

Proposed Rules

Federal Register

Vol. 60, No. 77

Friday, April 21, 1995

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 146

[Docket No. 94N-0452]

RIN 0905-AC48

Canned Fruit Nectars; Proposal to Revoke the Stayed Standard of Identity

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revoke the standard of identity for canned fruit nectars. This standard has never gone into effect, having been stayed by the filing of objections. This proposal is based in part on a letter from the organization that petitioned for the nectar standard. This organization now states that the standard is not necessary in view of the FDA regulations that require declaration of the percentage of juice in beverage products that purport to contain juice. The agency tentatively concludes that revocation of the stayed standard will minimize confusion in the labeling of canned fruit nectars and will facilitate the marketing of these foods.

DATES: Written comments by July 5, 1995. The agency proposes that any final rule that may issue based on this proposal become effective on the date of publication of the final rule in the **Federal Register**.

ADDRESSES: Submit written comments, data, or information to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nannie H. Rainey, 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

A. Introduction

In the **Federal Register** of October 1, 1964 (29 FR 13535), FDA published a proposal to establish a standard of identity for canned fruit nectars in § 146.113 (21 CFR 146.113) (formerly 21 CFR 27.126) (42 FR 14302, March 15, 1977). The proposal responded to a petition filed by the National Canners Association (now the National Food Processors Association (NFPA)). FDA issued the final regulation adopting the proposed standard in the **Federal Register** of May 7, 1968 (33 FR 6862). Several organizations filed objections to the standard and requested a hearing, based principally on the minimum soluble solids (Brix) values to be applied to the fruit ingredients of the unconcentrated or reconstituted single-strength fruit nectars. Consequently, FDA published a notice staying the regulation in its entirety in the **Federal Register** of July 27, 1968 (33 FR 10713), pending resolution of issues raised by the objections. No hearing on the objections has been held.

Even though the canned fruit nectars standard was stayed, FDA has often referred to the standard for guidance in the naming of diluted juice products with the term "nectar." The standard defined canned fruit nectars as the pulpy, liquid foods prepared from one or more of the optional fruit ingredients listed in the standard (i.e., apple, apricot, blackberry, boysenberry, cherry, guava, loganberry, mango, nectarine, papaya, passion fruit, peach, pear, pineapple, or plum in various forms: Fruit puree, pulp, juice, or concentrated juice), water, and sweeteners. The standard also specified minimum requirements for consistency, minimum Brix values for the fruits, and the level of such fruit, depending on fruit type or combination, that must be in the finished food.

B. The Nutrition Labeling Act of 1990 (the 1990 Amendments)

On November 8, 1990, President Bush signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). Section 7 of the 1990 amendments amended section 403(i) of the Federal Food, Drug, and Cosmetic Act to provide that: "a food * * * shall be deemed to be misbranded unless its label bears (1) The common and usual

name of the food * * * and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice in the food * * *." This provision in the 1990 amendments provided the framework for a requirement for label declaration of information on the juice content of products, including diluted juices such as nectars, that permits consumers to make purchasing decisions based on the level of juice in these foods. This requirement also led to the termination of a number of rulemaking actions pertaining to the labeling of diluted juice products (see 56 FR 30452, July 2, 1991). However, FDA took no action with respect to the stayed standard for canned fruit nectars.

C. Agency's Response to the 1990 Amendments

In the **Federal Register** of July 2, 1991, FDA proposed requirements for declaration of the percentage of juice in foods that purport to be beverages containing fruit or vegetable juice. This proposal was based on section 7 of the 1990 amendments and on a petition from the National Food Processors Association (Docket No. 80N-0140). In addition to a requirement for percentage juice declaration in a new § 101.30 (21 CFR 101.30), FDA also proposed to establish minimum Brix values for 100 percent juice products that would serve as a basis for accurate and consistent percentage juice declarations and that would assist the agency in its enforcement actions. The Brix values were based primarily on information that FDA received from the National Juice Products Association. The agency also proposed to delete the similar provision for percent juice declaration from an existing common or usual name regulation for diluted fruit or vegetable juice beverages in § 102.33 (21 CFR 102.33) and to revise the provisions of that regulation regarding establishment of common or usual names for juice products. In addition, FDA proposed to revoke the common or usual name regulation for noncarbonated beverage products containing no fruit or vegetable juice in § 102.30 because these products would be covered by the labeling provisions in proposed §§ 101.30 and 102.33.

In the **Federal Register** of January 6, 1993 (58 FR 2897), FDA published a

final rule on the July 2, 1991, proposal. As proposed, FDA adopted minimum Brix values in § 101.30 for 51 fruit and vegetable juice products, including values for all of the fruits listed in the canned fruit nectars standard. In adopting the final Brix values, FDA considered the minimum Brix values in the stayed canned fruit nectars standard along with the information received in comments on the proposal. Thus, the agency concludes that the Brix values in the canned fruit nectars standard have been effectively superceded by the values in § 101.30. Moreover, § 101.30 requires that the label of products that purport to contain fruit or vegetable juice, including canned fruit nectars, declare the total percentage of juice contained in such products. This provision ensures that consumers will be able to make value comparisons based on the level of juice used in the beverage.

Finally, in the January 6, 1993, final rule, FDA adopted § 102.33 on the common or usual names of juice beverages that purport to contain fruit or vegetable juice. Canned fruit nectars are among the foods that must be labeled in accordance with § 102.33. This regulation permits products that traditionally have been considered to be canned fruit nectars to continue to bear the term "nectar."

D. Conclusions and Proposal

The agency points out that the stayed standard of identity for canned fruit nectars was established under section 701(e) of the act (21 U.S.C. 371(e)), which required formal rulemaking in any action for the establishment, amendment, or repeal of a food standard. However, the 1990 amendments removed food standards rulemaking proceedings, except for the amendment or repeal of standards of identity for dairy products and maple syrup, from the formal rulemaking requirements of section 701(e) of the act (see section 8 of the 1990 amendments). Therefore, rulemaking proceedings to revise or repeal the stayed standard for canned fruit nectars are subject to section 701(a) of the act.

In considering its options with respect to the stayed standard, the agency considered proposing to amend it to incorporate the revised Brix values as a means of responding to the objections on the canned nectars final rule. FDA rejected this option because the Brix values in the standard would duplicate the provisions in § 101.30. In addition, § 102.33 provides for the use of an appropriately descriptive name for diluted juice beverages, including fruit nectars. FDA believes that use of an

appropriately descriptive name, along with a declaration of the percentage of juice, will provide adequate information to consumers regarding the nature of fruit nectars, and that a separate standard of identity for canned fruit nectars is not necessary. Thus, the agency tentatively concludes that the stayed standard of identity for canned fruit nectars should be removed.

The agency's tentative view is supported by the petitioner for the canned fruit nectars standard. In a letter to the agency dated July 8, 1994, and filed under Docket No. 80N-0140, NFPA stated that the opinion of its members is that, with the advent of mandatory percent juice labeling for any food that purports to be a beverage that contains a fruit or vegetable juice (§ 101.30), the stayed standard is no longer necessary and should be removed from the Code of Federal Regulations. Accordingly, NFPA requested that the agency take such action.

Thus, in view of the petitioner's request and of the existing requirements for percent juice declaration in § 101.30 and for naming diluted juice beverages in § 102.33, FDA tentatively concludes that the standard of identity for canned fruit nectars in § 146.113 is not needed, and that no further action on the objections filed to the May 7, 1968, final rule establishing that standard is warranted. Therefore, FDA is proposing to revoke the stayed standard of identity for canned fruit nectars.

II. Economic Impact

As required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 354), FDA has examined the economic implications of this proposed rule that would remove the stayed standard of identity for canned fruit nectars in 21 CFR part 164. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act requires that the agency analyze options for regulatory relief for small businesses.

FDA believes that there will be no economic impact on the juice processing industry from this proposed rule because the removal of the stayed standard will not result in any new costs or requirements. Canned fruit nectars, currently marketed as nonstandardized foods, will continue to be named and labeled in accordance with the existing requirements of

§§ 101.30 and 102.33. Removal of the stayed standard will eliminate confusion regarding the compositional requirements for juice products named by use of the term "nectar."

Thus, FDA concludes that this is not a significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act, the agency certifies that the final rule will not have a significant impact on a substantial number of small businesses.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(1) 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.

IV. Request for Comments

Interested persons may, on or before June 20, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 146

Food grades and standards, Fruit juices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, it is proposed that 21 CFR part 146 be amended as follows:

PART 146—CANNED FRUIT JUICES

1. The authority citation for 21 CFR part 146 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

§ 146.113 [Removed]

2. Section 146.113 *Canned fruit nectars* is removed from subpart B.

Dated: February 8, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95-9949 Filed 4-20-95; 8:45 am]

BILLING CODE 4160-01-F