substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR Part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *

ACE KS D Olathe, KS [Amend]

Olathe, New Century Aircenter, KS
(Lat. 38°49′54″ N., long. 94°53′24″ W.)

* * * * *

Paragraph 6005 Class E airspace areas extending from 700 feet or more above the surface of the earth.

* * * * *

ACE KS E5 Olathe, KS [Amend]

Olathe, New Century Aircenter, KS
(Lat. 38°49′54″ N., long. 94°53′24″ W.)

* * * * *

Issued in Kansas City, MO, on February 6, 1997.

Herman J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

[FR Doc. 97–4501 Filed 2–21–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 131 and 133

[Docket Nos. 95P–0125, 95P–0250, 95P–0261, and 95P–0293]

Lowfat and Skim Milk Products, Lowfat Cottage Cheese: Revocation of Standards of Identity

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to objection and denial of the request for a hearing; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is responding to objections and is denying the requests that it received for a hearing on the final rule removing the standards of identity for lowfat milk and skim milk as well as those for other lower-fat dairy products. After reviewing the objections to the final rule, the agency has concluded that the objections do not raise issues of material fact that justify granting a hearing. Therefore, FDA is confirming the effective date for the final rule. The final rule was based, in part, on petitions filed jointly by the Milk Industry Foundation and the Center for Science in the Public Interest and on a petition filed by the American Dairy Products Institute. This action is also part of the agency's ongoing review of existing regulations under President Clinton's Regulatory Reinvention Initiative.

DATES: Effective date confirmed: January 1, 1998. This rule is applicable to all products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Compliance may begin on November 20, 1996. Any labels or labeling that require revision as a result of this revocation shall comply no later than January 1, 1998.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. Background—The Final Regulation

In the Federal Register of November 20, 1996 (61 FR 58991), FDA issued a final rule entitled ''Lowfat and Skim Milk Products, Lowfat and Nonfat Yogurt Products, Lowfat Cottage Cheese: Revocation of Standards of Identity; Food Labeling, Nutrient Content Claims For Fat, Fatty Acids and Cholesterol Content of Food'' which removed the standards of identity for the following lower-fat dairy products: Sweetened condensed skimmed milk (21 CFR 131.122), lowfat dry milk (21 CFR 131.123), evaporated skimmed milk (21 CFR 131.132), lowfat milk (21 CFR 131.135), acidified lowfat milk (21 CFR 131.136), cultured lowfat milk (21 CFR 131.138), skim milk (21 CFR 131.143), acidified skim milk (21 CFR 131.144), cultured skim milk (21 CFR 131.146), sour half-and-half (21 CFR 131.185), acidified sour half-and-half (21 CFR 131.187), and lowfat cottage cheese (21 CFR 133.131) (the November 1996 final rule). The final regulation also amended the standard of identity for dry cream in 21 CFR 131.149 by removing the reference to 21 CFR 131.135 (the lowfat milk standard). FDA announced that it was deferring action, for 120 days, on its proposal to remove the standards of identity for lowfat and nonfat yogurt (21 CFR 131.203 and 131.206). Further, the final rule amended the nutrient content claims regulations for fat, fatty acids, and cholesterol content to provide for ''skim'' as a synonym for ''nonfat'' when used in labeling milk products.

Interested persons had until December 20, 1996, to file written objections to the revisions in parts 131 and 133 (21 CFR parts 131 and 133) or to request a hearing on the specific provisions to which there were objections. FDA received one letter, from Mid-America Dairymen, Inc., Associated Milk Producers, Inc., and Swiss Valley Farms (hereinafter referred to as ''Mid-America'' or ''the objector'') containing objections to portions of the November 1996 final rule and requests for a hearing on those objections. Under section 701(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)), FDA has carefully considered the objections and requests for a hearing, and other responses. The specific objections and the agency's conclusions follow.

II. Standards for Granting a Hearing

Section 701(e) of the act provides that, within 30 days after publication of an order relating to standards of identity for dairy products, any person adversely affected by such an order may file objections, specifying with particularity the provisions of the order ''deemed objectionable, stating the grounds therefor,'' and requesting a public hearing based upon such objections. FDA may deny a hearing request if the objections to the regulation do not raise genuine and substantial issues of fact that can be resolved at a hearing (*Community Nutrition Institute* v. *Young,* 773 F.2d 1356, 1364 (D.C. Cir. 1985), *cert. denied,* 475 U.S. 1123 (1986)). Specific criteria for determining whether a request for a hearing is justified are set forth in 21 CFR 12.24(b).

A party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing.'' (See *Costle* v. *Pacific Legal Foundation,* 445 U.S. 198, 214–215 (1980) *reh. den.*, 445 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–621 (1973).) If a hearing request fails to identify any factual evidence

that would be the subject of a hearing, there is no point in holding one.

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held (*Pineapple Growers* v. *FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982)). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing (*Dyestuffs and Chemicals, Inc.*, v. *Flemming*, 271 F.2d 281 (8th Cir. 1959) *cert. denied*, 362 U.S. 911 (1960)). A hearing is justified only if the objections are made in good faith, and if they ''draw into question in a material way the underpinnings of the regulation at issue'' (*Pactra Industries* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977)). Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy. (See *Citizens for Allegan County, Inc.*, v. *FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC*, 256 F.2d 233, 240 (5th Cir.) *cert. denied*, 358 U.S. 872 (1958).)

In sum, a hearing request should present sufficient credible evidence to raise a material issue of fact, and the evidence must be adequate to resolve the issue as requested and to justify the action requested.

III. Objections and Requests for a Hearing

1. The first objection was about the removal of the standards of identity for lowfat milk (21 CFR 131.135) and skim milk (21 CFR 131.143). In the November 1996 final rule, FDA removed the standards of identity for lower-fat dairy products, including the standards for lowfat milk and skim milk, so that these products would be subject to the requirements in 21 CFR 130.10 (the general standard). FDA concluded that the final regulation will provide for consistency in the nomenclature and labeling of most nutritionally modified dairy products and other foods bearing ''lowfat'' and ''nonfat'' claims; promote honesty and fair dealing in the interest of consumers; increase flexibility for manufacturers of lower-fat dairy products; and increase product choices available to consumers.

Mid-America objected to the removal of the standards for lowfat and skim milk stating that those standards were issued because the Commissioner of Food and Drugs (the Commissioner) found that they would promote honesty and fair dealing in the interest of consumers. In support of this objection, Mid-America cited section 401 of the act (21 U.S.C. 341) which provides:

> Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity.

Mid-America also included by reference ''all of the factual findings made by the Commissioner when the lowfat and skim milk standards were promulgated.''

In further support of the objection, Mid-America maintained that new nutrition and other labeling requirements do not obviate the need for standards of identity for lowfat milk and skim milk. Mid-America acknowledged that some of the rationale in the preamble to the November 1996 final rule may be sound for products other than lowfat milk and skim milk, because of the new labeling requirements. However, according to Mid-America, these new requirements cannot be interpreted to mean that removing the standards for lowfat milk and skim milk will be in the interest of consumers because the standards were issued to promote honesty and fair dealing in the interest of consumers.

Mid-America did not specify to which new labeling requirements it was referring. FDA assumes the reference is to the January 6, 1993, final rules implementing the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). These final rules included new requirements for nutrition labeling, uniform definitions for nutrient content claims and health claims, and more complete ingredient declaration, particularly for standardized foods. Further, the objection did not identify the foods to which it was referring in saying that the new nutrition labeling regulations may justify removal of the standards of identity in part 131 or 133, nor did it offer any reason for treating lowfat milk and skim milk differently from other lower-fat dairy products with respect to the new nutrition labeling requirements. Thus, this part of the objection does not present any substantive evidence in support of the objection.

In addition, Mid-America included by reference all the ''factual findings'' made by the Commissioner in establishing the standards for lowfat and skim milk. The objection's premise appears to be that if those findings justified issuance of the standards of identity, they must now preclude removal of the standards. However, an evidentiary hearing was not held when the standards were originally issued, and, therefore, there were no formal findings of fact.

FDA assumes that by referring to ''factual findings,'' without any more specific references, Mid-America may have intended to include by reference all conclusions reached by the agency during the course of the rulemaking that resulted in the standards for lowfat milk and skim milk. This rulemaking spanned 14 years, however, and Mid-America has provided no specific information to help the agency focus its attention on any factual evidence or legal arguments that Mid-America might present at a hearing. Consequently, it is difficult for the agency to determine the specific issues to which the objection refers. Nonetheless, FDA has carefully reviewed the record of the rulemaking that resulted in the standards for lowfat milk and skim milk to see whether there were any findings or conclusions that were in conflict with the agency's determination in the November 1996 final rule to revoke these standards and to replace them with the general standard.

Most of the objections to the original final rule issuing standards for lowfat and skim milk (38 FR 27924, October 10, 1973) (the 1973 final rule), as discussed in a notice in the Federal Register of December 5, 1974 (39 FR 42351), have no bearing here. For example, FDA received objections to the requirement in the 1973 final rule that milk be pasteurized. Other objections concerned the failure of the standards for fluid milks to provide for fortification with minerals and vitamins other than vitamins A and D.

The only issue that the agency found that could be even partially related to Mid-America's objection was one over whether FDA should have provided for the use of stabilizers and emulsifiers, and the basis for limiting the permitted amounts of these substances, in lowfat milk and skim milk. The 1973 final rule establishing standards of identity for lowfat milk and skim milk provided for limited use of stabilizers and emulsifiers in these foods. FDA received a number of objections and requests for a hearing based on its failure to provide for unrestricted use of stabilizers. These objections maintained that stabilizers could improve the palatability of lower-fat milks and would be more economical than nonfat milk-derived solids.

On December 5, 1974, FDA published a notice staying the provision that would have limited the use of stabilizers and emulsifiers in lower-fat milks (39 FR 42351). In an attempt to avoid a hearing, FDA proposed to amend the standards for lowfat milk and skim milk to expand the uses of stabilizers and emulsifiers (41 FR 46873, October 26,

1976) (the 1976 proposal). Subsequently, based on comments to the 1976 proposal, FDA published a final rule in the Federal Register of December 12, 1980 (45 FR 81734), terminating the 1976 rulemaking and continuing the stay on the provisions in the 1973 standard that would have restricted the use of stabilizers and emulsifiers in lowfat and skim milks. In 1983, FDA published a notice announcing a public hearing on stayed provisions of the 1973 final rule. Based on a motion by FDA for summary judgment, and a lack of opposition by the original objectors, an administrative law judge issued an order, dated December 12, 1983, finding that the provisions in the original standards that limited the use of stabilizers and emulsifiers would promote honesty and fair dealing in the interest of consumers (51 FR 40313, November 6, 1986).

After carefully reviewing the record on this issue, FDA concludes that nothing in the record of the 1973 final rule raises an issue of fact about the agency's decision with respect to the use of stabilizers and emulsifiers that is embodied in the November 1996 final rule. The controversy in 1973 concerned a comparison between lower-fat milks containing stabilizers and emulsifiers and lower-fat milks to which milk solids not fat (msnf) are added so that the finished product contains 10 percent msnf. In that context, FDA concluded (45 FR 81734 at 81736) that lower-fat milks thickened with stabilizers and emulsifiers would be nutritionally inferior to the same products containing not less than 10 percent msnf, and that, therefore, use of stabilizers and emulsifiers to thicken lower-fat milk products would not promote honesty and fair dealing in the interest of consumers. No conclusions were reached in that rulemaking on the broader issue of adding ingredients, including stabilizers and emulsifiers, to a nutritionally modified food (that is, foods to which vitamins have been added to avoid nutritional inferiority) to restore functional properties that are reduced or lost when fat is removed compared to the same food without added ingredients, which is the issue that FDA decided in replacing the standards in 21 CFR 131.135 and 131.143 with the general standard in the November 1996 final rule.

Furthermore, and more importantly, the finding of an administrative law judge in 1983 that a standard of identity will promote honesty and fair dealing in the interest of consumers does not mean that that standard cannot be changed. FDA's administrative regulations in 21 CFR 10.30 provide that interested persons may petition the agency to amend standards to reflect changes in consumer needs and perceptions, along with advances in technology, whenever such changes will promote honesty and fair dealing in the interest of consumers. Further, FDA can propose on its own initiative to amend a standard when the agency considers the amendment to be appropriate. To raise an issue of fact that would justify a hearing, an objector must do more than point out that a standard has changed, yet that is all the objector has done here.

In addition, Mid-America appears to misunderstand the impact of the November 1996 final rule in at least one important regard. Removing the standards of identity for lowfat milk and skim milk in 21 CFR 131.135 and 131.143 does not mean that these foods are not covered by a standard of identity. Rather, these foods will continue to be regulated as standardized foods under the requirements in the general standard (21 CFR 130.10).

Mid-America failed to identify any specific evidence in support of its objection. FDA has carefully reviewed the record associated with issuing the original standards of identity for lowfat and skim milk. The agency has been unable to find anything in that record that conflicts with the agency's determination that creating new standards for lower-fat milk products under the general standard will promote honesty and fair dealing in the interest of consumers, in a way that raises a material issue of fact.

FDA concludes that the objection did not raise a genuine and substantial issue of fact that might be readily resolved by the evidence identified in the objection. Therefore, Mid-America's first objection fails, under 21 CFR 12.24(b)(1), to justify a hearing, and thus its request for a hearing on this objection is denied.

2. Mid-America objected to the removal of the standards for lowfat milk and skim milk on the basis that relying on other sections of the regulations to protect consumers is factually unsound. In support of its second objection, Mid-America maintained that a number of factual issues remain unresolved. This assertion was followed by a series of questions, including, for example: ''(1) What ingredients may be added to lowfat milk and skim milk [under 21 CFR 130.10]?'' and ''(2) In what amount may those ingredients be added?'' These questions were not accompanied by any additional information that could have clarified the position of Mid-America or that indicated why resolution of the question in any particular way might be in conflict with the agency's action in the November 1996 final rule.

First, FDA notes that most of the questions asked by Mid-America have already been addressed by the agency, either in the preamble of the November 1996 final rule or in the preambles to the proposal (56 FR 60512, November 27, 1991) and final rule (58 FR 2431, January 6, 1993) establishing the general standard, and Mid-America has not provided any basis for finding that a factual issue persists with respect to these questions. For example, both the November 20, 1996, and the January 6, 1993, final rules contain extensive discussions about the extent to which a nutritionally modified food named using a nutrient content claim and a standardized term may deviate from the food for which it substitutes and the types of labeling necessary to inform consumers about such deviations (61 FR 58991 at 58994 and 58 FR 2431 at 2433). In addition, requirements limiting such deviations are codified in 21 CFR 130.10. The objector's questions raised no new issues that have not previously been considered by the agency. Secondly, to the extent that any of the questions posed by Mid-America are not fully answered, Mid-America did not provide any basis to find that there is a factual issue with respect to any of those questions. Thus, the questions represent nothing more than mere allegations. Under 21 CFR 12.24(b)(2), a hearing will not be granted on the basis of mere allegations. Thus, the questions posed in support of the objection do not justify the granting of a hearing.

Furthermore, as noted in the agency's response to the first objection, it is not clear whether the objection takes into consideration that, although FDA removed the standards of identity in 21 CFR 131.135 and 131.143, there are new standards for lower-fat milk products under 21 CFR 131.10. Mid-America did not provide any evidence that would provide a basis for questioning the agency's finding that the new standards for lower-fat milk products under 21 CFR 130.10 are in the interest of consumers and promote fair dealing.

FDA concludes that Mid-America's second objection did not raise any genuine and substantial issue of fact that would justify a hearing. Rather, the questions posed in support of the second objection amount to little more than ''mere allegations or denials or general description and contentions'' that the agency has said in 21 CFR 12.24(b)(2) will not justify a hearing. Consistent with this regulation, the relevant case law provides that where a party requesting a hearing only offers allegations without an adequate proffer to support them, the agency may properly disregard those allegations

(*General Motors Corp.* v. *FERC*, 656 F.2d 791, 798 n.20 (D.C. Cir. 1981)). Mid-America failed to submit any evidence that creating new standards for lowfat milk and skim milk under the general standard will not promote honesty and fair dealing in the interest of consumers. Because it did not proffer support for its allegations, Mid-America did not justify a hearing on this issue. Therefore, FDA denies the request for a hearing on the second objection.

3. Mid-America cited the agency's desire to reduce the burden of regulation and a need for increased flexibility in at least some standards of identity. At the same time, Mid-America said that none of these facts justify removing the standards for lowfat milk and skim milk that promote honesty and fair dealing in the interest of consumers. As with its second objection, Mid-America maintained that this objection raised several ''factual issues'' and proceeded to list a series of questions. The questions included: ''What do consumers expect when they purchase 'lowfat milk' or 'skim milk'?'' ''Would honesty and fair dealing in the interest of consumers be promoted if products labeled as 'lowfat milk' and 'skim milk' are permitted to contain any 'safe and suitable ingredients'?''

Mid-America's third objection did not raise any genuine and substantial issue of fact that might be readily resolved by any evidence identified in the objection. Again, the questions posed in support of the objection amount to little more than mere allegations or denials or general description and contentions that, under 21 CFR 12.24(b)(2), will not justify a hearing. Therefore, FDA denies the request for a hearing on this objection.

FDA notes that the letter containing objections and a request for a hearing was filed within the time specified in 21 CFR 12.22(e). However, as noted in section III.1. and III.2. of this document, the objections to the final rule removing the standards for lowfat and skim milk and placing these foods under new standards in 21 CFR 130.10 do not raise genuine and substantial issues of fact for resolution through a public hearing or other procedure as provided for under 21 CFR 12.24, nor did the objections provide any evidence that the November 1996 final rule would not promote honesty and fair dealing in the interest of consumers. Therefore, in accordance with 21 CFR 12.28, FDA is denying Mid-America's requests for a hearing. There were no objections to the November 1996 final rule other than those addressed above.

List of Subjects

21 CFR Part 131

Cream, Food grades and standards, Milk, Yogurt.

21 CFR Part 133

Cheese, Food grades and standards, Food labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 401, 403, 409, 701, 721 (21 U.S.C. 321, 341, 343, 348, 371, 379e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is hereby given that the objections received did not justify a hearing, and that the final regulation to amend parts 131 and 133 by removing the standards of identity for various lower-fat milk, sour half-and-half, and cottage cheese products and amending the standard of identity for dry cream, as issued in the Federal Register of November 20, 1996 (61 FR 58991), will become effective on January 1, 1998. Any labels or labeling that require revision as a result of the final regulation must comply no later than January 1, 1998.

Dated: February 14, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–4365 Filed 2–18–97; 4:10 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 723

Board for Correction of Naval Records

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending the Procedures for the Board for Correction of Naval Records. This revision incorporates format changes and clarifies various minor provisions of the part.

DATES: *Effective date:* February 24, 1997.

FOR FURTHER INFORMATION CONTACT: W. Dean Pfeiffer, Executive Director, Board for Correction of Naval Records, 2 Navy Annex, Washington, DC 20370–5100, (703) 614–1402.

SUPPLEMENTARY INFORMATION: The Department of the Navy has determined that this rule is not a major rule because it will not have an annual effect on the economy of $100 million or more. The Assistant Secretary of the Navy (Manpower and Reserve Affairs) certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601–611, and does not have a significant economic impact on small entities as defined by the Act. This rule imposes no obligatory information requirements beyond internal Navy use. The proposed rule was published for comment on October 12, 1995, at 60 FR 53153. No comments or objections to the proposed rule were received. The final rule contains no substantive changes from the proposed rule.

List of Subjects in 32 CFR Part 723

Administrative practice and procedure, Claims, Military personnel.

Accordingly, part 723 of chapter VI of title 32 of the Code of Federal Regulations is revised as follows:

PART 723—BOARD FOR CORRECTION OF NAVAL RECORDS

Sec.

Authority: 10 U.S.C. 1034, 1552.

§ 723.1 General Provisions.

This part sets up procedures for correction of naval and marine records by the Secretary of the Navy acting through the Board for Correction of Naval Records (BCNR or the Board) to remedy error or injustice. It describes how to apply for correction of naval and marine records and how the BCNR considers applications. It defines the Board's authority to act on applications. It directs collecting and maintaining information subject to the Privacy Act of 1974 authorized by 10 U.S.C. 1034 and 1552.

§ 723.2 Establishment, function and jurisdiction of the Board.

(a) *Establishment and composition.* Under 10 U.S.C. 1034 and 1552, the Board for Correction of Naval Records is established by the Secretary of the Navy. The Board consists of civilians of the executive part of the Department of the Navy in such number, not less than three, as may be appointed by the Secretary and who shall serve at the pleasure of the Secretary. Three members present shall constitute a quorum of the Board. The Secretary of the Navy will designate one member as Chair. In the absence or incapacity of