DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to implement section 4 of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). This section provides for State enforcement of certain requirements of the Federal Food, Drug, and Cosmetic Act (the act), so long as the State gives FDA 30 days notice of its intent to act, and certain other conditions apply. The agency is adopting 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. The final rule also describes relevant State and Federal obligations.

EFFECTIVE DATE: February 5,1993.

FOR FURTHER INFORMATION CONTACT: Janice F. Oliver, Center for Food Safety and Applied Nutrition (HFS-CGO), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4187.

SUPPLEMENTARY INFORMATION:

I. Background

In response to the requirements of the 1990 amendments (Pub. L. 101-535), FDA published in the **Federal Register** of November 27, 1991 (56 FR 60534), a proposal to implement section 4 of those amendments. Section 4 amended section 307 of the act (21 U.S.C. 337) to provide for State enforcement of certain requirements of the act, so long as the State provides 30 days notice of its intent to act, and certain other conditions apply. The agency proposed to adopt regulations that would provide the States with instructions on how to give the requisite 30-day notice and to describe relevant Stats and Federal obligations. Interested persons were given until February 25, 1992, to comment.

FDA received approximately 24 responses to this proposal, each containing one or more comments, from trade (associations, government organizations, individual States, food manufacturers, consumers, and consumer groups. The comments generally supported the proposal. Several comments addressed issues outside the scope of the proposal (e.g., delaying implementation of the regulations and delaying enforcement of the regulations) that will not be discussed here. A number of comments disagreed with various aspects of the proposal. These comments suggested modification and revision of various provisions of the proposal. A summary of these comments and the comments' suggested changes, along with the agency's responses, follows.

II. State Enforcement Provisions of the 1990 Amendments

A. Informal Enforcement Actions

In proposed § 100.2(j), FDA defined "informal enforcement actions," a term that is used in section 307(b)(2)(B) and (C) of the act, and defined in the agency's proposed implementing regulations, to include warning letters, recalls, and detentions as well as other administrative actions.

1. One comment suggested that FDA remove detentions as a type of informal enforcement action because FDA has no detention authority for foods.

The use of the word "detentions" in the proposal refers to detentions of imports under the provisions of section 801 of the act (21 U.S.C. 381) and detentions authorized under the provisions of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). The agency is authorized to detain imported food products if it appears that the products have been manufactured, processed, or packaged under insanitary conditions, or that the products are adulterated or misbranded, under the act. The agency also is authorized to detain meat, poultry, and egg products if they are found outside a plant inspected by the U.S. Department of Agriculture, and the agency has reason to believe that the products are adulterated or misbranded, under 21 U.S.C. 467f(b), 679(b), and 1052(d). Import detentions and detentions under the FMIA, PPIA, and EPIA are all administrative enforcement actions, and, therefore, informal actions under proposed § 100.2(i)(1). Consequently, the agency concludes that no change in the regulation in response to this comment is necessary.

2. Another comment suggested that FDA remove warning letters as a type of informal enforcement action. This comment stated that the agency often issues warning letters when no further action is planned by FDA, and that no response stating that corrections have been made is required from the recipient.

FDA disagrees with this comment. Warning letters are used by the agency to notify a firm that it is not in compliance with the act or with agency regulations, that failure to correct these violations may result in formal enforcement actions by FDA, and that a reply with a full statement of all corrections that have been or will be made is required within 10 days. A study of warning letters by FDA revealed that approximately 93 percent of the warning letters issued by FDA elicit a response from the recipient. Because of these facts, FDA continues to believe that it is appropriate to include warning letters as a type of informal enforcement action in the final rule. If the firm does not respond to the warning letter within the time provided in the warning letter, and the agency does not take any further action, the State will be free to act after 90 days under section 307(b)(2)(B) of the act.

3. Two comments suggested that adverse publicity be included as a type of informal enforcement action because FDA has the authority to issue publicity under section 705 of the act (21 U.S.C. 375). The agency acknowledges that it has the authority to issue publicity under section 705 of the act. The authority is conferred to the agency in situations involving imminent danger to health or gross deception of the consumer. However, the agency does not believe that it is necessary to specifically list publicity as a type of informal enforcement action in the final rule below. This type of action is included among the "other administrative enforcement actions" that are listed in proposed § 100.2(j)(1).

4. Several comments expressed concern that informal enforcement actions taken by FDA will preclude formal enforcement actions that could be taken by the State. One of these comments said there was no indication in the 1990 amendments that Congress intended the States to be preempted by anything other than formal action by FDA. Several comments wanted FDA to clarify that State and local enforcement mechanisms remain unaffected by the 1990 amendments.

Section 307(b)(2)(C) of the act states that no proceedings for the civil enforcement, or to restrain violations, of certain enumerated sections of the act may be commenced by a State if FDA has settled an informal or formal enforcement action against that food. Thus, contrary to what at least one

comment asserted, State action can be precluded by informal FDA action. Section 307 of the act, however, only applies to actions by a State to enforce certain sections of the act. Nothing in this section would preclude a State from taking action against a particular food under its own State law, even if FDA has commenced or settled an enforcement action against that food.

B. State Intervention in Criminal Proceedings

5. Several comments expressed concern that proposed § 100.2 would permit States to intervene as a matter of right in Federal criminal proceedings. The comments stated that no criminal authority was conferred upon the States by section 307(b)(1) of the act.

In response to these comments, FDA reconsidered whether to include criminal proceedings among the formal enforcement actions listed in proposed § 100.2(j)(2). While section 307(b) of the act is not clear on its face as to whether a pending criminal proceeding would, under section 307(b)(2)(B) or (C) of the act, preclude State action, there is nothing in the act to require the agency to hold that it would.

Therefore, FDA has decided to reverse the position that it tentatively took in the proposal. FDA is striking criminal actions from the list of formal enforcement actions in proposed § 100.2(j). FDA is revising this section to include only civil judicial enforcement action. As a result. § 100.2(j)(2) is coextensive with section 307(b)(1) of the act. A second result of this change will be that a pending Federal criminal action that arises out of a misbranding under the sections listed in section 307(b)(1) of the act will not serve to preclude a State from bringing a civil action under the act in Federal court against the underlying misbranding.

C. Agency Action Barring State Action Against Food in Federal Court

6. Several comments discussed the agency's statement that an agency action anywhere in the United States against the food in question would, under section 307(b)(2) of the act, bar a State action against the same food in Federal court. The majority of the comments agreed with this statement. One of the comments said that this preclusive effect should not be limited to FDA actions. This comment said that an action by a State to enforce the Federal law against a food within its jurisdiction precludes a second enforcement proceeding by another State or by FDA against the same food. The comment also said that if the States can enforce identical State regulations in the State courts, such actions should preclude an FDA action in the same State. Another comment, objecting to the agency's interpretation of the preemptive provisions of the 1990 amendments, argued that a State's action should be preempted only in cases where the FDA action will result in the discontinuation of the illegal practice in that State and in the nation. Finally, one comment requested that FDA revise proposed § 100.2 to provide that if the agency, upon notification by the State under section 307(b)(2) of the act, advises a State not to proceed, that State may not thereafter independently initiate enforcement proceedings based upon the same violations in State court under an identical State law.

The agency agrees in part with these comments. The enforcement actions available to the States under the provisions of section 307 of the act are seizure and injunction. The agency agrees that if FDA or a State brought a seizure action against a particular misbranding violation, the action would have a preclusive effect on another State or FDA. Section 304 of the act prohibits multiple seizures based on the same alleged misbranding of food. In light of the changes in section 307 of the act, who brings the first action, whether it is FDA or a State, would not be significant for the purposes of section 304 of the act. The first action filed would preclude any others.

In the case of an injunction, however, there is nothing in the act that limits the number of such actions that can be brought. Therefore, while an FDA injunction action would preclude State r enforcement actions under the act for at least 90 days under section 307(b)(2), such action by a State would have no effect on FDA's or another State's ability to bring an action. However, the agency also notes that particularly in this time of limited government resources, it is highly unlikely that any jurisdiction would bring a duplicative injunction action.

The agency does not agree that a State action to enforce a State law that is identical to the act against food in its own jurisdiction precludes an FDA action based on the same violation. Section 307 of the act applies only to proceedings to enforce the act. State law cannot act to preempt Federal law or to preclude Federal action. Conversely, the act does not give FDA the authority to preclude a State from enforcing an identical State law. If FDA advises a State that the agency is commencing or has settled an enforcement action or proceeding, then the State is precluded from bringing an action under the act in Federal court. The act does not prohibit a State from enforcing an identical State law. Nonetheless, FDA intends to work with the States to attempt to ensure that State provisions that are identical to provisions in the act are interpreted by the States in a way that is as consistent as possible with FDA's interpretation of the Federal provisions.

D. State Notification Letter

7. Several comments wanted States to provide FDA with evidence supporting the proposed action. The comments said that FDA should require the same evidence from a State that it requires from one of its district offices when reviewing proposed enforcement actions. These comments also wanted a State to inform FDA of the type of enforcement action that it expects to bring. On the other hand, one comment said that FDA was requiring too much information from States, and that the information that FDA is seeking may not be available at the beginning of an investigation. The comment stated that the 1990 amendments only require that a State give notice to FDA that it intends to bring an action, and that the detailed information being asked for by FDA would needlessly delay State enforcement action where an FDA action may not even be contemplated.

FDA stated in the preamble to the proposed regulation that it wanted the States to inform it of the type of action that they planned to take (56 FR 60534 at 60535). FDA included this provision as part of a parenthetical statement in the proposed format in § 100.2(d) (i.e., "name of products covered by the notification and the enforcement action that is to be initiated"). In view of the comments, and to eliminate any possible confusion, the agency is revising proposed § 100.2(d) to include in the format for the State's notification specific provision under item I., "Type of Enforcement Action," for the State to inform FDA of the type of action it is planning to take.

The agency disagrees with the suggestion that it require more specific information as part of the State notification, including a description of the evidence that the State is relying on to support its action. The agency considered the need for States to submit evidence to support the proposed action. However, the factors that FDA will consider in reviewing State notices of their intent to enforce certain sections of the act bear on different concerns than those that the agency considers in reviewing a recommendation from a district office.

When a district recommendation for an enforcement action is reviewed within the agency, there is a great deal

of concern about the merits of the case. A decision must be made as to whether to commit the agency's resources to prosecuting it. In reviewing a State notice of intent, FDA is not responding to the merits or strengths of the State's proposed action. The agency is only trying to determine whether FDA has taken is taking, or, in the near future, is likely to take action. The States may proceed if FDA has not commenced or settled an action. It is up to the courts to decide the merits of the Stated case. The information that the agency is asking a State to submit as part of its notification is the information that is necessary to ensure that the State and FDA are not duplicating efforts. Thus, FDA rejects the suggestion that it require the same information from a State as from its district offices.

The agency also disagrees with the request that the agency limit the information necessary in a notice. The comment suggested that the notice should be limited to only the names of the State and of the official giving notice, the name of the product involved, a copy of the label involved, when appropriate, and the alleged violation of the act. Although the 1990 amendments only require that the State give notice to the agency that it intends to bring an action, the information that the agency is asking the State to include in the notification letter is the information that is necessary if the agency is to provide a timely response to the State's notice.

The purpose of section 4 of the 1990 amendments is to provide a role for State enforcement of Federal statutory provisions that have preemptive effect (See 136 Congressional Record H5840 (July 30, 1990)). However, such a role requires close coordination between State and Federal officials. The agency believes that it is requesting the minimum amount of information that is necessary to ensure that such close coordination exists. As mentioned above, the types of action that are available to the States for the enforcement of the act under the provisions of section 307 of the act are seizure and injunction. The agency would expect that a State would normally have the information requested in proposed § 100.2(d) before it could initiate these types of actions. Thus, the agency doss not believe that compiling the information that it is requesting in proposed § 100.2 will delay State action.

However, the agency has reconsidered the provisions for the State notice in light of this comment, and has determined that format items E and F are redundant. Moreover, the agency recognizes that there may be situations, such as in the case of a seizure of misbranded food, where the identity of the responsible firm cannot be readily determined. Thus, the agency is modifying the format for the notice by deleting item F and revising item E to read "Name and Address of firm believed to be responsible for violations."

E. Response to State Notification Letter

8. Several comments disagreed with proposed § 100.2(h) that provided that the Director of the Division of Regulatory Guidance in the Office of Compliance at the Center for Food Safety and Applied Nutrition, FDA, will respond to the State notification letter. The comments suggested that the agency follow its existing procedures for formal enforcement actions under which such actions are taken with the concurrence of the Director of the Office of Compliance and the Chief Counsel along with review by the Office of Enforcement.

The agency disagrees with these comments. These comments do not correctly characterize the action that occurs as a result of the submission of a State notification. FDA's response to such a letter simply informs the State of action that FDA has taken or is taking, and it is not an evaluation of the merits of the State's case. The Division of Regulatory Guidance is the central focus within FDA for all enforcement actions regarding food. Thus, the agency concludes that it is appropriate that this division be given authority to inform a State whether Federal action is being taken concerning a particular product or firm.

9. Several comments stated that the relationship between the State and FDA once the State notification letter is submitted is not well understood.

Once a State has notified the agency of its intent to bring an action, FDA believes that it is incumbent on the agency to inform the State whether it (FDA) has commenced an informal or formal action pertaining to the food in question within 30 days of the State notification. FDA has reflected this obligation in proposed § 100.2(h). If FDA advises a State that the agency has commenced an informal or formal action, under section 307(b)(2)(B) of the act, the State must wait a total of 90 days before it can commence an action. FDA will also advise the State if the agency has not commenced an informal or formal action, in which case the State may proceed with its proposed action. FDA must either have an informal or formal action pending or begin such an action within 30 days of the State's initial notice, for the State to be precluded from taking the enforcement action, FDA will maintain communication with the State regarding the resolution of enforcement actions.

10. One comment requested that FDA clarify that once a State has begun an enforcement action against a particular product, "no new notice is required to add defendants to the State action there these defendants are involved in the same scheme or where these defendants are acting or participating with other defendants to sell the same product."

The question raised by the comment is too general for the agency to provide specific clarification. The agency notes that. it would generally agree that the simple addition of a corporate officer as a defendant or of an additional lot of a product in an action addressing a specific violation of the act would not require a new notice. However, the extension, of an action to include new corporate entities or differing products would likely require a new notice. The agency believes that proposed § 100.2(a) is sufficiently clear on this point that there is no need to revise the regulations.

F. Public Disclosure

11. One comment requested that FDA publicly disclose information contained in State notification letters, excluding trade secrets and confidential information. Several comments wanted public disclosure of information contained in FDA's response to State notification letters.

The agency believes that proposed § 100.2(1), regarding exemption from public disclosure of information in State notification letters, is appropriate. Section 20.61 of FDA's regulations (21 CFR 20.61) provides that trade secret and confidential commercial information is not available for public disclosure. Section 20.64 of FDA's regulations (21 CFR 20.64) provides that an investigatory record for law enforcement purposes may be withheld by the agency from public disclosure if disclosure of the record would interfere with enforcement proceedings and disclose investigative techniques and procedures. The State notification letter is an investigatory record in that it relates to a potential regulatory enforcement action. Such an investigatory record is available for public disclosure as provided in § 20.64(c) and (d).

Section 20.88 (21 CFR 20,88) provides that investigatory records compiled for law enforcement officials who perform counterpart functions to FDA at the State and local level are exempt from

public disclosure pursuant to § 20.64. The agency's response to a State notification letter is not available for public disclosure as provided by §§ 20.64 and 20.88.

G. Preemption and Enforcement

12. Several comments expressed concern that a State could enforce a State law that is identical to a section of the act but have an interpretation of the law that is different from FDA's interpretation of the act.

FDA realizes that it is possible for State laws that are identical to Federal laws to be interpreted differently by the different States. As discussed above, the agency believes that close cooperation between FDA and the States will ensure that goals of uniformity are met while still addressing the concerns of the citizens of a State.

H. FDA's Authority to Interpret the Act

In the preamble to the proposed regulations the agency stated that to avoid any suggestion of an unconstitutional delegation to States to enforce the 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. The agency stated that if FDA advises a State that its proposed action is inconsistent with FDA's interpretation, section 307 of the act requires that the State conform its interpretation to FDA's (56 FR 60534 at 605351060536).

13. Several comments agreed, and one comment disagreed, with this agency statement. One comment wanted the final rule to add a new § 100.2(h)(3) that would require the agency to advise the States that the interpretation of the act that they seek to enforce is inconsistent with FDA's interpretation, that the labeling in question does not violate the act, and that they may not bring an enforcement proceeding. The comment that disagreed said that it is up to the courts to decide the ultimate meaning of the provisions of the act in disagreements between the States and FDA.

As stated above, FDA generally will not be issuing an interpretation to the State of the Federal requirements when it responds to a State notification letter. It will merely inform the State that the agency has commenced or settled an informal or formal enforcement action or is prosecuting or has settled a court proceeding, or has done none of these things. Therefore, the final rule does not need to include a section to require the agency to advise a State that its interpretation is inconsistent with FDA's. However, after consideration of the comments, the agency continues to believe that the position that it enunciated in the proposal is correct for the reasons that it presented (see 56 PR 60534 at 60535 to 60536). Therefore, FDA reserves the right to advise a State that its proposed action is inconsistent with FDA's interpretation of the act and will do so as circumstances warrant.

14. Several comments wanted the agency to ensure that a mechanism was available to provide the States with agency interpretations. These comments wanted FDA to impose time limits upon itself to issue interpretations.

Whenever a State would like an interpretation of the act, it may seek an advisory opinion under § 10.85 (21 CFR 10.85). FDA will respond to the request in a timely manner. The agency's Division of Federal-State Relations also will work closely with the States to ensure that FDA's interpretations of the act and the agency's regulations on food labeling are made available to the States. The State Training Branch of FDA's Office of Regulatory Affairs will conduct training classes for the States after implementation of the final regulations.

15. One comment recommended that the agency consider establishing an advisory panel of State and local officials to assist FDA in the development of interpretations.

FDA is charged by Congress to enforce requirements of the act. Therefore, FDA believes that as a general matter, it is its responsibility to interpret the act. However, the agency also recognizes the value of receiving input from State and local officials as well as others in the development of its interpretations. To this end the agency is establishing a Food Advisory Committee that will consider a broad range of questions concerning food (57 FR 8128, March 6, 1992). FDA will be including representatives from State and local governments on this committee. The agency notes that it utilizes a number of other approaches to ensure that it is aware of State and local government concerns, including participation in activities of the Association of Food and Drug Officials and regular contacts with the State through FDA's Division of Federal-State Relations. Thus, FDA does not believe that it is necessary to establish a separate standing advisory panel of State and local officials as a regular part of FDA's process of interpreting the act.

III. Conclusion

FDA is revising proposed § 100.2(d) in response to comments submitted regarding the proposal on the State enforcement provisions of the 1990 amendments (56 FR 60534). FDA has revised proposed § 100.2(d), regarding the State notification letter format, by modifying the format item E to read "E. Name and address of firm believed to be responsible for violations." deleting item F, renumbering items G, H, and I as F, G, and H, and including a new format item I to read "I. Type of enforcement action." FDA has also modified proposed § 100.2(j)(2) to read: "formal enforcement actions" include seizures, injunctions, or other civil judicial enforcement actions that pertain to the food in question. The agency has adopted the remainder of the provisions of § 100.2 as proposed with only minor editorial revisions because the agency did not receive any comments concerning them, or because, as discussed above, the comments that it did receive did not justify a change.

IV. Economic Impact

In its November 1991 proposal, FDA concluded that the proposed requirements did not constitute a major rule and that no significant impact on a substantial number of small entities, including small business, would derive from this action. FDA has not received any new information or comments on the proposal that would alter its previous determination.

V. Paperwork Reduction

Section 100.2 of this final rule contains notification requirements that were submitted for review and approval to the Director of the Office of Management and Budget (OMB), as required by section 3504(h) of the Paperwork Reduction Act of 1980. The requirements were approved and assigned OMB control number 0910-0275.

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, 21 CFR part 100 is amended as follows:

PART 100—GENERAL

1. The authority citation for 21 CFR part 100 continues 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 (the 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 product(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.

To Whom It May Concern:

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 ———. (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 believed to be responsible for violations.

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

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

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

I. Type of enforcement action.

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 202-205-4642.

(g) FDA will notify the State of the date in 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, FDA, 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 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, or other civil judicial enforcement actions that pertain to the food in question.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910-0275.)

Dated: October 20,1992

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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