DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to provide for petitions requesting exemption from preemption for State or local food standards and for certain other State or local labeling requirements that are preempted under the provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). The 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.

EFFECTIVE DATE: February 5, 1993.

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SUPPLEMENTARY INFORMATION:

I. Background

In response to requirements of the 1990 amendments (Pub. L. 101-535) FDA published in the **Federal Register** of November 27, 1991 (56 FR 60528), a proposal to provide for petitions requesting exemption from preemption for State or local food standards and for certain other State or local labeling requirements that are preempted under the provisions of 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. Interested persons were given until February 25, 1992, to comment.

FDA received over 50 letters, each containing one or more comments, from industry, trade associations, States, government organizations, consumer organizations, a Congressman, and a consumer. The comments generally supported the proposal. Several letters submitted in response to the proposal addressed issues outside the scope of the proposal and will not be discussed here. A number of comments disagreed with, and requested clarification of, various aspects of the 1990 amendments or the proposal. Some of these comments suggested modification and revision in various provisions of the proposal. A summary of the comments and the agency's responses follow.

II. General Comments

1. One comment asserted that individuals should have the right to petition for exemption. The comment stated that this would allow for a more universally equitable resolution of preemption Issues.

Only States and political subdivisions of States have legal standing to petition for exemption. Section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343-1(b)) provides only that upon the petition of a State or a political subdivision, of a State, the Secretary may exempt a State or local requirement from the effect of section 403A(a) of the act Thus, Congress did not provide for petitions from other parties, and the agency has no authority to grant the comment's request.

2. Some comments wanted to know if State requirements were preempted when the products in question were strictly intrastate products.

The agency advises that under section 403A(a) of the act, State requirements are not subject to preemption to the extent that they apply to intrastate products.

III. What State Laws are Covered

A. "Not Identical To"

3. One comment suggested that whether a State or political subdivision of a State needs to seek exemption from preemption for a law or regulation should be based on whether there are substantive differences between the State and the Federal requirements.

The agency does not accept the comment. While the results under the comment's suggested test might be the same as under the agency's proposal, FDA believes its proposal is more consistent with the statutory test. Under § 100.1(c)(4), if the State requirement is identical to the Federal law, it is not subject to preemption under section 403A(a) of the act. In addition, if the State requirement, does the same thing that the Federal law does, even if the words are not the same, then it is effectively the same requirement as the Federal requirement. FDA's' view, as embodied in § 100.1(c)[4), is that such a State or local requirement need not be preempted, and that there is consequently no need to exempt it from preemption. Therefore, the only State requirements that are subject to preemption are those that are affirmatively different on matters that are covered by section 403A(a) of the act.

A State will only petition for exemption of a requirement from preemption if the requirement is, or the State has a good reason to believe that it is, subject to preemption. The agency believes that the petition process that it is establishing provides States with an appropriate mechanism for requesting such an exemption from preemption. If a State can adequately demonstrate the need for the labeling requirement, that such requirement will not cause a food to be in violation of Federal law, and that it will not unduly burden interstate commerce, then FDA will propose to grant the exemption.

B. More Stringent State Requirements

4. Several comments expressed concern that stringent State laws may be preempted by less restrictive Federal regulations. These comments said that States should retain the authority to enforce strict State laws that serve the needs of its citizens. One of the comments was concerned that its regulation pertaining to open dating for perishable and semiperishable food products would be preempted, and It would be precluded from enforcing these open-dating provisions. Another comment said that producers who are able to successfully differentiate their products based on superior quality should not be prevented by Federal law from marketing that product under a State standard that rewards that quality.

FDA acknowledges that some stringent State laws will be preempted by less restrictive Federal regulations. However, one of the goals of the 1990 amendments is national uniformity in certain aspects of food labeling, so that the food industry can market its products efficiently in all 50 States in a cost-effective manner (Statement of Rep. Madigan, 136 Congressional Record H12954, October 26, 1990). Thus, in enacting the 1990 amendments, Congress decided that even though Federal requirements may preempt more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result. In regard to open dating, the agency notes that Stats laws and regulations will not be preempted because FDA does not have authority to establish such requirements under the

sections of the act that have been given preemptive effect. Therefore, a State will not be precluded from enforcing its open-dating provisions With respect to the latter comment, the agency advises that producers who choose to market a superior quality product are not precluded by Federal preemption from doing so.

In response to inquiries from State officials and food producers concerned about the consequences of the preemption provisions, FDA has informed them that while the agency may act in the future to remove from its regulations any provisions that permit more stringent State requirements, those provisions remain in place for the moment and presumably have the force and effect of law. FDA does not intend to interfere with actions by States to enforce their standards based on existing regulations.

C. State Common or Usual Name Regulations

5. Several comments questioned whether a State common or usual name regulation was preempted if the regulation was promulgated in conformance with § 102.5 *General principles* (21 CFR 102.5), and it is a food for which FDA has not adopted a common or usual name as a standard.

Section 403(i)(1) of the act, which requires that the label of a food bear its common or usual name, if any, is one of six misbranding sections of the act identified in section 403A(a)(3) of the act that were the subject of a study mandated by section 6(b) of the 1990 amendments. The purpose of the study was to determine which of the six sections are adequately being implemented by FDA regulations and which are not. The agency contracted with the National Academy of Sciences, Institute of Medicine (IOM) to conduct the study.

On July 28,1992 (57 FR 33283), as required by the 1990 amendments, the agency published its proposed lists of those sections that are adequately being implemented and those sections that are not. Based on the IOM's recommendations, the agency tentatively concluded that FDA regulations in part 102 (21 CFR part 102) adequately establish procedures for the development and application of common or usual names under section 403(i)(1)of the act.

The agency is publishing elsewhere in this issue of the **Federal Register** a final rule entitled, "Certain Misbranding Sections of the Federal Food, Drug, and Cosmetic Act That Are, and That Are Not, Adequately Being Implemented by Regulation Notice of Final Lists." Based upon FDA's evaluation of the recommendations of the IOM, its consideration of the comments on the proposed lists, and other available information, the agency provides in that final rule its finding that section 403(i).(1) of the act is being adequately implemented.

Section 6(b))(3)(B) of the 1990 amendments provides that "With respect to a section which is found by the Secretary to be adequately implemented, no State or political subdivision of a State may establish or continue in effect as to any food in interstate commerce any requirement which is not identical to such section." Thus, a State common or usual name regulation promulgated in conformance with § 102.5 for a food for which there is no specific Federal common or usual name regulation is preempted. However, the agency would consider an exemption for preemption based on the conditions that led the State to believe that there was a need for the State common or usual name regulation.

D. State Standards of Identity, Quality, or Fill Regulations

6. Several comments asked whether a State standard of identity, quality, or fill is preempted if it is for a food for which there are no Federal standards.

Under section 403A(a)(1) of the act, a State may not establish or continue in effect a standard of identity, quality, or fill for a food that is the subject of a standard of identity under section 401 of the act (21 U.S.C. 341) that is not identical to the Federal standard. If there is no Federal standard of identity, quality, or fill for a particular food, then there is no basis, under the terms of section 403A(a)(1) of the act, for finding that there is Federal preemption. By contrast, under section 403A(a)(2) through (a) (5) a State may not establish or continue in effect any requirement "of the type" set forth in the sections of the act specified in section 403A(a)(2) through (a](5). Thus, State or local requirements can be preempted under section 403A(a)(2) through (a)(5) even if no analogous Federal regulation had been promulgated.

7. A comment noted that there was a typographical error in proposed § 100.1(c)(4) in that the word "quantity" should be "quality" instead.

The agency acknowledges the typographical error, and it has replaced the word "quantity" with the word "quality" in § 100.1 (c)(4) set forth below.

E. State Laws Adopted from the U.S. Department of Commerce Handbook

8. Two comments asked if the weights and measures standards for food products adopted by States from U.S. Department of Commerce publications, contained in the National Institute of Standards and Technology (NIST) Handbook 130 1992 (Uniform Packaging and Labeling Regulation and the Uniform Regulation for the Method of Sale of Commodities) and the NIST Handbook 133 (Checking the Net Contents of Packaged Goods), would be preempted under the 1990 amendments. The comments said that the requirements of these publications do not appear to be different than those in § 101.105 *Declaration of net quantity of contents when exempt* (21 CFR 101.105) but do go into more detail. The comments asked if FDA would adopt these U.S. Department of Commerce publications as part of its regulations.

The agency advises that State requirements adopting U.S. Department of Commerce publications would not be subject to preemption if the State requirements can be considered to be identical to § 101.105. FDA's view, as reflected in § 100.1(c)(4), is that the fact that the State requirements contain more detail than found in the Federal regulation does not necessarily mean that the State requirements would be subject to preemption. Preemption would occur only if the detailed information included in the State requirements imposes different or stricter requirements than provided for in §101.105.

To resolve any concerns that a State may have about a potential conflict between its requirement and a Federal requirement, a State may petition the agency for exemption from preemption for its requirement. If FDA concludes that the State requirement is identical to the Federal requirement, the agency will advise the State of that fact and deny the Stated petition without prejudice. While the agency's opinion is not binding, it will, if a question of preemption with regard to that State requirement is raised in court, provide evidence that the State requirement, in FDA's view, is not preempted. If the court later decides otherwise, the State still has the option of petitioning FDA for en exemption from preemption.

FDA is not adopting the U.S. Department of Commerce publications as part of its regulations at this time. However, because the issues surrounding the harmonization of FDA's regulations and the U.S. Department of Commerce publications that have been adopted and enforced by States are both

important and complex, the agency would welcome a meeting with the National Conference on Weights and Measures, State officials, and other interested Federal agencies to decide what steps are necessary and appropriate to ensure that FDA's regulations and the relevant Department of Commerce publications are harmonized.

9. A comment asked whether all the States that had adopted regulations identical to those the Department of Commerce publications had to petition for exemption, or whether FDA could issue a blanket example on for all of those States.

The agency advises that it will accept blanket exemption petitions that cover circumstances such as those represented by the example of the State regulations adopted in response to the U.S. Department of Commerce's publications. If, because of the detailed information from such publications that is included in the States' requirements, the States consider their regulations to be subject to preemption, one or more States should submit an exemption petition that meets the requirements set forth below in § 100.1. Among other things, the exemption petition would need to show the authority for the petitioner to act on behalf of the other States or political subdivisions of the States, identify the State requirements and the dates that they were enacted, and include a statement of the grounds upon which the petition is based. Depending upon the circumstances, the agency will consider granting an exemption from preemption for the requirements of each of the States or political subdivisions covered by the petition.

IV. State Petitions

A. General

10. Several comments objected to the statutory provision that allows a State to petition for an exemption from preemption by Federal food labeling regulations. These comments were of the view that all State laws regarding food labeling should be preempted by Federal food labeling regulations, and that States should not be allowed to petition for an exemption. On the other hand, another comment said that State laws regarding food labeling should not be preempted by Federal regulation, and thus there is no need for a process to petition for an exemption.

Section 403A(b) of the act specifically allows a State, or a political subdivision of a State, to petition the Secretary for an exemption from preemption. It states that the Secretary may, upon being petitioned by a State, or political subdivision of a State, exempt any State or local requirement that: (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) is designed to address a need for information that is not met by the misbranding sections of the act referred to in section 403A(a) of the act. Given this provision, the agency has concluded that the procedures that it is establishing for the submission and consideration of petitions for exemption from preemption are necessary to effectuate the law. Therefore, the agency rejects the comments on this point.

B. Use of Medical Device Amendments as a Model

11. One comment suggested that FDA model its regulations on State petitions for exemption from preemption under the 1990 amendments after FDA's medical device regulations for such exemptions (21 CFR 803.20, 808.25, and 808.35) rather than after the Consumer Product Safety Commission (CPSC) regulations. The comment asserted that the medical device regulations are better suited as a model because they are more comprehensive than the CPSC regulations. The comment noted that the medical device regulations require States to provide more information in the petition than they would be required to provide under proposed § 100.1 and provide interested persons with an opportunity to have an oral hearing on whether a petition should be granted.

The agency does not believe that the medical device regulations on exemption petitions are an appropriate model for implementing the 1990 amendments. The statutory provisions under which the medical device regulations were promulgated are different from the 1990 amendments in a fundamental respect. The medical device statutory provisions require a hearing. The 1990 amendments do not. Consequently, the agency chose to model its regulations after the CPSC regulations rather than the medical device regulations because the CPSC regulations provided a mechanism in which no hearing is required.

Moreover, the agency believes that the information proposed by FDA for submission by a State in its exemption petition is appropriate because it responds directly to the criteria established by section 403A(b) of the act. Accordingly, FDA is not making the suggested changes.

12. Several comments requested that FDA provide for the periodic review of granted exemptions and for the revocation of an exemption if the conditions that were present when the exemption was granted no longer exist. One comment noted that the medical device procedures provide for such revocation of previously granted exemption petitions.

The agency understands the concerns expressed by these comments and is open to citizen petitions to revoke an exemption if such revocation is warranted. However, the agency does not have the resources to commit itself to periodic reviews of exemptions granted to States. If an interested person becomes aware of a change in the conditions that led FDA to grant an exemption, that person can submit a citizen petition under § 10.30 *Citizen petition* (21 CFR 10.30) requesting revocation of that exemption. The agency will review any such petition that is submitted. If the petition shows that the conditions that justified an exemption no longer exist, the agency will consider revoking that exemption.

C. What the Petition Must Show About Effect on Interstate Commerce

13. Several comments suggested that FDA should balance a State or locality's particular need against the burden on interstate commerce in determining whether an exemption petition should be granted.

The agency does not believe that the test for whether a State requirement does, in fact, "unduly burden" interstate commerce is one of balancing burden versus need. The statute anticipates that a State or locality's need for a particular labeling requirement will be assessed separately under section 403A(b)(3). In case law interpreting "undue burden," the court equated the term with unfairness. (*See Mid-South Bottling Co. v. NLRB*, 876 F.2d 458, 461 (5th Cir. 1989)). Applying this unfairness standard, one could argue, for example, that if a State requirement can be readily accommodated (e.g., a stick-on label) or is not applied to out-of-state firms, it does not unduly burden interstate commerce. On the other hand, if the State requirement required a completely different label than would be appropriate everywhere else in the country, a strong argument could be made that it does unduly burden interstate commerce. Accordingly, the agency is not including the suggested balancing test as a criterion for determining whether a State's petition for exemption from preemption should be granted.

14. Several comments objected to the amount of information required in a State petition on the effect that granting it will have on interstate commerce. These comments were particularly

opposed to the agency's position that States should obtain information in the form of statements from producers of food products indicating that it is practical and feasible for them to comply with the State requirement.

The congressional intent in enacting the 1990 amendments was to provide national uniformity and to allow industry to conduct business in an efficient and cost-effective manner (136 Congressional Record H12954, October 26, 1990). Accordingly, the State has the burden to show why an exemption is appropriate, and why such an exemption, if granted, would not unduly burden interstate commerce.

To meet this burden, a State will need to contact industry to determine the effect of its regulations upon interstate commerce. Although a company may say that the burden is significant, the State would have the opportunity to show as part of its petition that the company's view is overstated and, therefore, does not provide a basis for denying the petition. Accordingly, the agency is retaining this requirement in the final rule.

15. Some comments requested that FDA require States to include more information in their petitions to show not only the costs of distributing products labeled differently for different States but also the cost of changing labels if an exemption petition is granted.

The agency proposed in § 100.1(d)(2) (Part C, Statement of Grounds) to only provide States with guidance as to what a petition for exemption from preemption should contain. The agency continues to believe, and it was not persuaded by the comments to conclude otherwise, that it is not appropriate to establish requirements on the contents of a State petition for an exemption from preemption. Therefore, FDA rejects the comments on this point. However, the agency does agree that the costs of changing labels and of using different labels in different localities bear on the issue of burden on interstate commerce and, therefore, should be included in the State's petition as part of the cost of compliance.

16. Some comments suggested that, with respect to possible burdens on interstate commerce, FDA should give more specific guidance about what it intends to consider in deciding whether to grant an exemption from preemption for a State or local requirement. One comment stated that the factors depicted in proposed § 100.1(d)(2) (i.e., economic feasibility, comparison of costs of compliance, effects on the availability of a food to consumers, and the practicality of industry compliance) do not accurately or fully summarize the constitutional considerations employed by Federal courts. The latter comment suggested that a State must be able to show: (1) The important public interests its regulation supposedly furthers. (2) that the regulation treats in-state and out-of-state manufacturers or advertisers evenhandedly, (3) the degree of burden imposed by the regulation, (4) that the burden is not clearly excessive in relation to any putative local benefits, (5) that the regulation does not project the State's standards into other States, and (6) that the regulation does not unduly impede the free flow of interstate commerce.

The agency believes that the guidance that it has provided in § 100.1(d)(2) (Part C, Statement of Grounds) as to the information necessary to support an exemption petition fully reflects the considerations that the Federal courts have applied in determining whether there is an undue burden on interstate commerce. The agency, however, with the exception of item (2) above, does not object to a State addressing the listed items in an exemption petition. With respect to item (2), the agency notes that it does not have jurisdiction over products manufactured and distributed in intrastate commerce, nor does it have jurisdiction over advertising, which is regulated by the Federal Trade Commission. Therefore, FDA considers this item to be of marginal relevance to the determination that the agency must make.

D. Particular Need for Information

17. Several comments argued that FDA has misinterpreted the portion of the 1990 amendments requiring a State to show a "particular need for information" to mean that a State or locality must show that a labeling requirement fulfills a unique local need in order to exempt a requirement from preemption. The comments stated that a petition for exemption from preemption should not be denied simply because the need for information is also national in scope.

While the agency agrees with the Comments' interpretation of the statute, an agency decision to grant an exemption from preemption is likely to be based largely on the agency's evaluation of the situation within the requesting State. If the need for an exemption is not only local, the agency is likely to consider whether it would not in fact be more appropriate to amend the relevant Federal regulation rather than grant an exemption. Therefore, while the agency is open and willing to consider any need for exemption asserted in a State petition, it seems prudent for such a petition to address the question of why the agency should limit its consideration to the exemption and not address the broader concern.

18. One comment suggested that FDA include a provision in the final rule that requires that petitions for exemption that are based on a claim that a particular Federal requirement fails to meet the petitioning State's particular local need be accompanied by a citizen's petition under § 10.30 to amend the Federal requirement. The comment said that the agency should defer consideration of the exemption petition until it has ruled on the citizen's petition.

The agency does not believe that such a requirement is appropriate or necessary. It would be an unnecessary burden on States to require that they submit all the information necessary for a citizen petition to amend FDA's regulations. The agency, however, has no objection to other interested persons submitting a citizen petition under § 10.30 for an amendment to a Federal regulation. Although the agency cannot commit itself to acting on such citizen petition first, it will review it as appropriate and in an expeditious manner.

19. Several comments suggested that States should be required to identify alternatives that might be used to meet the need for information without negating Federal preemption and to explain why those alternatives could not be reasonably implemented within the State. These comments argued that this requirement would satisfy the State's burden to prove that uniformity should be compromised. Not every perceived shortcoming in Federal requirements, the comment stated, must be remedied by different labeling requirements.

The 1990 amendments provide only that a State show that its requirement would not cause any food to be in violation of Federal law, would no unduly burden interstate commerce and is designed to meet a particular need for information that is not met by the Federal requirements. There is no provision in the 1990 amendments that requires that the States identify and consider a number of alternatives beyond that for which it is seeking exemption from preemption. Accordingly, FDA is not including the suggested provision in the final rule.

V. Procedural Provisions

A. When to File—Submission of Petition Before a State Rule is Finalized

20. Several comments disagreed with the proposed requirement in § 100.1(c)(1) that States submit an exemption petition only after the State requirement has been enacted or issued as a final rule by an authorized State official and is in effect or would be in effect but for the provisions of section 403A of the act. The comments suggested that States be allowed to petition for exemption at any time once a State rulemaking proceeding starts, or when the State believes that the rule will become final. The comments said that it would be too burdensome to promulgate a State regulation only to have it preempted by the Federal regulation. The comments also requested guidance from FDA about preemption and its effects on current and possible future State laws.

Acceptance of a State petition for exemption from preemption for a State law or regulation that has not been enacted or promulgated could result in a waste of FDA resources if the State subsequently decides not to enact the law or not to adopt the regulation. FDA is willing to communicate and work with States when questions about preemption arise. However, the agency does not believe that it is prudent to accept exemption petitions for laws or regulations that are not yet enacted. Because preemption can only occur if there is a State law or regulation in effect, the agency will not grant an exemption to a proposed State law or regulation.

The agency, however, advises that a State should be aware of the possible preemption problems at the time it considers whether to adopt the law or regulation. Realizing that the primary purpose of preemption is uniformity of State laws, the State will need to find that there are particular needs that compel it to adopt the law or regulation if it is to do so in the face of the likelihood of preemption. Those are exactly the needs that ought to be brought to the agency's attention as part of the exemption from preemption process.

B. Filing State Exemption Petitions

21. Several comments recommended that proposed § 100.1 (c) be revised in the final rule to set "threshold requirements for the acceptance of petitions for suitability for filing of State petitions." The comments noted that the proposed prerequisites would establish only that there is a State requirement, that the State and Federal requirements are not identical, and that the petitioner is an appropriate State official. These comments suggested that FDA not accept for filing in the first instance any exemption petition unless it contains a prima facie showing that the statutory prerequisites are met; i.e., that the proposed exemption will not result in a violation of any 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 (section 403A(b) of the act). One comment viewed a demonstration of threshold compliance with the statutory prerequisites as critical in light of the fact that under section 10(b)(2) of the 1990 amendments, a petition submitted by May 8, 1992, has the effect of staying Federal preemption until FDA takes action on the petition. The comment was concerned that because the State petitioning regulation itself is not proposed to become effective until November 8, 1992, FDA action on State petitions submitted before May 8, 1992, will be deferred for a very long time. Consequently, the comment argued that without a meaningful petition threshold regulation, even a State petition unapprovable on its face would stay Federal preemption for that time.

The agency believes that the threshold requirements it proposed in § 100.1(c) are more than adequate for determining whether a petition for exemption from preemption should be accepted for filing. The requested prima facie showing that the exemption petition has met the statutory prerequisites goes to the merits of the petition, and whether it should be granted or denied, not to whether it is suitable for filing. Given this fact, along with the complexities of the factors to be considered in determining whether the statutory prerequisites have been met by the petitioner, and the amount of time (90 days) in which the agency is expected to make a final decision on the merits of each exemption petition, FDA is not amending § 100.1(c) to grant the comments' request.

The agency notes that the suggested inclusion of additional threshold requirements for the acceptance of exemption petitions will not address the concerns expressed by the comments. The comments address the provision of section 10(b)(2) of the 1990 amendments that exempts a State requirement described in section 403A(a)(3) through (a)(5) of the act from preemption for a limited period of time if the State submits a petition under section 403A(b) of the act by May 8, 1992. Because the time limit of May 8, 1992, for submitting exemption petitions that would temporarily except State requirements from preemption has passed, any value in establishing threshold requirements for petitions submitted by that date is moot. Moreover, the agency does net believe that it can retroactively establish threshold requirements that would exclude certain or all State petitions from the exemption provisions of section 10(b)(2) of the amendments.

22. Several comments recommended that § 100.1(f)(4) and (f)(5) be revised to provide for public notification in the **Federal Register** of the filing of State exemption petitions. One comment suggested that a notice of filing of an exemption petition be sent to the petitioner. Some comments also recommended that FDA provide for a comment period between the filing of an exemption petition and the agency's response. Other comments wanted the submission of an exemption petition and the agency's responses to be made public. These comments expressed concern that without public notification, an interested person may not know that his or her interests require the filing of comments. Some comments suggested that FDA also should establish a specific time between the receipt and the filing of an exemption petition so that interested persons may provide meaningful comment.

The agency does not believe public notification in the **Federal Register** of the submission or filing of exemption petitions is necessary. Nor does the agency find it necessary to establish a comment period for either submitted or filed petitions. The procedures for the handling of petitions for exemption from preemption are generally consistent with those in § 10.30 for citizen petitions. Section 100.1(e) provides that once an exemption petition is accepted for filing, it will be made available for public examination and copying at the Dockets Management Branch under the rules provided for in § 10.20(j) (21 CFR 10.20(j)). In addition, § 100.1(f)(3) provides that the petitioner will be notified in writing of the filing and docket number of the petition. Section 100.1(f}(4) allows any interested person to submit written comments to the Dockets Management Branch on a filed petition, as provided in § 10.30(d). If the agency tentatively decides that an exemption petition has merit, it will publish in the **Federal Register** a proposal to grant the exemption, and interested persons will have an opportunity to comment on the proposal at that time.

The agency recognizes that not providing for a public notice of the filing or submission of an exemption petition in the procedures that it is establishing may limit the ability of a person who might consider the petition significant to comment on the petition before the agency makes a decision to propose to grant the exemption or to deny the petition. The agency has concluded, however, that there is no prejudice from this fact because the petition will be available at the Dockets Management Branch, comments can be submitted on the petition, and the agency will not grant the petition until after there has been rulemaking on whether such action is appropriate. Interested persons will thus have ample opportunity to comment on the petition,

23. One comment requested that FDA establish a comment period for accepting comments to a proposal to grant an exemption.

The agency points out that all FDA published proposals are subject to the requirements of § 10.*40 Promulgation of regulations for efficient enforcement of the law* (21 CFR 10.40), Section 10.40(b)(2) provides that the proposal will provide 60 days for comment, although the Commissioner of Food and Drugs may shorten the comment period (to not less than 10 days) or lengthen this time period for good cause.

24. One comment-said that FDA should make a decision on the exemption petition in 90 days and not just issue a response that It has not made a decision

The agency advise that it intends to make every effort to make its decisions on exemption petitions within the 90-day period. However, there are circumstances that arise, such as other agency priorities and a need for additional information, that may not permit the agency to respond within 90 days. Accordingly, the agency has concluded that a provision for a tentative response, similar to that which is permitted in § 10.30(e)(2)(iii), is both appropriate and warranted.

25. Some comments wanted FDA to publish a list of all petitions filed before May 8, 1992, and to act promptly on these petitions.

Five petitions from States requesting exemption from preemption were submitted to the agency by May 8, 1992. As announced in the **Federal Register** of March 14, 1991 (56 FR 10906), the agency has deferred action on these petitions and has not reviewed them to any extent at this time. These petitions are: State of California petitions on milk, dated January 7, 1991 (Docket No. 91P-0009); slack fill, dated May 6, 1992 (Docket No. 92P-0361): bottled water, dated May 8,1992 (Docket No. 92P-0216); State of Michigan petition on nonalcoholic beverages, dated March 15, 1991 (Docket No, 92P-0360); State of Vermont petition on maple syrup, dated July 30,1991 (Docket No. 92P-0359); and a joint petition by 44 states, territories or jurisdictions on net content, dated November 9, 1992 (Docket No. 92P-0441). The agency fully intends to respond to these petitions in the very near future.

26. One comment from a foreign country requested that FDA notify it of any State exemption petitions that could affect trade. The comment expressed concern that any exemptions not violate the General Agreement on Tariffs and Trade or the Free Trade Agreement with Canada.

The agency advises that if it should tentatively decide that an exemption petition has merit, it will publish a proposal in the **Federal Register** to grant the exemption through rulemaking. Any foreign government concerned about trade implications would have an opportunity to comment on such a proposal al that time. The agency believes that publication of proposals to grant an exemption in the **Federal Register** will provide adequate notice to foreign governments of State petitions for exemption from preemption.

C. Exemption Granted through Notice and Comment Rulemaking

27. Several comments were opposed to granting exemptions through rulemaking. The comments said there is nothing in the language of the 1990 amendments indicating the necessity for issuing exemptions in the form of regulations.

The agency considered these comments but finds no basis to change its tentative conclusion that granting of exemptions through notice and comment rulemaking is the best. procedure to follow. The agency believes that rulemaking is appropriate because section 403A(b) provides that FDA is to grant the exemption by regulation, and because the granting of an exemption from preemption will have the force and effect of law. In addition, rulemaking will ensure that all interested persons have an opportunity to comment, and that all opinions are expressed. Accordingly, FDA is retaining § 100.1(f)(5)(i), as proposed, but is adding the phrase "under such conditions as it [FDA] may prescribe by regulation" to the last-sentence of § 100.1(a)(2) to reflect the language of section 403A(b).

After considering the comments that FDA received on the proposal, FDA is adding a new subpart A, consisting of §100.1.

VI. Paperwork Reduction Act

Section 100.1(d) of this final rule contains information collection 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 0MB control number 0910-0277.

VII. 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 businesses, would derive from this action. FDA has not received any new information or comments on the proposal that would alter its previous determination.

VIII. Environmental Impact

The agency previously determined under 21 CFR 25.24(a)(8), as announced in the proposed rule and published in the **Federal Register** of November 27, 1991 (56 FR 60528), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental assessment or an environmental impact statement is not required.

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 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. 323, 331, 337, 342, 343, 348, 371).

2. A new subpart A consists 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, under such conditions as it may prescribe by regulation, 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 (21U.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 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, quality, and fill. "Not identical to" 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) An original and one copy of the petition shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. (Petitioners interested in submitting a disk should contact the Center for Food Safety and Applied Nutrition for details.)

(3) Petitions 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, MD20857.

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)_____

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB number 0910-0277).

(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 403 A (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 submitted 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: October 26, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W.Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92-31509 Filed 12-28-92; 8:45 am]

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