogen, from its standards (Ref. 17).

Thus, in FDA's view, "certification" does not provide a reliable index of whether milk or milk products are contaminated with pathogenic bacteria. For example, certified raw milk cannot be certified free of *Salmonella* organisms (Ref. 13). Milk is an excellent vehicle of infection because its fat content protects pathogens from gastric acid, and, being fluid, it has a relatively short gastric transit time. Opportunities for the introduction and persistence of *Salmonella* organisms on dairy premises are numerous and varied, and technology does not exist to eliminate *Salmonella* infection from dairy herds or to preclude the re-introduction of *Salmonella* organisms. Moreover, recent studies show that cattle can carry and shed *S. dublin* organisms for many years and demonstrated that *S. dublin* organisms cannot be routinely detected in cows that are "mammary gland" shedders (Ref. 13).

In light of the foregoing, FDA concludes that the certification process alone provides no assurance that raw milk is free of *Salmonella* and other harmful organisms.

E. Effectiveness of Requiring Pasteurization as a Means of Controlling Disease

Stueve contended that the effects of past bans on raw milk in Scotland and (on a temporary basis) in California support the proposition that the overall rate of *S. dublin* related outbreaks from all possible sources of exposure will not decline if a ban on certified raw milk and raw milk products is imposed.

Stueve did not submit data or information adequate to support these conclusions, and information available to the agency on the effects of the ban on raw milk in Scotland contradicts Stueve's contention of no effect. During 1960 through 1982, 3 years before the pasteurization requirement in Scotland went into effect, there were 14 outbreaks of milk-borne *Salmonella* infections involving over 1,090 people. In the year that followed the ban of raw milk, only two small outbreaks involving a total of nine persons who consumed raw milk at a local dairy farm were reported (Ref. 11).

It is true that the population exposed to certified raw milk in interstate commerce is relatively small compared to the population exposed to other sources of *S. dublin* (Ref. 12), and that one would, therefore, not expect a significant change in the rate of *Salmonella* infection in the overall population if interstate sales were banned as a result of this rule. Such expectations regarding the effect of a ban on the overall rate of *Salmonella* infections are not dispositive, however, in light of the fact that the relative risk of infection for those who do consume raw milk, including certified raw milk, appears to be quite large. The proposed ban on all raw milk would eliminate the risk arising from milk and milk products in interstate commerce.

Stueve also contended that heating milk at 80 °C for 30 minutes (one form of pasteurization) would not completely kill *S. dublin* microorganisms. Stueve submitted no data in support of this proposition, but did refer to an unpublished 1961 (later published in 1962) paper for its authority. The paper appears to be based on laboratory procedures now recognized as totally inadequate for thermal resistance testing since they allow a portion of the bacterial population to receive incomplete heating and to appear to be thermoresistant survivors. All information available to the agency documents that pasteurization, when performed as prescribed in the final rule, effectively eliminates *S. dublin* as well as numerous other harmful microorganisms.

F. Health Benefits of Consuming Raw Milk

The theoretical health benefits of raw milk have never withstood scientific scrutiny. Conversely, the fact that raw milk presents a substantially greater inherent risk of infectious disease has been documented repeatedly. Numerous articles have reported that pasteurization has either no effect or practically no effect on the major nutrients in milk. These reports also document that pasteurization has little or no effect on milk's protein, minerals, riboflavin, fat, carbohydrate, niacin, pantothenic acid, vitamin B_6, vitamin A, vitamin D, vitamin E, and vitamin K (Ref. 19). Also, a recent investigation found that pasteurization of human milk

profoundly reduces the number of bacteria but does not significantly affect the milk's immunological factors (Ref. 20). Based upon this and related information contained in the administrative record, FDA concludes that pasteurization does not significantly change the nutritive or immunologic value of milk and that the risks associated with the consumption of raw milk, including certified raw milk, outweigh any alleged health benefits that may arise from consuming raw milk and certified raw milk.

III. Alternatives to a Ban

In proposing to require raw milk and raw milk products in final package form for direct human consumption, including certified raw milk, to be pasteurized before being shipped in interstate commerce, the agency requested comments on possible alternatives to such a requirement. The overwhelming majority of the comments that addressed alternatives opposed any approach other than ban.

One alternative the agency suggested for comment was the use of labeling to ensure that consumers who voluntarily choose to consume raw milk are informed as to the risks inherent in that choice. Although Stueve indicated support for the concept of consumer choice in its comments, no appropriate labeling was suggested in comments on the proposed rule; in fact, all comments (including Stueve) opposed labeling. The effectiveness of labeling to address a public health problem like that presented by the consumption of raw milk and raw milk products was questioned on several grounds. For example, the risk of infection from consuming raw milk and raw milk products does not arise from the misuse or abuse of the product but rather from its customary food use. Consumers are not generally expected to take any additional steps to reduce the potential risk and are poorly equipped to assess the likelihood of infection. The infirm, the elderly, and the young are particularly susceptible to serious risks of infection presented by consuming raw milk and raw milk products and, in many cases, may not have the ability or the opportunity to understand the risks identifed in labeling. For these reasons, the agency concludes that labeling is not an acceptable alternative approach.

The agency also requested comments on whether available laboratory methods and analytical methodologies would permit rapid detection of harmful bacteria and could be used either alone or in conjunction with labeling as an alternative to banning raw milk and raw milk products in interstate commerce.

In reponse, Stueve and Flavorcraft, Inc., who objected to the pasteurization requirement, identified several possible methodologies, each of which is too time consuming (no shorter than 24 hours in duration) to be of practical value in the dairy industry. In addition to the problems noted above (Section II. C), the short shelf life of milk and the existence of multiple organisms that may pose human health concerns remain major obstacles to relying on a system designed to detect microorganisms. Regarding this subject, the agency agrees with the comment of the American Academy of Pediatrics: "The fact is that there is no laboratory test available that will simultaneously and instantaneously screen for brucellosis, tuberculosis, salmonellosis, listeriosis * * *." Existing screening technologies are an inadequate alternative to pasteurization as a means of ensuring the safety of milk and milk products (Ref. 17).

IV. Conclusion

As noted in Section I. A, most milk and milk products in interstate commerce are pasteurized. Some unpasteurized milk and milk products, particularly certified raw milk and raw milk products, are currently shipped in interstate commerce. As noted in the preamble to the proposal, however, the amount of such products in interstate commerce is small. Currently, Stueve is the only producer of certified raw milk in the United States. Stueve distributes its raw milk products primarily within the State of California. Accordingly, the health problems associated with raw milk and raw milk products appear, as Stueve contends, to be associated mostly with products shipped intrastate. For this reason, FDA has been of the view that State and local authorities may be better situated to deal with the public health problems attributable to unpasteurized milk and that an interstate ban would have a limited effect on these problems (Ref. 18).

Comments disagreed with this view, contending, in effect, that any form of raw milk in interstate commerce poses a health risk and, therefore, Federal regulation in this area is appropriate. The Court held a similar view: "Federal regulation is warranted regardless of the absolute volume of certified raw milk sold interstate." (653 F. Supp. at 1240.)

The difference in viewpoint between the agency and the Court and comments received has concerned the appropriate way to use Federal resources and the level of government that is best suited to dealing with problems created by raw milk, not the fact that unpasteurized milk and milk products present health risks. FDA recognizes that the pasteurization requirement for raw milk and raw milk products shipped in interstate commerce is legally and scientifically defensible. In light of the opinions expressed in the comments; the documented risks presented by raw milk, including raw milk and raw milk products; the fact that such products are, indeed, shipped in interstate commerce; and the likelihood that a pasteurization requirement for such products in interstate commerce will result in some benefit to the public health, FDA has concluded that the use of Federal authority and resources to eliminate health problems caused by the interstate shipment of raw milk is justifiable. Accordingly, the agency believes that a final rule requiring the pasteurization of all raw milk and raw milk products in interstate commerce should issue in this proceeding. The final rule does not apply to the interstate transportation of raw (unpasteurized) milk to dairy processing plants for pasteurization or to raw milk and raw milk products in intrastate commerce. The final rule also does not apply to milk and milk products for which an alternative to pasteurization is established in a standard of identity regulation published pursuant to 21 U.S.C. 341.

V. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule of June 11, 1987 (52 FR 22340). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. Economic Impact

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as defined by the Order. The agency has not received any new

information or comments that would alter its previous determination.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Morrison, F. R., Research Program Specialist, Department of Health Services, Health and Welfare Agency, State of California, letter to Paul M. Fleiss, July 7, 1983, Re: "Attack rates for *S. dublin* Infection and Raw Milk Use."

2. Richwald, G. A., et al., UCLA School of Public Health, "An Assessment of Risks Associated with Raw Milk Consumption in California," March 31, 1986.

3. Lyman, D. O., Chief, Health Protection Division, Department of Health Services, Health and Welfare Agency, State of California, letter and report to FDA, August 30, 1984, Re: "Disease in California Associated with Certified Raw Milk."

4. Potter, M. E., et al., "Unpasteurized Milk, The Hazards of a Health Fetish," *Journal of the American Medical Association*, 252 (15): 2048–2052, October 19, 1984.

5. Chin, J., "Raw Milk: A Continuing Vehicle for the Transmission of Infectious Disease Agents in the United States," *Journal of Infectious Diseases*, 146 (3): 440–441, September 1982.

6. Morbidity and Mortality Weekly Report, "*Salmonella dublin* and Raw Milk Consumption—California," April 13, 1984, Centers for Disease Control, HHS/PHS.

7. Werner, S. B., et al., "Association Between Raw Milk and Human *Salmonella dublin* Infection," *British Medical Journal*, July 26, 1979.

8. Fierer, J., "Invasive *Salmonella dublin* Infections Associated with Drinking Raw Milk," *Western Journal of Medicine*, 138 (5): 665–669, May 1983.

9. Potter, M. E., Veterinary Epidemiologist, Center for Infectious Diseases, Centers for Disease Control, HHS/PHS, Presentation on the Adverse Health Effects on Consuming Raw or Unpasteurized Milk, September 1984.

10. Foege, W. H., Assistant Surgeon General, Director, Centers for Disease Control, HHS/PHS, letter to J. C. Bolton, May 27, 1983, Re: "The Safety of Raw Milk and Its Association With Human Diseases."

11. Sharp, J. C. M., Consultant Epidemiologist, Communicable Diseases (Scotland) Unit, Ruchill Hospital, Glasgow, letter to M. E. Potter, Centers for Disease Control, HHS/PHS, May 29, 1984, Re: "Experience in Scotland of Milk-Borne Infection Subsequent to the Introduction of Compulsory Pasteurization on August 1, 1983."

12. Werner, S. B., Medical Epidemiologist, Infectious Disease Section, Department of Health Services, Health and Welfare Agency, State of California, letter to J. Bolton, July 12, 1983, Re: "Statistics on How the Risk of Contracting *S. dublin* Infections in Association With Raw Milk Exposure Compares With that in Persons Not Using Raw Milk."

13. Currier, R. W., "Raw Milk and Human Gastrointestinal Disease: Problems Resulting from Legalized Sale of 'Certified Raw Milk,'" *Journal of Public Health Policy*, pp. 226–234, September 1981.

14. Korlath, J., et al., "A Point-Source Outbreak of Campylobacteriosis Associated with Consumption of Raw Milk," *Journal of Infectious Diseases*, 152 (3): 592–596, 1985.

15. Osterholm, M., et al., "An Outlook of a New Recognized Chronic Diarrhea Syndrome Associated with Raw Milk," *JAMA*, 256 (4): 484–490, 1986.

16. Werner, S. Benson, Department of Health Services, Health and Welfare Agency, State of California, letter dated July 10, 1987, to Dockets Management Branch, FDA, Re: "Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce—Docket No. 81N–204C."

17. Strain, James E., Executive Director, American Academy of Pediatrics, letter to Dockets Management Branch, FDA, July 13, 1987, Re: "Requirements Affecting Raw Milk for Human Consumption in Interstate Commerce—Docket No. 81N–204C."

18. Letter dated March 15, 1985, from the Commissioner of Food and Drugs to Sidney M. Wolfe.

19. National Dairy Council, statement relative to the comparison of the nutrient content of raw versus pasteurized milk products.

20. Goldbaum, R. M., et al, "Rapid High-Temperature Treatment of Human Milk," *Journal of Pediatrics*, 104 (3): 380–385, March 1984.

List of Subjects in 21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act, it is proposed that Part 1240 be amended as follows:

PART 1240—CONTROL OF COMMUNICABLE DISEASES

1. The authority citation for 21 CFR Part 1240 is revised to read as follows:

Authority: Secs. 215, 311, 361, 368, 58 Stat. 690, 693, 703 as amended, 706 (42 U.S.C. 216, 243, 264, 271); 21 CFR 5.10, 5.11.

2. By adding new § 1240.61 to Subpart D to read as follows:

§ 1240.61 Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.

(a) No person shall cause to be delivered into interstate commerce or shall sell, otherwise distribute, or hold for sale or other distribution after shipment in interstate commerce any milk or milk product in final package form for direct human consumption that has not been pasteurized except where alternative procedures are provided by regulation, such as Part 133 of this chapter for curing of certain cheese varieties.

(b) Except as provided in paragraphs (c) and (d) of this section, the terms "pasteurization," "pasteurized," and similar terms shall mean the process of heating every particle of milk and milk product in properly designed and operated equipment to one of the temperatures given in the following table and held continuously at or above that temperature for at least the corresponding specified time:

Temperature	Time
145 °F (63 °C) [1]	30 minutes.
161 °F (72 °C) [1]	15 seconds.
191 °F (89 °C)	1 second.

[1] If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 5 °F (3 °C).

Temperature	Time
194 °F (90 °C)	0.5 second.
201 °F (94 °C)	0.1 second.
204 °F (96 °C)	0.05 second.
212 °F (100 °C)	0.01 second.

(c) Eggnog shall be heated to at least the following temperature and time specification:

Temperature	Time
155 °F (69 °C)	30 minutes.
175 °F (80 °C)	25 seconds.
180 °F (83 °C)	15 seconds.

(d) Neither paragraph (b) nor (c) of this section shall be construed as barring any other pasteurization process that has been recognized by the Food and Drug Administration to be equally efficient in the destruction of microbial organisms of public health significance.

Frank E. Young,

Commissioner of Food and Drugs.

Otis R. Bowen,

Secretary of Health and Human Services.

Dated: August 6, 1987.

[FR Doc. 87–18190 Filed 8–6–87; 3:13 pm]

BILLING CODE 4160-01-M

DEPARTMENT OF STATE

Bureau of Consular Affairs

22 CFR Parts 22 and 51

[108.863]

Schedule of Fees for Consular Services and Refund of Fees

AGENCY: Department of State, Bureau of Consular Affairs.

ACTION: Final rule.

SUMMARY: The Department of State is amending its regulations to provide that refunds of fees or other payments for

amounts totaling $5.00 or less will not be made unless specifically requested by the person who has overpaid. The amendment will eliminate the cost to the Department and to the Treasury of processing and mailing checks that is not commensurate with the amounts involved. The amendment to the regulation will save the Government a considerable amount of money and time.

EFFECTIVE DATE: August 10, 1987.

FOR FURTHER INFORMATION CONTACT: William B. Wharton, Director, Office of Citizenship Appeals and Legal Assistance, Telephone (202) 326–6172.

SUPPLEMENTARY INFORMATION: Present regulations provide for the refund of any excess fees submitted to the Department or posts abroad with a passport application or a request for other consular services. When individuals remit payments in excess of the amount due, the Department deposits the payments directly into the U.S. Treasury and then requests the Treasury to refund any excess.

It has been established that refunds of $5.00 or less are not cost effective. Approximately 65 percent of refunds are for overpayments of two dollars or less. The cost of processing these refunds far exceeds the amounts to be refunded. The Comptroller General in Decision B–220942 has approved that refunds of overpayments of $5.00 or less should not be made unless specifically claimed.

Under the provisions of the Regulatory Flexibility Act (5 U.S.C. 301 *et. seq.*), it is certified that this rule will not have a significant economic impact on a substantial number of small entities.

The provisions of the Paperwork Reduction Act do not apply. (44 U.S.C. Ch. 35). On February 25, 1987, at 52 FR 5549 the Department of State published a Proposed Rule to amend the regulations at 22 CFR 22.6 and 51.64. Interested parties were invited to submit written comments by April 27, 1987. No comments were received.

List of Subjects

22 CFR Part 22

Foreign Service, Passports and visas.

22 CFR Part 51

Passports and visas.

PART 22—[AMENDED]

1. The authority citation for Part 22 is revised to read as follows:

Authority: Secs. 3, 4, 63 Stat. 111, as amended; 22 U.S.C. 211a; 214, 2651, 2658, 3921, 4219; 31 U.S.C. 9701; E.O. 10718, 22 FR 4632; E.O. 11295, 31 FR 10603; 3 CFR, 1954–1958 Comp. p. 507 unless otherwise noted.

2. Section 22.6 is revised to read as follows:

§ 22.6 Refund of fees.

(a) Fees which have been collected for deposit in the Treasury are refundable:

(1) As specifically authorized by law (See 22 U.S.C. 214a concerning passport fees erroneously charged persons excused from payment, 22 U.S.C. 216 concerning passport fees in cases where the appropriate representative in the United States of a foreign government refuses a visa and 46 U.S.C. 8 concerning fees improperly imposed on vessels or seamen);

(2) When the principal officer at the consular post where the fee was collected (or the officer in charge of the consular section at a combined diplomatic/consular post) finds upon review of the facts that the collection was erroneous under applicable law; and

(3) Where determination is made by the Department of State with a view to payment of a refunded in the United States in cases which it is impracticable to have the facts reviewed and refunded effected by and at the direction of the responsible consular office.

See § 13.1 of this chapter concerning refunds of fees improperly exacted by consular officers who have neglected to return the same.

(b) Refunds of $5.00 or less will not be paid to the remitter unless a claim is specifically filed at the time of payment for the excess amount. An automatic refund on overpayments due to misinformation or mistakes on the part of the Department of State will be made.

PART 51—[AMENDED]

3. The authority citation for Part 51 is revised to read as follows:

Authority: 44 Stat. 887; 63 Stat. 111, as amended; 22 U.S.C 211a–218, 2651, 2658; E.O. 11295, 31 FR 10603; 3 CFR, 1966–1970 Comp. p. 507, unless otherwise noted.

4. In § 51.64 a new paragraph (e) is being added:

§ 51.64 Refunds.

* * * * *

(e) For procedures on refunds of $5.00 or less see § 22.6(b) of this title.

Date: July 17, 1987.

For the Secretary of State.

Joan M. Clark,

Assistant Secretary, Bureau of Consular Affairs.

[FR Doc. 87–18083 Filed 8–7–87; 8:45 am]

BILLING CODE 4710–06–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

Approval of an Amendment to the Ohio Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

ACTION: Final rule.

SUMMARY: OSMRE is announcing the approval of a proposed amendment submitted by the State of Ohio as a modification to its permanent regulatory program (hereinafter referred to as the Ohio program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA).

The amendment consists of changes to Ohio's Reclamation Board of Review procedural rules. OSMRE published a notice in the **Federal Register** on April 10, 1987 (52 FR 11692), announcing receipt of the amendment and inviting public comment on the adequacy of the proposed amendment. The public comment period ended May 11, 1987. A public hearing was not held because no one requested to testify.

After providing opportunity for public comment and conducting a thorough review of the program amendment, the Director has determined that the amendment meets the requirements of SMCRA and the Federal regulations. Thus the Director is approving this amendment.

EFFECTIVE DATE: August 10, 1987.

FOR FURTHER INFORMATION CONTACT: Ms. Nina Rose Hatfield, Director, Columbus Field Office, Office of Surface Mining Reclamation and Enforcement, Room 202, 2242 South Hamilton Road, Columbus, Ohio 43232; Telephone: (614) 866–0578.

SUPPLEMENTARY INFORMATION:

I. Background on the Ohio Program

On August 16, 1982, the Ohio program was made effective by the conditional approval of the Secretary of the Interior. Information pertinent to the general background, revisions, modifications, and amendments to the Ohio program submission, as well as the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Ohio program can be found in the August 10, 1982 **Federal Register** (47 FR 34688). Subsequent actions concerning the conditions of approval and program

amendments are identified at 30 CFR 935.11 and 935.15.

II. Submission of Proposed Amendment

By letter dated January 28, 1987, the Ohio Department of Natural Resources, Division of Reclamation submitted proposed amendments to the Reclamation Board of Review (RBR) rules at Ohio Administrative Code (OAC) sections 1513–3–02, 1513–3–03, 1513–3–04, 1513–3–08, 1513–3–19, and 1513–3–21. The proposed amendments were submitted to satisfy an OSMRE requirement that the standards used by the RBR to award costs and attorney's fees be as effective as Federal counterparts. The amendments were also submitted to reflect changes in statutory language of Ohio Revised Code (ORC) section 1513.02(F)(3) and to include other changes in RBR procedures.

The April 10, 1987 **Federal Register** announced receipt of the proposed amendment and invited public comment on its adequacy (52 FR 11692).

III. Summary Description of Proposed Amendment

The proposed changes include amending OAC 1513–3–02(D) (5) and (6), 1513–3–04(D)(6) and 1513–3–19(F) (1), (2), (3), and (4) to reflect changes in the statutory language of O.R.C. 1513.02(F)(3). The amendments change "an escrow account" to "a penalty fund." OAC 1513–3–03(F) is amended to include langauge prohibiting ex parte communications between the Board and parties, or representatives of parties, regarding substantive issues of a pending case.

OAC 1513–3–08(G) is amended to include language prohibiting the RBR from granting temporary relief in cases where such relief would result in the issuance of a coal mining and reclamation permit.

The amendments proposed in OAC 1513–3–21(E) (3), (4), and (5) were required by OSMRE so that the Ohio rule would be no less effective than the Federal counterpart regulations. These amendments set forth the standards which the Board will apply in determining whether an award of costs and attorneys' fees is appropriate in a case before the RBR.

IV. Public Comments

The public comment period announced in the April 10, 1987 **Federal Register** ended May 11, 1987. No comments were received. The public hearing scheduled for April 30, 1987 was not held since no person requested an opportunity to testify at the hearing.

V. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment submitted to OSMRE by the State of Ohio on January 28, 1987. All revisions are found to be no less stringent than SMCRA and no less effective than the Federal regulations.

VI. Director's Decision

Based upon the findings, the Director is approving the amendment as submitted on January 28, 1987 and is amending Part 935 of 30 CFR Chapter VII to implement this decision.

VII. Procedural Requirements

1. Compliance with the National Environmental Policy Act

The Secretary has determined that, pursuant to section 702(d) of SMCRA, 30 U.S.C. 1292(d), no environmental impact statement need be prepared on this rulemaking.

2. Executive Order 12291 and the Regulatory Flexibility Act

On August 28, 1981, the Office of Management and Budget (OMB) granted OSMRE an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs. Therefore, this action is exempt from preparation of a Regulatory Impact Analysis and regulatory review by OMB.

The Department of the Interior has determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule will not impose any new requirements; rather, it will ensure that existing requirements established by SMCRA and the Federal rules will be met by the State.

3. Paperwork Reduction Act

This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3507.

List of Subjects in 30 CFR Part 935

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Date: August 3, 1987.

Brent Walquist,

Acting Deputy Director, Operations and Technical Services, Office of Surface Mining Reclamation and Enforcement.

PART 937—OHIO

30 CFR Part 935 is amended as follows:

1. The authority citation for Part 937 continues to read as follows:

Authority: Pub. L. 95–87, Surface Mining Control and Reclamation Act of 1977 (30 U.S.C. 1201 *et seq.*).

2. Paragraph (a) of § 935.12 is removed and reserved, to read as follows:

§ 935.12 State program provisions disapproved.

* * * * *

(a) [Reserved]

3. Paragraph (cc) is added to § 935.15 to read as follows: § 935.15 Approval of regulatory program amendments.

* * * * *

(cc) The following amendments submitted to OSMRE on January 28, 1987, were approved effective August 10, 1987: Ohio Administrative Code sections 1513–3–02, 1513–3–03, 1513–3–04, 1513–3–08, 1513–3–19, and 1513–3–21.

4. Paragraph (a) of § 935.16 is removed and reserved, to read as follows:

§ 935.16 Required program amendments

* * * * *

(a) [Reserved]

[FR Doc. 87–18048 Filed 8–7–87; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 09–87–14]

Special Local Regulations; East River Classic, Niagara River, North Tonawanda, NY

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: Special local regulations are being adopted for the East River Classic to be held on the Niagara River. This event will be held on 13 September 1987. The regulations are needed to provide for the safety of life and property on navigable waters during the event.

EFFECTIVE DATES: These regulations are effective from 10:00 A.M. until 1:30 P.M. on September 13, 1987.

FOR FURTHER INFORMATION CONTACT: CWO Gerald M. Trackim, Office of Search and Rescue, Ninth Coast Guard District, 1240 E 9th St., Cleveland, OH 44199, (216) 522–3982.