added to comply with paragraph (a)(3) of this section, and with or without safe and suitable bacterial cultures; and

(3) The product is not nutritionally inferior, as defined in § 101.3(e)(4), to butter as produced under 21 U.S.C. 321a.

(b) The performance characteristics (e.g., physical properties, organoleptic characteristics, functional properties, shelf life) of the product shall be similar to butter as produced under 21 U.S.C. 321a. If there is a significant difference in performance characteristics, the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for baking purposes"). Such statement shall appear on the principal display panel within the bottom 30 percent of the area of the label panel in type that shall be no less than ½ the size of the type used for such claim but no smaller than 1/16 of an inch.

(c) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of this part.

Dated: November 4, 1991.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 91-27158 Filed 11-26-91; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 100

[Docket No. 91N-0038]

RIN 0905-AD08

State Petitions Requesting Exemption From Federal Preemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to provide for petitions requesting exemption from preemption for certain State or local food standards and other labeling requirements that are preempted under the provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). The proposed regulations set out the procedures for the submission, and for agency review, of these petitions, and the information that the petitioner should supply. Petitions by State and local governments seeking exemption from specified preemptive Federal requirements are specifically authorized by the 1990 amendments.

DATES: Written comments by February 25, 1992. The agency is proposing that any final rule that may issue based upon this proposal become effective November 8, 1992, or 30 days after date of publication in the **Federal Register**, if earlier.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, 301-443-1731.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0229.

SUPPLEMENTARY INFORMATION:

I. Background

A. Federal Labeling Requirements Made Preemptive by the Nutrition Labeling and Education Act of 1990

The Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) (the 1990 amendments) amends the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*) (the act) to provide, among other things, for Federal preemption of certain food standards and labeling requirements issued by a State or a political subdivision of a State (hereinafter referred to collectively as "State"). Section 6(a) of the 1990 amendments adds section 403A to the act (21 U.S.C. 343-1) which provides that after the effective date of the operative provisions (prescribed in section 10(b) of the 1990 amendments), no State may directly or indirectly establish under any authority, or continue in effect as to any food in interstate commerce, any of the following types of requirements:

1. Any requirement for a food that is the subject of a standard of identity established under section 401 of the act (21 U.S.C. 341) that is not identical to such standard of identity or that is not identical to the requirements of section 403(g) of the act (21 U.S.C. 343(g)). Section 403(g) of the act states that a food is misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been established under section 401 of the act, unless it conforms to the definition and standard, and its label bears the name of the food specified in the definition and standard. Preemption of this type of requirement became effective on November 8, 1990, the date of enactment of the 1990 amendments (section 10(b)(1)(A) of the 1990 amendments).

2. Any requirement for the labeling of foods that relates to use of the term "imitation" that is not identical to the requirements of section 403(c) of the act; any requirement for label information identifying the manufacturer, packer, or distributor and the quantity of contents that is not identical to the requirements of section 403(e) of the act; and any requirement concerning the listing on the label of ingredients that is not identical to the requirements of section 403(i)(2) of the act. Preemption of these types of requirements (section 403A(a)(2) of the act) will take effect on November 8, 1991, 1 year after the date of the enactment of the 1990 amendments (section 10(b)(1)(B) of the 1990 amendments).

3. Any requirement for the labeling of food that is offered for sale under the name of another food that is not identical to the requirements of section 403(b) of the act; any requirement concerning a container that is so made, formed, or filled as to be misleading that is not identical to the requirements of section 403(d) of the act; any requirement concerning the prominence of required information on the label that is not identical to the requirements of section 403(f) of the act; any requirement concerning the labeling of a food purporting to be or represented as a food for which a standard of quality or a standard of fill has been established under section 401 of the act that is not identical to the requirement of section 403(h) of the act; any requirement that the label of a food bear the common or usual name of the food that is not identical to the requirements of section 403(i)(1) of the act; and any requirement that the label states whether a food contains any artificial flavoring, artificial coloring, or a chemical preservative that is not identical to the requirements of section 403(k) of the act. Under section 6(b) of the 1990 amendments, these six provisions (section 403A(a)(3) of the act) do not become preemptive until FDA determines that each is being adequately implemented by Federal regulations (see section 403(A)(a) of the act and section 10(b)(1)(C) of 1990 amendments).

Whether there is adequate implementation of the State and Federal requirements of the type addressed in section 403A(a)(3) of the act is being studied by the Committee on State Food Labeling of the National Academy of Sciences (the committee), Institute of Medicine, Food and Nutrition Board (56 FR 21388, May 8, 1991 (and 56 FR 55130, October 24, 1991)). Although the 1990 amendments state that the contract shall provide for completion of the committee's study by May 8, 1991, completion of the study and the committee's report has been delayed by unforeseen circumstances (56 FR 21388,

May 8, 1991 and 56 FR 55130, October 24, 1991). The committee has informed the agency that the study report will take more time than initially anticipated because of the magnitude of the undertaking and its importance, as well as the complexity of the issues involved.

The agency believes that the committee's report is crucial to the agency's development of a proposed list of which of the six provisions listed in section 403A(a)(3) of the act are being adequately implemented and which are not. Thus, a delay in publication of a proposed list beyond the August 8, 1991 date specified in the 1990 amendments is justified. The agency still expects to issue its final list of the sections of the act that are, and that are not, being adequately implemented by the November 8, 1992 deadline set in the 1990 amendments. If the agency does not issue a final list, the proposed list, which FDA expects to publish in early 1992, is to be considered the final list, and preemption will become effective on November 8, 1992 for those sections found to be adequately implemented in the proposed list.

Under the amendments, FDA is to also propose revisions by November 8, 1992, and issue final revisions by May 8, 1993, to any regulations found to be inadequately implemented (sec. 6(b)(3) of the 1990 amendments). Preemption will become effective on the effective date of the final revisions to any regulations initially found to be inadequate. If the agency does not issue final revisions by May 8, 1993, the proposed revisions will be considered the final revisions under the 1990 amendments, and preemption will become effective on May 8, 1993.

4. Any requirement for nutrition labeling or for nutrient content or health claims on food labels that is not identical to the requirements of section 403 (q) and (r) of the act. The 1990 amendments amended section 403 of the act by adding paragraphs (q) and (r) pertaining to nutrition labeling and label claims (nutrient content and health claims), respectively. Preemption of nutrition labeling requirements and requirements for label claims (section 403A (a)(4) and (a)(5) of the act) will become effective when regulations to implement sections 403 (q) and (r) of the act take effect (section 10 (b)(1)(D) and (b)(1)(E) of the 1990 amendments).

However, section 10(b)(2) of the 1990 amendments creates an exception to the effective dates for preemption granted under section 403A (a)(3), (a)(4), and (a)(5) of the act. Under this exception, if a State submits a petition for exemption from Federal preemption under section 403A(b) of the act within 18 months of enactment, i.e., by May 8, 1992, the State requirement will not be preempted until 24 months after the date of enactment of the 1990 amendments (November 8, 1992), or until FDA acts on the petition, whichever is later.

B. State Petitions for Exemption From Federal Preemption

The 1990 amendments also add section 403A(b) of the act, which permits the States to petition FDA for an exemption from the Federal preemption granted by section 403A(a) of the act. Three criteria must be met for an exemption to be granted. The State must show through the petition that the State requirement: (1) Would not cause any food to be in violation of any applicable requirement under Federal law, (2) would not unduly burden interstate commerce, and (3) addresses a particular need for information not met by the requirements of Federal law.

In the **Federal Register** of March 14, 1991 (56 FR 10906), the agency announced that it was developing procedural regulations to govern the content, substance, and agency review of State petitions in addition to the other types of petitions (petitions for health claims and nutrient content claims) specifically authorized by the 1990 amendments. In the March 14, 1991 notice, the agency stated its belief that the issuance of procedural regulations is a necessary first step in providing the framework within which a petitioner can develop the petitions authorized by the 1990 amendments, and within which the agency can evaluate and act on such petitions. In the same notice, the agency also advised that it will deny or defer action on any petition requesting action under the 1990 amendments that is submitted before issuance of final procedural regulations for petitions. However, as noted above, the 1990 amendments give special standing to States that submit petitions by May 8, 1992, seeking exemption from the preemption provisions of section 403A(a)(3), (a)(4), and (a)(5) of the act (section 10(b)(2) of the 1990 amendments). It would, therefore, be improper to deny such petitions because procedural regulations for State petitions have not been issued. The agency thus stated in the March 14, 1991 notice that it is likely to defer action on, rather than to deny, State petitions given this special standing until after this proposed rule is finalized. The agency requested information and comments from interested persons on the March 14, 1991 notice. The agency is reflecting section 10(b)(2) of the 1990 amendments in proposed § 100.1(g).

C. Comments to Agency Notice on Procedural Regulations

Twelve comments were received from States, industry, industry trade associations, and consumer interest groups in response to the March 14, 1991 notice. The comments were considered, and many of the recommendations were incorporated, or otherwise used, in the development of this proposed rule.

One comment requested that FDA withdraw the March 14, 1991 notice and not develop procedural regulations for petitions authorized by the 1990 amendments. The comment characterized the development of procedural regulations as a waste of agency resources, and stated that the development of regulations could take years to complete.

The agency disagrees with this comment. The 1990 amendments contemplate that the agency may issue regulations prescribing the conditions under which a State requirement may be exempt from Federal preemption. Section 403A(b) of the act specifically authorizes the agency to grant such exemptions from preemption "under such conditions as may be prescribed by regulation." Furthermore, the agency believes that it is essential that a State provide the agency with the necessary information to facilitate the agency's review of these petitions and to enable it to make the findings required by section 403A(b) of the act. The agency believes that the development of procedural regulations that specify the format of State petitions and the information that should be included in such petitions: (1) Will result in the most efficient use of the agency's and the States resources, (2) will expedite the review and the decision-making process, and (3) will enable the agency to evaluate all petitions in a consistent manner.

Some comments recommended that petitions for exemption from preemption be submitted as citizens' petitions under § 10.30 (21 CFR 10.30).

The agency believes that § 10.30 alone does not provide adequate guidance to a State seeking exemption from preemption, especially with respect to the specific showings required of a petitioner by the 1990 amendments. However, some of the provisions of § 10.30 are applicable to State petitions and have been adopted in the proposed procedural regulation as described in the next section.

Other comments recommended that the petition procedure be modeled after the Consumer Product Safety Commission's (CPSC) regulations for the

exemption of State requirements from preemption by the provisions of the Flammable Fabrics Act (15 U.S.C. 1191 *et seq.*), the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*), the Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*), and the Poison Prevention Packaging Act (15 U.S.C. 1471 *et seq.*) (56 FR 3414, January 30, 1991). As is the case for the 1990 amendments, the preemption provisions of the four CPSC administered acts expressly bar differing State requirements unless exemption is granted by the Federal agency upon petition by a State.

An exemption may be granted by the CPSC only if it finds that compliance with the State requirement will not result in a violation of the applicable CPSC requirements; that the State requirement provides a substantially higher degree of protection than the CPSC requirement from the risk of illness or injury that they both address; and that the State requirement does not unduly burden interstate commerce. In 1977, the United States District Court for the District of Minnesota in *Cosmetic, Toiletry and Fragrance Association, Inc., et al.* v. *State of Minnesota et al.*, 440 F. Supp. 1216 (D. Minn. 1977), *affirmed* 575 F.2d 1256 (8th Cir. 1978), in examining the preemption provisions of the CPSC administered acts, described this approach as representing "the most appropriate response to the factors present in the modern regulatory process—legislative rulemaking on a national scale, state attempts to provide a greater degree of protection, and corresponding burdens on interstate commerce. As it also represents the most recent Congressional response, the court suspects that it would probably be adopted if Congress were once again to legislate with regards to food, drug, and cosmetic products." The 1990 amendments are a more recent congressional response, and Congress did adopt similar criteria.

The recommendation that the CPSC regulations serve as a model for this proposed rule has merit because the CPSC regulations and this proposed rule pertain to the same matter-exemption from preemption. Further, the agency finds the general format of the CPSC regulations to be useful and appropriate as a general format for the procedural regulations that the agency is proposing herein. The agency has therefore followed the same general format in its proposed regulation as is in the CPSC regulations in 16 CFR part 1061. However, many of the substantive elements of FDA's regulation differ from those of the CPSC regulation inasmuch as they address the substantive requirements of 1990 amendments.

Some comments requested that individuals or parties other than States be accorded the right to petition for exemption.

The agency believes that only States have legal standing to petition for exemption. The agency's opinion is based on the wording in the 1990 amendments that, "Upon petition of a State or a political subdivision of a State, the agency may exempt * * *." Thus, Congress did not authorize petitions from other parties.

Two comments indicated to the agency that preemption is not well understood. These comments stated that a State should be able to petition for an exemption from preemption when the State has labeling requirements that are not addressed directly or indirectly by Federal law, or when the State requirement is not preempted by any Federal law, either explicitly or implicitly.

The agency is not taking any action in response to these comments. If a State requirement is not preempted by a Federal law, it simply makes no sense to provide a mechanism by which a State can seek exemption from preemption for that requirement. An exemption is an immunity from a requirement. If the requirement does not apply, that is, the State requirement is not subject to preemption, there is no need for a mechanism by which the immunity may be sought.

Moreover, section 6(c)(1) of the 1990 amendments clearly manifests Congress's intention that the 1990 amendments "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Act." Section 403A of the act is only operative in matters where there is a Federal requirement applicable to the labeling addressed in the State requirement. If there is no applicable Federal requirement that has been given preemptive status by Congress, there is no competing claim of jurisdiction, and, therefore, no basis under the 1990 amendments for Federal preemption or grounds to justify the submission of a State petition for exemption. Therefore, FDA has no authority under the 1990 amendments to rule on State petitions for exemption where the 1990 amendments have not imposed such Federal requirements. Of course section 6(c)(3) of the 1990 amendments provides that the amendments shall not affect any preemption, expressed or implied, which arises under the Constitution or other provisions of Federal law or regulation.

Several examples of the types of State requirements that would not be subject to the preemption provisions of the 1990 amendments were given in the Congressional Record of July 30, 1990 (H5843). The examples included State laws pertaining to issues for which there is no national framework, such as open date labeling, unit price labeling, container deposit labeling, religious dietary labeling, and previously frozen labeling.

Comments from States and consumer interest groups advocated that the agency apply liberal criteria in establishing the types and degree of information necessary to sustain a State's burden of proof in a petition. Comments from the food industry advocated strict construction of the 1990 amendments, and thus a more exacting standard for information requirements for State petitions.

In construing the provisions for exemption from preemption, the agency is guided by the policy in Executive Order 12612 (E.O. 12612) of October 26, 1987 on federalism (52 FR 41685 at 41687, October 30, 1987) that preemption of State law shall be restricted to the minimum level necessary to achieve the objectives of the statute. A corollary of this policy is that exemption from preemption should be liberally granted to the extent that the statutory objectives are fulfilled. FDA will consider E.O. 12612 as part of its review of any petitions that it receives.

The agency therefore must determine what effect a grant of an exemption from preemption will have on the congressional objective of providing national uniformity for certain aspects of food labels and labeling. Congress noted that since the enactment of the act in 1938, major changes have taken place in the marketing of foods in the U.S. The last 50 years have seen a decline in the numbers of plants and companies that serve regional markets and an increase in the nationwide distribution and marketing of foods. As one of the Senate sponsors of the bill that became the 1990 amendments stated:

> Today, we have a single food supply. Therefore, we need a single, integrated, and coordinated system with an appropriate allocation of regulatory responsibility among the Federal, State, and local governments. And, we need this for a reason: We must have confidence in the safety of our national food supply; and we must have consumers who can make informed decisions so they can adopt sound dietary practices.

(Congressional Record, S16611, October 24, 1990.)

Congress included limited express preemption in the 1990 amendments

because, according to one of the managers of the bill in the House,

> * * * it was decided that the fairest way to expect the food industry to support a nutrition labeling bill, was to give them some types of preemption of burdensome State laws that interfered with their ability to do business in all 50 States. Therefore, the bill provides industry with uniformity of law in a number of important areas—such as standards of identity, imitation labeling, and ingredient labeling—that will permit them to conduct their business in an efficient and cost-effective manner.

(Congressional Record, H12954, October 26, 1990.)

Congress reserved to the States the option of putting into effect composition or labeling requirements that differ from, and are more stringent than, Federal requirements providing that the States can demonstrate that the statutory criteria for exemption from preemption are met. The agency has included in the proposed regulations set forth below the matters that it considers necessary for a State to address to justify an exemption. A more liberal and less exacting interpretation of the types and depth of information required to sustain a State's burden of proof in a petition would undermine the congressional objective of national uniformity in certain aspects of food labeling.

Several States suggested that an exemption be granted by an advisory opinion rather than by regulation.

Although the 1990 amendments do not require that the exemption be granted by regulation, the agency believes that exempting a State requirement from Federal preemption is a type of action that may significantly affect many parties, including industry and consumers, and as such, the agency is proposing that such exemption be granted by notice and comment rulemaking. The rulemaking process will provide interested parties with the opportunity to comment on a proposed regulation granting exemption. If the agency determines that exemption should be granted, codification of the exemption in the food labeling regulations will ensure that all of the relevant information concerning the exemption, including its scope and conditions, is readily accessible for examination by all affected parties.

II. Proposed Regulation

The proposed rule states in § 100.1(a) the scope and purpose of the procedural regulation and cites the statutory authority for the agency to act on State petitions requesting exemption from preemption. Proposed § 100.1(b) defines the terms used in the proposed regulation.

In proposed § 100.1(c), the regulation lists the prerequisites that must be met for the merits of the petition to be considered. The State requirement must have been enacted in its final form and must either be in effect or would be in effect but for the provisions of section 403A(a) of the act (proposed § 100.1(c)(1)).

Under proposed § 100.1(c)(2), the preemptive Federal regulation also must have the full force and effect of law. However, FDA is proposing that a petition seeking exemption from a Federal requirement that has been published as a final rule with a designated effective date may be submitted before the effective date of that final rule. Petitions seeking exemption from Federal requirements that are preemptive under sections 403A (a)(3) through (a)(5) of the act and that are submitted before May 8, 1992 will be considered timely even though the requirements for which exemption from preemption is requested may not actually be in effect on that date. This portion of proposed § 100.1(c)(2) reflects the special standing given these petitions under section 10(b)(2) of the 1990 amendments.

Proposed § 100.1(c)(3) requires that the petitioner must be an official of the State having authority to act for, or on behalf of, the State in applying for an exemption.

Proposed § 100.1(c)(4) reflects that a State requirement is subject to preemption under section 403A(a) of the act if it is not identical to the corresponding Federal requirement. In proposed § 100.1(c)(4), the agency advises that it interprets the term "not identical" to mean that the State imposes obligations or contains provisions that are not imposed by or contained in the applicable Federal law regulation, including a standard of identity, quality, or fill, or that differ from those imposed by or contained by the applicable Federal law or regulation. Therefore proposed § 100.1(c) defines "not identical" as follows:

> "Not identical" does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that: (1) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act, or (2) differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the Act.

The requirements for petitions under section 403A(b) of the act are proposed in the petition format requirements in § 100.1(d). The petitioner should identify and document the State requirement for which exemption is sought, identify the Federal requirement that is believed to preempt the State requirement, explain the rationale of the State requirement, and compare it to the Federal requirement. The petitioner should address with specificity the grounds for exemption from preemption stated in the 1990 amendments. In this regard, the State will be expected to show that the State requirement will not cause a food label to be in violation of any applicable requirement under Federal law. In a case where a State requirement would allow for the violation of any Federal requirement, the agency could not grant the petition. The State would be free, however, to submit a citizen petition to the agency under § 10.30 to amend the Federal requirement to the extent the agency could affect such an amendment by regulation. The State will also have to supply specific information on the effect that the granting of exemption will have on interstate commerce. This information will be used by the agency in reaching a finding as to whether granting the exemption will unduly burden interstate commerce. Finally, the petitioner should identify and discuss the particular information need that the State requirement is designed to meet that is not met by Federal law. In this context, any public health considerations will be relevant.

The proposal also states that the petition needs to include a claim for a categorical exclusion under 21 CFR 25.24 or an environmental assessment under 21 CFR 25.31. Finally, the proposal states that the petition should include the name and address of the person to be notified of the agency's action concerning the petition and a certification by the petitioner that to his best knowledge and belief, the petition includes all information and views on which it relies.

The proposed rule provides in § 100.1(e) that public disclosure of State petitions will be governed by the rules specified in § 10.20(j). Proposed § 100.1(f) details the procedures for the agency's consideration of State petitions. Section 100.1(f)(1) states that unless otherwise specified, all relevant provisions and requirements of 21 CFR Part 10—Administrative Practices and Procedures, Subpart B—General Administrative Procedures, are applicable to State petitions requesting exemption from Federal preemption under section 403A(b) of the Act. Such provisions include the opportunity for an interested person to request

reconsideration of the agency's decision on a petition under § 10.33.

Proposed § 100.1(f)(2) provides that if a petition does not meet the prerequisite requirements of § 100.1(c), the agency will issue a letter to the petitioner denying the petition and stating in what respect the petition did not meet the prerequisite requirements. Proposed § 100.1(f)(3) states that if a petition appears to meet the prerequisite requirements in § 100.1(c), it will be filed by the Dockets Management Branch, stamped with the date of filing, and assigned a docket number to be used for all subsequent submissions relating to the petition. The filing of the petition is without prejudice concerning the agency's final action on the petition. Proposed § 100.1(f)(4) provides that any interested person may submit written comments on a filed petition as provided in § 10.30(d).

Proposed § 100.1(f)(5) provides that within 90 days of the date of filing, the agency will furnish a response to the petitioner. The response will either: (1) State that the agency has tentatively determined that the petition merits the granting of an exemption, and that FDA intends to publish in the **Federal Register** a proposal to grant the exemption through rulemaking, (2) deny the petition and state the reasons for such denial, or (3) provide a tentative response stating 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.

An exemption under this proposed regulation will be granted only to the petitioner State. Exemption from preemption is largely based on an evaluation of a unique situation within a State. Should a situation arise that is more national in scope, the agency would consider amending the Federal requirement because the action requested would be more universal than that envisioned by Congress in providing for exemption.

III. 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.

IV. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the provisions of § 100.1 *Petitions requesting exemption from preemption for State or local requirements* relating to submission of petitions 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.

V. Economic Impact and Federalism Implications

FDA has examined the economic implications of the proposed rule pertaining to 21 CFR part 100 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. As discussed in section I.C. of this document, FDA has fully considered the effect of Executive Order 12612.

This proposed regulation codifies procedures to be followed by a State or local government in petitioning the agency for an exemption from preemption by Federal food standards and labeling regulations. FDA has no information as to the cost to a State to prepare and submit the required petition to the agency; however, the petition process has been structured to minimize the paperwork burden on the State. If, for example, the required paperwork costs $100 per State action to prepare, it would take over 1 million enforcement actions to cause this proposed requirement to become a major rule, an unlikely event. Thus, 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.

VI. 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.

VII. 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, or 30 days after publication in the **Federal Register**, if earlier. The agency believes that November 8, 1992, is the appropriate effective date for these petition regulations because that is the date on which section 307 of the act becomes effective, under which States may bring enforcement actions in their own names in Federal courts for violations of Federal requirements having preemptive effect under the 1990 amendments. November 8, 1992, is also the date by which the agency is to have published final regulations implementing sections 403(q) and 403(r) (see sections 2(b) and 3(1)(B) of the 1990 amendments) as well as a list of sections adequately implementing the statutory requirements specified in section 403A(a)(3) (see section 6(b)(3)(B) 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 continues to read as follows:

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

2. A new subpart A consisting of § 100.1 is added to read as follows:

Subpart A—State and Local Requirements

§ 100.1 Petitions requesting exemption from preemption for State or local requirements.

(a) *Scope and purpose.* (1) This subpart applies to the submission and consideration of petitions under section 403A(b) of the Federal Food, Drug and Cosmetic Act (the act), by a State or a political subdivision of a State, requesting exemption of a State requirement from preemption under section 403A(a) of the act.

(2) Section 403A(b) of the act provides that where a State requirement has been preempted under section 403A(a) of the act, the State may petition the agency

for an exemption. The agency may grant the exemption if the agency finds that the State requirement will not cause any food to be in violation of any applicable requirement under Federal law, will not unduly burden interstate commerce, and is designed to address a particular need for information that is not met by the preemptive Federal requirement.

(b) *Definitions.* (1) *Act* means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

(2) *Agency* means the Food and Drug Administration.

(3) *Commissioner* means the Commissioner of Food and Drugs.

(4) *State* means a State as defined in section 201(a)(1) of the act (which includes a territory of the United States, the District of Columbia, and Puerto Rico) or any political subdivision of a State having authority to issue food standards and food labeling regulations having force of law.

(5) *State requirement* means any statute, standard, regulation, or other requirement that is issued by a State.

(c) *Prerequisites for petitions for exemption from preemption.* The Food and Drug Administration will consider a petition for exemption from preemption on its merits only if the petition demonstrates that:

(1) The State requirement was enacted or was issued as a final rule by an authorized official of the State and is in effect or would be in effect but for the provisions of section 403A of the act.

(2) The State requirement is subject to preemption under section 403A(a) of the act because of a statutory provision listed in that section or because of a Federal standard or other Federal regulation that is in effect, or that has been published as a final rule with a designated effective date, and that was issued under the authority of a statutory provision listed in that section. For the purposes of this subpart, all petitions seeking exemption from preemption under section 403A(a)(3) through (a)(5) of the act, if submitted before May 8, 1992, will be considered timely even though the applicable statutory provisions or regulations are not yet in effect.

(3) The petitioner is an official of a State having authority to act for, or on behalf of, the Government in applying for an exemption of State requirements from preemption.

(4) The State requirement is subject to preemption under section 403A(a) of the act because it is not identical to the requirement of the preemptive Federal statutory provision or regulation including a standard of identity, quantity, and fill. *Not identical* does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that:

(i) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act; or

(ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act.

(d) *Form of Petition.* (1) All information included in the petition should meet the general requirements of § 10.20(c) of this chapter.

(2) Four copies of the petition for exemption from preemption for a State requirement shall be submitted to the Dockets Management Branch in the following form:

(Date)_____

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

Petition Requesting Exemption From Preemption for State Requirement

The undersigned submits this petition under section 403A(b) of the Federal Food, Drug, and Cosmetic Act to request that the Food and Drug Administration exempt a State requirement from preemption.

The undersigned has authority to act for, or on behalf of, the (*identify State or political subdivision of the State*) because (*document petitioner's authority to submit petition on behalf of the State*).

A. Action Requested

1. Identify and give the exact wording of the State requirement and give date it was enacted or issued in final form.

2. Identify the specific standard or regulation that is believed to preempt the State requirement and the section and paragraph of the act that the standard or regulation implements.

B. Documentation of State Requirement

Provide a copy of the State requirement that is the subject of the application. Where available, the application should also include copies of any legislative history or background materials used in issuing the requirement, including hearing reports or studies concerning the development or consideration of the requirement.

C. Statement of Grounds

A petition for an exemption from preemption should contain the following:

1. An explanation of the State requirement and its rationale, and a comparison of State and Federal requirements to show differences.

2. An explanation of why compliance with the State requirement would not cause a food to be in violation of any applicable requirement under Federal law.

3. Information on the effect that granting the State petition will have on interstate commerce. The petition should contain information on economic feasibility, i.e., whether the State and Federal requirements have significantly different effects on the production and distribution of the food product; comparison of the costs of compliance as shown by data or information on the actual or anticipated effect of the State and Federal requirements on the sale and price of the food product in interstate commerce; and the effect of the State requirement on the availability of the food product to consumers. To the extent possible, the petition should include information showing that it is practical and feasible for producers of food products to comply with the State requirement. Such information may be submitted in the form of statements from affected persons indicating their ability to comply.

4. Identification of a particular need for information that the State requirement is designed to meet, which need is not met by Federal law. The petition should describe the conditions that require the State to petition for an exemption, the information need that the State requirement fulfills, the inadequacy of the Federal requirement in addressing this need, and the geographical area or political subdivision in which such need exists.

D. Environmental Impact

The petition shall contain a claim for categorical exclusion under 21 CFR 25.24 or an environmental assessment under 21 CFR 25.31.

E. Notification

Provide name and address of person, branch, department, or other instrumentality of the State government that should be notified of the Commissioner's action concerning the petition.

F. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies.

(Signature) _____
(Name of petitioner) _____
(Mailing address) _____
(Telephone number) _____

(e) *Submission of petition for exemption; public disclosure.* The availability for public disclosure of a petition for exemption will be governed by the rules specified in § 10.20(j) of this chapter.

(f) *Agency consideration of petitions.* (1) Unless otherwise specified in this section, all relevant provisions and requirements of subpart B of part 10 of this chapter, are applicable to State petitions requesting exemption from Federal preemption under section 403A(b) of the act.

(2) If a petition does not meet the prerequisite requirements of paragraph (c) of this section, the agency will issue a letter to the petitioner denying the

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