petition and stating in what respect the petition does not meet these requirements.

(3) If a petition appears to meet the prerequisite requirements in paragraph (c) of this section, it will be filed by the Dockets Management Branch, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the Dockets Management Branch for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. The Dockets Management Branch will promptly notify the petitioner in writing of the filing and docket number of a petition.

(4) Any interested person may submit written comments to the Dockets Management Branch on a filed petition as provided in § 10.30(d) of this chapter.

(5) Within 90 days of the date of filing the agency will furnish a response to the petitioner. The response will either:

(i) State that the agency has tentatively determined that the petition merits the granting of an exemption, and that it intends to publish in the **Federal Register** a proposal to grant the exemption through rulemaking;

(ii) Deny the petition and state the reasons for such denial; or

(iii) Provide a tentative response indicating why the agency has been unable to reach a decision on the petition, e.g., because of other agency priorities or a need for additional information.

(g) If a State submits a petition for exemption of a State requirement from preemption under section 403A(a)(3) through (a)(5) of the act before May 8, 1992, that State requirement will not be subject to preemption until:

(1) November 8, 1992; or

(2) Action on the petition, whichever occurs later.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27153 Filed 11-26-91; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 100

[Docket No. 91N-0343]

RIN 0905-AD08

State Enforcement Provisions of the Nutrition Labeling and Education Act of 1990

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to implement section 4 of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which provides for State enforcement of certain requirements of the Federal Food, Drug, and Cosmetic Act (the act), so long as the state provides 30 days notice of its intent to act and complies with other procedural requirements before taking any such enforcement action. The agency is proposing to adopt regulations that will provide the states with instructions on how to give the requisite 30-day notice. FDA has framed these instructions to ensure that this notification system functions efficiently. This proposal also describes relevant State and Federal obligations.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following its publication in accordance with requirements of the Nutrition Labeling and Education Act of 1990.

ADDRESSES: 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: Janice F. Oliver, Center for Food Safety and Applied Nutrition (HFF-310), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-485-0187.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). The 1990 amendments make the most significant changes in food labeling law since the passage of the act in 1938. In this document, FDA is proposing to adopt procedures to implement section 4 of the 1990 amendments, which amended section 307 of the act (21 U.S.C. 337) to authorize states to enforce certain sections of the act in their own names.

Before the passage of the 1990 amendments, section 307 of the act required that all enforcement proceedings be by, and in the name of, the United States. A state could only use its own laws to bring enforcement action against food located in that state. Any enforcement of the act had to be undertaken by the Federal government.

Under the 1990 amendments, section 307(b)(1) of the act has been revised to authorize a state to bring in Federal court in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 401 (Definitions and Standards for Foods) and of the misbranding provisions of sections 403(b) (offered for sale under another name), 403(c) (imitation of another food), 403(d) (misleading containers), 403(e) (name and address of manufacturer and net weight), 403(f) (prominence of information on label), 403(g) (representation as to definition and standard of identity), 403(h) (representation as to standard of quality and fill of container), 403(i) (common or usual name and ingredient labeling of all fabricated food), 403(k) (artificial flavoring, artificial coloring, or chemical preservative), 403(q) (nutrition information), and 403(r) (claims) of the act (21 U.S.C. 341, 343(b) through (i), (k), (q), and (r)), if the food that is the subject of the proceeding is located within the state. This provision will enable the states to supplement FDA s enforcement capabilities. It is effective 24 months after date of enactment. See section 10(a)(1)(C) of the 1990 amendments.

Under section 307(b)(2) of the act, however, a state's ability to exercise this new authority to enforce Federal law is predicated on certain conditions:

(1) A proceeding may not be commenced unless the state has given notice to FDA that it intends to bring such proceeding; also, the state must wait 30 days after giving notice before instituting action.

(2) If after receiving such notice, FDA, within 30 days, commences an informal or formal enforcement action pertaining to the food in question, the state may not bring its proceeding until an additional 60 days have passed (90 days from the initial notice by the state).

(3) If FDA is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal enforcement action or the formal enforcement action pertaining to such food, the state may not institute a proceeding. Section 307(b)(2) of the act, however, does permit a state to intervene as a matter of right in any court proceeding that has been brought by FDA.

Although the statute and legislative history are silent as to what is meant by "informal or formal enforcement action," FDA interprets "informal enforcement actions" to include warning letters, recalls, and detentions. It interprets "formal enforcement actions" to include seizures, injunctions, and prosecutions. Informal actions include those that FDA can take administratively, while formal actions

are those that require the initiation of a judicial proceeding.

FDA believes that for purposes of section 307(b)(2)(B) of the act, a criminal action would be a "formal enforcement action pertaining to the food," even though the criminal action is against a corporation or individual and not the food itself (as a seizure action is), so long as the food in question provides the factual basis, or part of the factual basis, for the criminal charge (e.g., the charge is for introducing misbranded food into interstate commerce, and the allegedly misbranded food is the product that is to be the subject of the State action). FDA also believes that it is appropriate to regard a criminal action in this way, even though section 307(b)(1) only authorizes the state to bring proceedings for the civil enforcement, or to restrain violations, of the specified sections of the act because criminal proceedings may have the effect of eliminating the alleged misbranding, which would be the purpose of the State proceedings. FDA requests comments on these matters.

FDA is incorporating its interpretation of "informal enforcement action" and "formal enforcement action" in proposed § 100.2(j).

FDA is proposing to adopt in 21 CFR 100.2 a set of regulations that reflect the requirements of section 307 of the act. Proposed § 100.2(a) incorporates and reflects the provisions of section 307(b)(1) of the act. Similarly, proposed § 100.2(b) incorporates the provisions of section 307(b)(2)(A), (b)(2)(B), and (b)(2)(C) of the act, and proposed § 100.2(c) incorporates the provisions of the last sentence of section 307(b)(2).

FDA is also proposing to adopt procedures that a state should follow in notifying the agency of its intention to institute an enforcement action. First, in § 100.2(d), FDA is proposing a standard format for the letter of notification. The agency is also delineating the information that should be submitted in this letter. The letter should include the name and address of the State agency, the name and address of the firm against which enforcement action is proposed (if applicable), the specific products covered by the notification, the type and size of each product container, the manufacturing code (if applicable), and the reason for and type of anticipated State enforcement action, including the section of the act violated. For example, the notification would state that the product is in violation of section 403(b) of the act in that it is a product that is sold under the name of another food. It would go on to state that the product is sold as 100 percent pure blackberry juice, whereas it is actually a combination of grape and blackberry juice with grape juice being the predominant ingredient. Finally, it would state that the anticipated action is seizure. This information will enable FDA to quickly review the proposed State action and to determine whether the agency is contemplating, or has undertaken, action against the food in question, or would undertake action in light of the facts brought to its attention by the State.

Under proposed § 100.2(e), the letter of notification should be signed by a state official authorized to institute the proposed action. Such a signature will ensure that the state actually intends to institute the action in question. Under proposed § 100.2(f), the letter should be sent to the Food and Drug Administration, Division of Regulatory Guidance (HFF-310), Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204. It is necessary that FDA headquarters be notified so that it can determine whether an action against the food in question has been brought or is contemplated anywhere in the country. Because Congress used the word "pertain" in section 307 of the act, FDA believes that an agency action anywhere in the United States against the food in question would, under section 307(b)(2), bar a State action against the food in Federal court. The agency does not interpret the act to require that FDA action be against the food in the state that has submitted a notice. This view is consistent with section 304(a)(1) of the act, which limits the number of actions against a particular misbranding to one, except in limited circumstances not applicable in this context.

FDA is proposing in § 100.2(g) and (h) to set out the procedures that it will follow in responding to a State's notification. Under proposed § 100.2(g), FDA will notify the state of the date on which it received the letter of notification within 2 working days after date of receipt of such letter. This notification is necessary so that the state is aware of the date on which the time periods set by section 307 of the act begin to run.

Under proposed § 100.2(h), the Director, Division of Regulatory Guidance, Office of Compliance, Center for Food Safety and Applied Nutrition will, within 30 days of the date of notification, respond to the notification by advising:

(1) Whether FDA has commenced an informal or formal enforcement action pertaining to the food that is the subject of the notification; or

(2) Whether FDA is prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled informal or formal enforcement action pertaining to such food.

The agency believes that the proposed regulations will be beneficial to the states and to FDA because having these procedures firmly in place will expedite the agency review process, will ensure an orderly and timely response to the state, and will facilitate coordinated Federal/State enforcement action against violative products in the marketplace.

State notifications to FDA pursuant to section 307 of the act will contain information compiled for law enforcement purposes and may contain trade secret or confidential commercial or financial information. Accordingly, FDA is proposing in § 100.2(i) that information contained in these required notifications will be exempt from public disclosure to the same extent to which such information would be so exempt pursuant to 21 CFR 20.61, 20.64, and 20.88 of this chapter.

FDA notes that it does not believe section 4 of the 1990 amendments on State enforcement precludes a state from taking enforcement action under its own statute or regulations in State court. It is the opinion of the agency that State regulations that are identical to Federal regulations are not preempted by section 6 of the 1990 amendments. Under section 6(c)(1) of the 1990 amendments, a provision of State law is not preempted unless such provision is expressly preempted under section 403A of the act (21 U.S.C. 343-1). Each clause of section 403A(a) of the act expressly preempts only those State regulations that are "not identical" to Federal requirements of section 403A(a) of the act (21 U.S.C. 343-1(a)(1)-(a)(5)). Accordingly, State regulations that are identical to Federal requirements are not preempted. Thus, a state may initiate enforcement proceedings under its own statute or regulations in State court. However, to facilitate uniformity in enforcement, FDA encourages states to discuss their State-court enforcement activities with the local FDA district office. Continued close cooperation between FDA and State regulatory agencies will ensure that the goals of uniformity and certainty underlying the act are met.

In implementing section 307 of the act, to avoid any suggestion of an unconstitutional delegation to states to enforce the (Federal) act, FDA retains full authority to advise states of what FDA believes is the proper interpretation of any of the sections of the act that they may seek to enforce. If FDA advises a state that its proposed

action is inconsistent with FDA's interpretation, FDA believes section 307 of the act requires that the state conform its interpretation to FDA's.

II. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the provisions of § 100.2 *State enforcement of Federal regulations* relating to submission of information to FDA will be submitted for approval to the Office of Management and Budget (OMB). These provisions will not be effective until FDA obtains OMB approval. FDA will give notice of OMB approval of these requirements in the **Federal Register** as part of any final rule that is based on this proposal.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a) 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. Economic Impact

FDA has examined the economic implications of the proposed rule pertaining to part 101 requirements as required by Executive Order 12291 and the Regulatory Flexibility Act. Executive Order 12291 compels agencies to use cost-benefit analysis as a component of decisionmaking and the Regulatory Flexibility Act requires regulatory relief for small businesses where feasible.

This proposed regulation codifies conditions under which states can enforce certain sections of the act and provides a format for notification of FDA of a state's intent to enforce those provisions. FDA has no information as to the cost of the required submission by states, although the information requested is the minimum required for notification purposes. If, for example, the required paperwork costs $100 per state action to prepare, it would take over one million enforcement actions to cause this proposed requirement to become a major rule, an unlikely event.

Because very little paperwork is required to be submitted, FDA concludes that this proposed rule is not a major rule as defined by Executive Order 12291. In addition, FDA certifies that this action will not result in a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

V. Comments

Interested persons may, on or before February 25, 1992, 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.

VI. Effective Date

The agency intends to issue final regulations pertaining to the state enforcement provisions of the 1990 amendments by November 8, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective November 8, 1992, in accordance with the requirements of the 1990 amendments.

List of Subjects in 21 CFR Part 100

Administrative practice and procedure, Food labeling, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 100 be amended as follows:

PART 100—GENERAL

1. The authority citation for 21 CFR Part 100 is revised to read as follows:

Authority: Secs. 201, 301, 307, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 337, 342, 343, 348, 371).

2. Section 100.2 is added to Subpart A to read as follows:

§ 100.2 State enforcement of Federal regulations.

(a) Under section 307 of the Federal Food, Drug, and Cosmetic Act, a state may bring, in its own name and within its own jurisdiction, proceedings for the civil enforcement, or to restrain violations, of sections 401, 403(b), 403(c), 403(d), 403(e), 403(f), 403(g), 403(h), 403(i), 403(k), 403(q), or 403(r) of the act if the food that is the subject of the proceedings is located in the state.

(b) No proceeding may be commenced by a state under paragraph (a) of this section:

(1) Before 30 days after the state has given notice to the Food and Drug Administration (FDA) that the state intends to bring such proceeding.

(2) Before 90 days after the state has given notice to FDA of such intent if FDA has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding.

(3) If FDA is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

(c) A state may intervene as a matter of right, in any court proceeding described in paragraph (b)(3) of this section.

(d) The notification that a state submits in accordance with paragraph (b) of this section should include the following information and be submitted in the following recommended format:

(Date)

Name of State agency———————————

Post office address ———————————

Street address ———————————

City, State, and ZIP code ———————————

Name of products(s) covered by the notification

Reporting official, title, and telephone No.

FAX No.———————————

Agency contact (if different from reporting official), title, and telephone No.

Director, Division of Regulatory Guidance (HFF-310), Center for Food Safety and Applied Nutrition, Food and Drug Administration,
200 C St. SW.,
Washington, DC 20204.

Dear Sirs: The undersigned, _____, submits this letter of notification pursuant to section 307(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 337(b)(1)) with respect to

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(name of products covered by the notification and the enforcement action that is to be initiated)

Attached hereto, and constituting a part of this letter of notification are the following:

A. The name of the product.

B. The type and size of each product container.

C. Copy of the label and labeling of the product.

D. Manufacturing code (if applicable).

E. Name and address of firm responsible for violations.

F. Name and address of manufacturer or distributor responsible for violations

G. Name and address of parent firm (if known).

H. Reason for the anticipated state enforcement action (list specific violations, including sections of the law violated).

I. Name of firm against which action is anticipated (if applicable)

Yours very truly,
Reporting Agency
By ———————————
(Indicate authority)

(e) The letter of notification should be signed by a State official authorized by

the State to institute the contemplated enforcement actions.

(f) The letter of notification should be sent to the Division of Regulatory Guidance (HFF-310), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, FAX number 202-472 1542.

(g) FDA will notify the state of the date on which its letter of notification was received by FDA, Center for Food Safety and Applied Nutrition, Division of Regulatory Guidance (HFF-310) (within 2 working days after date of receipt). This date will be the date of notification for the purposes of paragraph (b) of this section.

(h) The Director, Division of Regulatory Guidance, Office of Compliance, Center for Food Safety and Applied Nutrition, Food and Drug Administration, will respond to the State's notification within 30 days of the date of notification by advising:

(1) Whether FDA has commenced an informal or formal enforcement action pertaining to the food that is the subject of the notification; or

(2) Whether FDA is prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled informal or formal enforcement action pertaining to such food.

(i) Information contained in State notification letters required by this section shall be exempt from public disclosure to the same extent to which such information would be so exempt pursuant to §§ 20.61, 20.64, and 20.88 of this chapter.

(j) *Definitions.* (1) "Informal enforcement actions" include warning letters, recalls, detentions, or other administrative enforcement actions that pertain to the food in question.

(2) "Formal enforcement actions" include seizures, injunctions, prosecutions, or other judicial enforcement actions that pertain to the food in question.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27152 Filed 11-26-91; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 20 and 101

[Docket No. 85N-0061]

RIN 0905-AB67

Labeling; General Requirements for Health Claims for Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing general requirements pertaining to: (1) The use of health claims that characterize the relationship of a food component to a disease or health-related condition on the labels and in labeling of both conventional foods and dietary supplements, and (2) the content of petitions regarding the use of such health claims pertaining to specific substances in food. This proposal is issued in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims. It supersedes in all respects FDA's reproposed rule concerning health messages (February 13, 1990, 55 FR 5176). Elsewhere in this issue of the **Federal Register**, FDA is issuing proposals that respond to the 1990 amendments directive that the agency consider 10 topics associating nutrients with diseases or health-related conditions. Those proposals have been developed in accordance with the general principles of the proposed requirements in this document.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective 6 months following publication of a final regulation pertaining to health claims in food labeling in accordance with requirements of the 1990 amendments.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, 301-443-1751.

FOR FURTHER INFORMATION CONTACT: Victor P. Frattali, Center for Food Safety and Applied Nutrition (HFF-261), Food and Drig Administration, 200 C St., SW., Washington, DC 20204, 202-245-1064.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). This new law amends the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the most notable aspects of the 1990 amendments is that they confirm FDA's authority to regulate nutrient content claims and health claims on food labels and in labeling. With respect to health claims, the new provisions provide that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards contained in regulations established under section 403(r)(1)(B) of the act (21 U.S.C. 343 (r)(1)(B))

The enactment of the 1990 amendments reflects a determination by Congress that an orderly and accountable process is needed to control the dissemination of information concerning the relationship between diet and disease or other health-related conditions on the food label and in labeling. Congress characterized this need as "compelling" (Ref. 1). FDA is proposing general requirements to ensure that this information in food labeling will be valid, truthful, nonmisleading, and useful for consumers.

The agency fully recognizes the importance of conveying to American consumers information on the value of improved nutrition to help achieve or maintain good health. FDA is committed to facilitating the provision of such information wherever adequate scientific evidence confirms the validity of the information.

II. Regulatory History

For many years, FDA has permitted firms to label foods with truthful, nonmisleading information about the nutrient content of food. In the past, however, the agency did not permit firms to provide consumers with information on the label or in labeling concerning how the food may be used to affect a disease or health-related condition. FDA generally took a position that including disease-related information on food labeling resulted in the food being a drug within the meaning of the act. The act (section 201(g)(1)(B)) defines a drug, in part, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease in man * * *" (21 U.S.C. 321(g)(1)(B)). Thus, the agency has viewed mention of a disease on a food label as evidence that the product was intended to be used as a drug.

In addition, in the **Federal Register** of March 14, 1973 (38 FR 6950 at 6951), FDA promulgated regulations that provided, in part, that a food shall be deemed to be misbranded if its labeling represents, suggests, or implies that the food, because of the presence or absence of