

resolution of issues raised by the objections. No hearing on the objections was held.

### *B. The Nutrition Labeling and Education Act of 1990*

Section 7 of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) amended section 403(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(i)) 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 \* \* \* ." In response to this provision, FDA adopted § 101.30 *Percent juice declaration for foods purporting to be beverages that contain fruit or vegetable juice* (21 CFR 101.30) on declaring the juice content of certain food products (58 FR 2897, January 6, 1993). Section 101.30 establishes minimum Brix values for 51 fruit and vegetable juice products, including values for all of the fruits listed in the canned fruit nectars standard to which objections had been raised. The Brix values are minimum values for 100 percent juice products and serve as a basis for accurate and consistent percentage juice declarations. In addition, FDA adopted § 102.33 *Beverages that contain fruit or vegetable juice* (21 CFR 102.33) setting forth requirements for establishing common or usual names for juice beverages that purport to contain fruit or vegetable juice, including beverages such as canned fruit nectars.

### *C. The Proposal to Revoke the Canned Fruit Nectars Standard*

In the Federal Register of April 21, 1995 (60 FR 19866), FDA proposed to revoke the standard of identity for canned fruit nectars. In the preamble to that proposal (60 FR 19866 at 19867), the agency pointed out that it had adopted the stayed standard of identity under section 701(e) of the act (21 U.S.C. 371(e)), which required formal rulemaking in any action for the establishment or amendment of a food standard. However, the agency also pointed out that the 1990 amendments removed food standards rulemaking proceedings for most foods from the coverage of section 701(e) of the act, and that, as a result, further rulemaking on the stayed standard was subject to section 701(a) of the act.

The agency initiated the proposed action in response to the petitioner's request that it revoke the stayed

standard, and because it had tentatively concluded that the standard was no longer needed. Canned fruit nectars are adequately provided for as nonstandardized foods under the regulations for percent juice declaration in § 101.30 and the common or usual name regulation for beverages that purport to contain fruit or vegetable juice in § 102.33. FDA proposed that if it were to revoke the standard, that action would be effective on the date of publication of the final rule in the Federal Register. Interested persons were given until July 5, 1995, to comment on the proposal.

### II. The Revocation

Four letters, one each from the petitioner, a second industry trade association, a juice processor, and several consumers (commenting jointly), were received in response to the proposal. All expressed support for revocation on the standard of identity for canned fruit nectars.

Thus, in view of the support expressed by the comments and the existing requirements for percent juice declaration in § 101.30 and for naming diluted juice beverages in § 102.33, FDA 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 revoking the stayed standard of identity for canned fruit nectars. Products traditionally considered to be canned fruit nectars may continue to be labeled with the term "nectar" provided that they also comply with the applicable sections for the food labeling regulations set forth in parts 101 and 102 (21 CFR parts 101 and 102).

### III. Economic Impact

As required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA has examined the economic implications of the proposed rule that would remove the stayed standard of identity for canned fruit nectars. 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 tentatively concluded that there will be no economic impact on the juice processing industry from the 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 tentatively concluded that the proposed rule will not constitute a significant regulatory action as defined by Executive Order 12866. In compliance with the Regulatory Flexibility Act, the agency certified that the final rule will not have a significant impact on a substantial number of small businesses. FDA has not received any information or data that will change the tentative conclusions that it set forth in the proposal. Therefore, FDA concludes that this final rule is not a significant regulatory action, and that it will not have a significant impact on a substantial number of small businesses.

### IV. 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.

### 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, 21 CFR part 146 is

### **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: October 18, 1995.

William B. Schultz,

*Deputy Commissioner for Policy.*

[FR Doc. 95-27713 Filed 11-8-95; 8:45 am]

**BILLING CODE 4160-01-F**

**21 CFR Part 429****[Docket No. 91N-0173]****RIN 0910-AA07****Fees for Certification of Drugs Composed Wholly or Partly of Insulin****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Interim final rule; opportunity for public comment.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an interim final rule to amend its regulations establishing the fee schedule for the insulin certification program. The interim final rule decreases the fees charged for insulin certification services because experience has demonstrated that the current fee schedule does not accurately reflect FDA's actual cost of administering the insulin certification program.

**DATES:** The interim final rule is effective December 11, 1995, written comments by February 7, 1996.

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

**FOR FURTHER INFORMATION CONTACT:** Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1049.

**SUPPLEMENTARY INFORMATION:****I. Introduction**

In 1941, Congress amended the Federal Food, Drug, and Cosmetic Act (the act) to require FDA to certify batches of drugs composed wholly or partly of insulin (Pub. L. 77-366). This amendment created section 506 of the act (21 U.S.C. 356), which requires the agency to provide for the certification of a batch of a drug composed wholly or partly of insulin if the "drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity [that are] \* \* \* necessary to adequately insure safety and efficacy of use \* \* \*." Section 506 of the act also requires FDA to promulgate regulations governing the certification of drugs containing insulin. Uncertified batches of insulin that are shipped in interstate commerce are misbranded under section 502 of the act (21 U.S.C. 352) and are subject to seizure and other sanctions under the act.

FDA's regulations providing for insulin certification are set forth in part

429 (21 CFR part 429). These regulations include requirements for packaging and labeling (§§ 429.10 through 429.12), product standards (§§ 429.25 and 429.26), tests and methods of assay (§ 429.30), and the contents of requests for certification and samples required to be submitted (§ 429.40), as well as setting forth the standards for review and approval of requests for certifications (§ 429.41). In addition, insulin is considered to be a new drug subject to section 505 of the act (21 U.S.C. 355). Therefore, drug products containing insulin must have an approved new drug application, submitted and approved under section 505 of the act and 21 CFR part 314 of the regulations, to market the drug in interstate commerce.

Under FDA's insulin certification program, insulin manufacturers submit a "Request for Certification of an Insulin Batch" containing manufacturing and analytical data, as well as product samples of the master lot of insulin crystals and insulin finished dosage forms, to FDA's Division of Prescription Drug Compliance and Surveillance and FDA's insulin laboratory in the agency's Center for Drug Evaluation and Research. The Division of Prescription Drug Compliance and Surveillance reviews the incoming requests and determines which tests that FDA needs to perform. After review of the analytical data, physical examination, and completion of testing, FDA's insulin laboratory forwards its report and recommendation to the Division of Prescription Drug Compliance and Surveillance, where the data is reviewed and compared with the data reported in the manufacturer's request for certification. If both documents show that the batch conforms to the requisite standards of identity, strength, quality, and purity, the agency issues an insulin certificate.

**II. Fee Schedule**

Section 506(b)(5) of the act requires FDA to establish such fees as are necessary to provide, equip, and maintain an adequate certification service. These fees are intended to recover the full costs of operation of FDA's insulin certification program. The current fee schedule set forth in § 429.55(b) was published as an interim final rule in the Federal Register of October 4, 1991 (56 FR 50248). This interim final rule revises those fees to more accurately reflect the cost of maintaining the insulin certification program. FDA currently charges \$3,900 to certify each master lot and \$2,800 to certify each dosage form batch. Under the new fee schedule, FDA will charge

\$2,400 to certify each master lot and \$1,700 for each dosage form batch. All cost estimates are described in detail in a September 1995 FDA study of the insulin certification program's cost. A copy of the study has been placed on file at the Dockets Management Branch (address above). A provision of the current fee schedule allowing FDA to increase fees as Government salaries increase has been retained, with minor changes to emphasize the discretionary nature of any such fee increase. Fee increases based on salary increases will not take place before January 1, 1997.

**III. Environmental Impact**

The agency has determined under 21 CFR 25.24(a)(8) 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. Analysis of Impacts**

FDA has examined the impacts of the interim final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). 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, and other advantages; distributive impacts; and equity). The agency believes that this interim final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the interim final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA estimates that the fee schedule set out in this interim final rule will result in a decrease of approximately \$400,000 annually in fees collected by the agency, and will not result in any increase in cost to manufacturers of drug products containing insulin. The agency certifies that the interim final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

**V. Effective Date and Opportunity for Public Comment**

The agency is issuing this amendment as an interim final rule effective December 11, 1995. The establishment of fees necessary to provide, equip, and maintain an adequate certification program for insulin has been mandated by Congress under section 506(b) of the act (21 U.S.C. 356(b)). As certification services are provided to manufacturers directly by FDA, the setting of a fee schedule to pay for these services is a matter particularly within the purview and expertise of the agency. The fees established by this regulation have been based on cost accounting methods using data compiled by the agency. The cost accounting methods used are the same as those used in two previous rulemakings that established fees for insulin certification. FDA invited comment on these rulemakings, but received none addressing either the adequacy of the fees or accuracy of the cost accounting methods used. Moreover, FDA's experience under the 1991 fee schedule indicates that the fees in that fee schedule do exceed the amounts needed to provide for the insulin certification program and are, therefore, in excess of the fees authorized by the act. For the foregoing reasons, FDA finds for good cause that notice and public procedure would be unnecessary, and contrary to the public interest, and, therefore, a public comment period before the establishment of this rule may be dispensed with under 5 U.S.C. 553(b)(B).

FDA believes that it is appropriate to invite and consider public comments on the provisions of this interim final rule, to determine if these provisions should be amended in the future. Therefore, under 21 CFR 10.40(e), interested persons may, on or before February 7, 1996, submit to the Dockets Management Branch (address above) written comments regarding this document. FDA will use any comments received to determine whether this interim final rule should be modified or other administrative actions taken. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 429**

Administrative practice and procedure, Drugs, Labeling, Packaging

and containers, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 429 is amended as follows:

**PART 429—DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN**

1. The authority citation for 21 CFR part 429 continues to read as follows:

Authority: Secs. 502, 506, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 356, 371).

2. Section 429.55 is amended by revising paragraph (b) to read as follows:

**§ 429.55 Fees.**

\* \* \* \* \*

(b) The fees for requests for certification submitted under § 429.40 are as follows:

(1) \$2,400 for each master lot or mixture of two or more master lots or parts thereof.

(2) \$1,700 for each dosage form batch.

(3) The fees established in this paragraph may increase as Federal salary costs increase. The rate of increase will be no higher than Federal salary increases, commencing with pay raises on or after January 1, 1997. Notification of the exact fees established and adjustments will be communicated directly to the manufacturers of insulin products.

\* \* \* \* \*

Dated: November 2, 1995.

William B. Schultz,

*Deputy Commissioner for Policy.*

[FR Doc. 95-27714 Filed 11-8-95; 8:45 am]

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**DEPARTMENT OF THE INTERIOR**

**Office of Surface Mining Reclamation and Enforcement**

**30 CFR Part 914**

**[IN-110, Amendment Number 93-7, Part I]**

**Indiana Regulatory Program**

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

**ACTION:** Final rule; approval of amendments.

**SUMMARY:** OSM is approving part of a proposed amendment to the Indiana permanent regulatory program (hereinafter referred to as the Indiana program) under the Surface Mining Control and Reclamation Act of 1977

(SMCRA). The amendment consists of proposed changes to the Indiana Surface Mining Rules provisions concerning OSM Regulatory Reform I, II and III issues, required program amendments, and State initiatives. This final rule notice is addressing the first of three subparts of the original amendment. The primary focus of the amendments in this subpart is on soil capability and restoration standards, individual civil penalties, significant/nonsignificant revisions, coal exploration, and performance bonds. The amendment is intended to resolve outstanding issues that remain present in the approved Indiana program resulting from changes to the Federal program. The amendment would also incorporate changes desired by the State that address various parts of the State rules.

**EFFECTIVE DATE:** November 9, 1995.

**FOR FURTHER INFORMATION CONTACT:**

Mr. Roger W. Calhoun, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, IN 46204, Telephone (317) 226-6166.

**SUPPLEMENTARY INFORMATION:**

- I. Background on the Indiana Program.
- II. Submission of the Amendment.
- III. Director's Findings.
- IV. Summary and Disposition of Comments.
- V. Director's Decision.
- VI. Procedural Determinations.

**I. Background on the Indiana Program**

On July 29, 1982, the Indiana program was made effective by the conditional approval of the Secretary of the Interior. Information pertinent to the general background on the Indiana program, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Indiana program can be found in the July 26, 1982 Federal Register (47 FR 32107). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 914.10, 914.15, and 914.16.

**II. Submission of the Amendment**

Since July 29, 1982 (the date of conditional approval of the Indiana program), a number of changes have been made to the Federal regulations concerning surface coal mining and reclamation operations. Pursuant to the Federal regulations at 30 CFR 732.17, OSM informed Indiana on May 22, 1985 (Regulatory Reform I), on August 24, 1988 (Regulatory Reform II), and September 20, 1989 (Regulatory Reform III), that a number of Indiana regulations