

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Ch. I

[Docket No. 91N-0134]

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

AGENCY: Food and Drug Administration HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing, in accordance with the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), final lists delineating which of six sections of the Federal Food, Drug, and Cosmetic Act (the act) that define circumstances in which a food is misbranded are adequately being implemented by FDA regulations and which are not. These six sections are: Sections 403 (b) (offered for sale under the name of another food), 403(d) (misleading container), 403(f) (information of appropriate prominence), 403(h) (compliance with standard of quality and fill), 403(j)(1) (common or usual name), and 403(k) of the act (declaration that the product contains artificial flavoring, coloring, or preservatives) (21 U.S.C. 343(b), 343(d), 343(f), 343(h), 343(i)(1), and 343(k)).

Based upon its evaluation of the recommendations of the National Academy of Sciences, Institute of Medicine, Food and Nutrition Board (hereinafter referred to as IOM), its consideration of the comments on the proposed lists, and other available information, the agency finds that all but section 403(d) of the act are adequately being implemented.

EFFECTIVE DATE: The final lists of sections of the act that are, and that are not, being adequately implemented become effective on February 5, 1993.

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SUPPLEMENTARY INFORMATION:

I. Background

In response to section 6(b) of the 1990 amendments (Pub. L. 101--535), FDA published in the **Federal Register** of July 28, 1992 (57 FR 33283), proposed lists that identified which of six sections of the act (sections 403(b), 403(d),

403(f), 403(h), 403(i)(1), and 403(k)) that define circumstances in which a food is misbranded are adequately being implemented by FDA regulations and which are not adequately being implemented. The agency tentatively concluded that sections 403(b), 403(f), 403(h), 403(i)(1), and 403(k) of the act are adequately being implemented, and that section 403 (d) is not adequately being implemented. FDA's tentative conclusions were based on the recommendations of IOM, with whom FDA had contracted, in accordance with section 6(b) of the 1990 amendments, to study:

(A) State and local laws that require the labeling of food that is of the type required by sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the Federal Food, Drug, and Cosmetic Act, and

(B) the sections of the Federal Food, Drug, and Cosmetic Act referred to in subparagraph (A) and the regulations issued by the Secretary to enforce such sections to determine whether such sections and regulations adequately implement the purposes of such sections.

Interested persons were given until September 28, 1992, to comment. FDA received six letters, each containing one or more comments, from two trade organizations, a food manufacturer, a professional organization, and a consumer organization. A summary of the issues raised by the comments and the agency's responses follow.

II. Response to Comments

A. Adequate Implementation

1. One comment objected to the criteria used by IOM to determine whether a particular section is adequately being implemented. Specifically, the comment interpreted the legislative history to provide that "adequate implementation" means full implementation of the six misbranding sections and thus requires Federal adoption of the strongest legal standards that effectively accomplish the goals of the provisions under study. The comment stated that:

IOM's conclusions are contrary to the NLEA because the legislative history indicates that Congress intended to avoid preempting state and local governments unless the FDCA has been fully implemented, and no additional federal regulation is necessary.

The agency disagrees with this comment. The agency can find no support in the legislative history or in the 1990 amendments for a conclusion that the intent of the procedures established by section 6(b) was to

identify the strongest regulations relevant to each of the six sections listed in section 403A(a)(3) of the act and to have FDA adopt those regulations.

In discussing the preemption provisions of the 1990 amendments, Congressman Waxman identified two principles that should be considered in preempting State laws. First, State laws should not be preempted unless the nature of the laws at issue makes it difficult and even impossible for companies to operate in interstate commerce. Secondly, the States should never be preempted unless a strong Federal regulatory system is in place (136 Congressional Record H5840 (July 30, 1990)). Mr. Waxman noted that the requirements for nutrition labeling and for health claims that were in the bill that had been reported out of the House Committee on Energy and Commerce (and that became the 1990 amendments) created such a strong regulatory system (id.). Implicitly, Congress also recognized the strength and adequacy of FDA's implementation of sections 401 of the act (standards of identity) and 403(g) of the act (standards of identity labeling) to which it gave preemptive effect on the date of enactment and of sections 403(c) (imitation foods), 403(e) (name and address of responsible firm and net contents declaration), and 403(i)(2) of the act (ingredient labeling) which Congress made preemptive 1 year after enactment.

However, Mr. Waxman stated that Congress was unable to determine whether the Federal standard is strong in the areas covered by sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the act (136 Congressional Record H5840). Thus, he said, the bill provides for a study of Federal and State standards to determine whether additional Federal regulations on each of the sections is needed.

Further information on the nature of the study is provided by the House Managers report:

The purpose of this study is to provide the Secretary information upon which to determine whether federal laws are adequate once the state laws are preempted. It is anticipated that the study will identify all federal regulations that are applicable as well as State laws that will be preempted. The study should also survey local laws, but it is not anticipated that every local law will need to be identified. (136 Congressional Record H5842 (July 30, 1990)).

It is clear from this legislative history that what Congress intended was for FDA, through a contractor, to compare its regulations implementing the sections of the act in question with those of the States. To the extent that

that study identified major matters covered by those sections that the States were addressing but FDA was not, FDA would have to address those matters before the sections in question would be preemptive.

However, there is nothing in the statute or the legislative history that suggests that the purpose of the study was to identify the strongest State standard on each of the matters covered by those sections of the act and for FDA to implement that provision. Therefore, FDA rejects this comment.

2. One comment stated that the IOM had erred in failing to consider the level of FDA enforcement in determining whether a particular section has been adequately implemented.

The agency disagrees that its enforcement record is appropriately a factor in determining adequacy of implementation. There is nothing in the act or the legislative history that would indicate that it should be. Nor does it make any sense in light of the legislative history that level of enforcement is a relevant factor. Congress cited nutrition labeling and health claims as topics on which a strong Federal regulatory system is in place, even though the statutory provisions on these topics had never been enforced (136 Congressional Record H5840 (July 30, 1990)). Apparently, Congress did so because it anticipated that adoption of the regulations necessary in response to the 1990 amendments would establish such a strong regulatory system. Thus, it is appropriate to look to the regulatory systems in place for each of the sections in question—that is, to the regulations that effect those sections—to determine whether they are adequately being implemented.

3. One comment stated that IOM cannot legally determine whether a particular section is adequately being implemented without considering the level of industry compliance.

FDA disagrees. Because IOM received no information from FDA or the States concerning industry compliance, and because only anecdotal information exists, IOM concluded, that there was no objectively verifiable data regarding compliance that could be used to evaluate adequacy of implementation of the misbranding sections. Therefore, IOM decided that to evaluate compliance on the basis of such limited data would be contrary to the intent of the 1990 amendments.

Again, there is nothing in the legislative history that would suggest that industry compliance was a factor that either IOM or FDA should consider in deciding whether the Federal regulations implementing the sections

in question are adequate. If compliance is a problem, what the statute seems to contemplate is that FDA would establish a strong national standard that the States and the agency would then work together to enforce. As Congressman Waxman said: "Third, any preemption provision must recognize the important contribution that the State can make in regulation, and it must leave a rote for the states." (136 Congressional Record H5840 (July 30, 1990)). Thus, FDA rejects this comment.

B. Preemption

4. One comment argued that IOM misinterpreted the 1990 amendments as to the extent of preemption by concluding that all State and local requirements, not just those that conflict with Federal law, should be preempted if FDA determines that the section under study has, as a whole, adequately been implemented. The comment argued that the national uniformity portion of the 1990 amendments was intended to ease the burden to industry by preempting inconsistent labeling requirements. The comment stated that, therefore, State and local requirements that serve consumer protection purposes should only be preempted if they conflict with FDA regulations.

The comment noted as an example that under IOM interpretation, a State requirement for a common or usual name for a particular product would be preempted even if there is no Federal requirement for a common or usual name for that product. The comment summarized its position by concluding that the IOM had incorrectly interpreted which State and local requirements were "of the type" or "related to" the six areas under study. As support for its position, the comment cited the FDA November 27, 1991, proposal entitled "State Petitions Requesting Exemption From Federal Preemption" (hereinafter referred to as the State petitions proposal) (56 FR 60528).

The agency disagrees with this comment. The comment misinterprets the extent of preemption that occurs under section 403A of the act.

FDA sought to address this issue in its proposal on State petitions for exemption from preemption. In that proposal the agency stated:

Section 403A 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.

(56 FR 60528 at 60530)

In discussing examples of State laws that would not be preempted, FDA listed the following:

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.

These examples do not include situations that are covered by the sections of the act that are given preemptive effect by section 6(b) of the 1990 amendments or regulations issued under those sections. With respect to those sections, however, the preemptive effect is quite broad. Section 403A(a)(3) of the act, for example, states that no State or political subdivision of a State may directly or indirectly establish or continue in effect as to any food in interstate commerce " * * * any requirement of the type required by section 403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k) that is not identical to the requirement of such section." Thus, under this provision, as is discussed below in this document and as explained more fully in the final rule entitled "State Petitions Requesting Exemption from Federal Preemption," published elsewhere in this issue of the **Federal Register**, a State common or usual name regulation promulgated in conformance with the requirements of § 102.5 (21 CFR 102.5) for a food for which there is no specific Federal common or usual name would apparently be preempted. It would be a requirement of the type required by section 403(i)(1) of the act, but it would not be identical to the provisions that FDA has adopted under that section.

C. The Six Misbranding Sections Under Review

1. Section 403 (b)—Offered for Sale Under the Name of Another Food

5. Four comments supported FDA's tentative determination that section 403(b) of the act is adequately being implemented. However, one comment argued that section 403(b) of the act is not adequately being implemented because FDA has issued no regulations under this section nor has it prosecuted many cases under this section. The comment also noted that IOM, while finding section 403(b) of the act adequately implemented, suggested that FDA should promote the development and introduction of new foods by pursuing more aggressively the regulatory options that will allow the formal naming of new nonstandardized foods.

Having considered the comments to the proposal, the IOM report, and other available information, the agency concludes that IOM was correct in its recommendation, and is finding that section 403(b) of the act is adequately being implemented. The agency notes, as did IOM, that it does have a regulation that implements section 403(b) of the act, §101.18 *Misbranding of food* (21 CFR 101.18). Moreover, none of the comments pointed to State regulations that implement provisions that are similar to section 403(b) of the act that address matters not covered by FDA's regulations.

As to the enforcement, or lack thereof, of section 403(b) of the act, FDA agrees that there are not many actions brought against manufacturers solely under this general misbranding provision. Any such action taken by FDA against a manufacturer under section 403(b) of the act would almost always be brought in conjunction with counts that charge a violation of the more specific misbranding provisions of section 403, namely section 403(g) (standards of identity) and section 403(i)(1) (common or usual name). However, as discussed above, the level of enforcement is not relevant to the inquiry mandated by Congress.

The agency believes that IOM'S suggestion that FDA actively pursue its regulatory options to allow the formal naming of nonstandardized foods was misinterpreted by the comment. IOM was simply offering a suggestion. There is no indication in IOM'S report that IOM believed that there was a problem with the implementation of section 403 (b) of the act, as evidenced by its recommended finding that this section is being adequately implemented. For these reasons, FDA rejects this comment.

2. Section 403 (d)—Misleading Container

6. Two comments cited FDA's current requirements for net weight declaration and standards of fill regulations as evidence that section 403 (d) of the act is adequately being implemented. One of the comments added that IOM's determination that section 403(h) of the act (fill of container) is adequately being implemented precluded the IOM from finding that section 403(d) is not adequately being implemented.

The agency disagrees with the comments. The suggestion that the provisions for net weight declaration (as provided by section 403(e) of the act) and standards of fill (as provided by section 403(h)(2) of the act) serve to implement section 403(d) of the act would basically serve to render section 403(d) of the act a nullity. Although

there is clearly an interrelationship among the three sections, the agency believes that the presence of an accurate net weight statement or compliance with a standard of fill does not eliminate the misbranding that occurs when a container is made, formed, or filled so as to be misleading.

7. One comment argued that it would not be cost effective for FDA to implement section 403(d) of the act by promulgating detailed specific commodity and container regulations, such as those the agency has adopted in the past under section 401 of the act and enforced under section 403(h)(2) for all food products or specific food product classes. The comment also argued that further regulatory activity would be inappropriate in light of the IOM'S failure to identify any State commodity and package regulations that should be adopted and of FDA's previous determination that the expenditures of agency resources that would be needed to implement such regulations would exceed potential benefits.

FDA disagrees. The fact that IOM was unable to identify any specific state law that FDA should adopt was not a basis for ending their consideration of whether a particular section is being adequately implemented. As noted above, the task was to determine the adequacy of Federal implementation by considering: (1) The extent of State regulation for each topic and the corresponding Federal regulation and (2) whether the States were doing anything that FDA should be doing. FDA notes that IOM did mention California's experience in this area suggested using the provisions of the Fair Packaging and Labeling Act (FPLA) as a guide for Federal regulations to implement section 403(d) of the act.

The agency's earlier decisions not to implement general or individual regulations concerning slack-fill or deceptive packaging were in relation to the efficient utilization of the agency's resources, not the adequate implementation of the intent of section 403(d) of the act. The provisions of the 1990 amendments require that the agency-examine its implementation of section 403(d) of the act from a different perspective, i.e., not in terms of efficient use of resources but instead whether its regulations adequately implement the intent of section 403(d) of the act. Based upon the findings of IOM and its own review of the record, FDA concludes that section 403(d) of the act is not adequately being implemented.

8. One comment, without addressing whether the IOM recommendation concerning 403(d) of the act is correct, urged the agency to take whatever

action is necessary to implement section 403(d) of the act adequately. The comment suggested that the agency consider using the definition for slack-fill that appears in section 5 of the FPLA. Another comment opposed the proposed determination that section 403 (d) of the act is not being adequately implemented by FDA on the basis that the IOM report, in supporting its determination of inadequacy, does no more than suggest that FDA adopt some general regulations merely parroting the language of section 5(c)(4) of the FPLA which: (1) Authorizes FDA to adopt product-by-product regulations to prevent the nonfunctional slack-fill of packages when it finds such regulations are necessary to prevent the deception of consumers or to facilitate value comparisons, and (2) provides that a package shall be deemed to include nonfunctional slack-fill if it is filled to substantially less than capacity for reasons other than: (a) Protection of the contents of such package or (b) the requirements of machines used for enclosing the contents in such package. The comment argued that the adoption of a general regulation to implement statutory language of the FPLA would provide no further guidance to the agency, the public, or the industry than is now provided in the relevant case law under section 403(d) of the act and in the legal literature discussing nonfunctional slack-fill. Moreover, the comment argued, any attempt to write more specific requirements in a general slack-fill regulation would certainly founder on the widely different considerations that apply to different foods and different packages—as is graphically illustrated in the differing fill of container standards adopted by FDA.

The issue here is not how to adequately implement section 403 (d) of the act, but whether it is being adequately implemented. Based on the evidence cited by IOM, FDA finds that the States have addressed fill of container matters that are not addressed by FDA's regulations. Therefore, FDA concludes that section 403(d) of the act is not adequately being implemented. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposal entitled "Misleading Containers; Nonfunctional Slack-fill" which is based on the FPLA definition for nonfunctional slack-fill but goes beyond it in ways that the agency has tentatively found to be appropriate to address the types of concerns that were raised by the latter comment. FDA urges that interested persons comment on that proposal.

3. Section 403(f)—Information of Appropriate Prominence

9. One comment stated that IOM was incorrect in recommending that FDA find that section 403(f) of the act is adequately being implemented. The comment stated that, although numerous regulations have been promulgated under this section, several important problems have not been addressed. For example, the comment cited the IOM report's concern that FDA's current regulations "do not provide as precise a definition of 'conspicuous' and 'prominent' as do some States." The IOM report had expressed concern that this lack of definition may place a greater enforcement burden on FDA. The comment submitted excerpts from "Guidelines for Document Designers," a product of the Document Design Project funded by the National Institute of Education as support for its concern on the readability of labels. The comment noted that there is no Federal regulation against obstructing important label information with, for example, price tags.

The agency disagrees with the comment. While FDA has not adopted as precise a definition for "conspicuous" and "prominent" as some States, the regulations adopted by FDA have specific requirements for placement of mandatory information such as product name, net weight, ingredients, and name and address of manufacturer with specifications for type size. FDA finds that these requirements adequately implement section 403(f) of the act. Although FDA has not explicitly enunciated definitions of "conspicuous" or "prominent" its regulations reflect the standard of prominence and readability in *United States v. 46 Cases, More or Less, Welch's Nut Caramels*, 204 F. Supp. 321,323 (D.R.L 1962):

*** The Act prescribes no minimum specific standard as to how prominent such statements should be. It would seem that the requirements of said section 403(f) are met in a particular case if such statements are prominent enough to be seen and understood by the ordinary individual who is interested in discovering and learning the information disclosed thereby, and who makes the minimum examination of the package to determine its net weight and the ingredients of the candy contained in said package.

While studies on readability may suggest methods of highlighting label information, the question is whether or not the product meets the legal standard of being seen and understood by the ordinary individual. Section 101.1 requires that the principal display panel "shall be large enough to accommodate

all the mandatory label information required *** with clarity and conspicuousness and without obscuring design, vignettes, or crowding." Section 101.2 requires that all information that must appear either on the principal display panel or the information panel must be prominent and conspicuous, but in no case may the letters or numbers be less than one-sixteenth inch in height unless otherwise exempted. These requirements meet the legal standard by ensuring that the information can be seen and understood by the ordinary individual. Thus, while FDA has not chosen to implement section 403(f) of the act in the same way as some of the States, it has adequately implemented that section and established a strong standard.

As to the issue of obscuring label Information, § 101.1 prohibits "obscuring design, vignettes, or crowding." The agency has not adopted more specific regulations regarding obscuring by price tags or other means because these tags are placed on the product at the retail level for the most part, and FDA does not have the resources to police individual food outlets across the nation. While the States do regulate at that level, FDA finds that the language of § 101.1 will give them an appropriate and adequate tool to address this problem.

4. Section 403 (h)—Compliance With Standards of Quality and Fill

10. One comment set forth what it considered to be four major problems with IOM'S conclusion that section 403 (h) of the act is adequately being implemented. First, the comment argued that the statements that a product is substandard provided in § 130.14(a) and (b) (21 CFR 130.14(a) and (b)) do not adequately inform consumers of the reason the product is below standard. The comment suggested that FDA require an additional line in both statements to explain briefly the defect in quality or fill (e.g., similar to that which is provided in § 103.5(b) for bottled water, "contains excessive bacteria"). Secondly, the comment argued that the IOM'S conclusion that section 403(h) is adequately being implemented should not be based on the fact that companies rarely use the statement "Below Standards in Quality," because it is equally plausible that companies are simply not complying with the requirement, or that there are insufficient substantive standards of quality, fill, and identity to make this determination. Thirdly, the comment stated that IOM'S reliance on the lack of court cases involving section 403(h) of the act is not a valid criterion

for determining whether the section is adequately being implemented because it is possible that FDA simply does not enforce this section. Finally, the comment argued that IOM did not consider the adequacy of the substantive standards themselves (i.e., the standards of identity, quality and fill) in determining whether section 403(h) of the act is adequately implemented.

Under section 403(h) of the act, a food is considered misbranded if it purports to be or is represented to be a food for which either a standard of quality or fill of container has been prescribed by regulations under section 401 of the act, and its quality or fill falls below such standards. The purpose of the disclosure requirements in § 130.14 (21 CFR 130.14) is simply to permit manufacturers, if they so choose, to sell a product that is not in compliance with section 403(h) of the act because of inadvertent manufacturing error.

The agency points out that the lack of an additional line in the disclosure statement explaining the defect in quality and fill is not germane to determining whether section 403(h) of the act is adequately being implemented for purposes of section 6(b) of the 1990 amendments. Under section 6(b) of the 1990 amendments, the standard that FDA is to use in determining the adequacy of its implementation of section 403(h) of the act is whether States or localities have adopted laws or regulations to implement requirements of this type that address matters not covered by FDA's regulations. Neither the comment nor the IOM report have shown that there are matters with respect to standards of quality or fill covered by States laws that FDA is not addressing.

With respect to the fact that companies rarely use the disclosure statements (e.g., "Below standard in fill"), the comment offered no evidence, nor is FDA aware of any such evidence, to substantiate that its claim that companies are not complying with section 403(h) of the act is in fact true. FDA's compliance efforts have not produced any evidence to this effect. Therefore, FDA can give no credence to this argument.

The agency notes that the lack of court cases involving section 403(h) of the act is not germane to determining whether this section is adequately being implemented. As noted elsewhere in this document, enforcement is not a criterion for making a determination of adequate implementation.

The last argument put forth by the comment is also not germane because the sufficiency of individual standards is not at issue in determining whether

The agency is adequately implementing section 403(h) of the act.

Therefore, FDA rejects the comment and concludes that section 403(h) of the act is adequately being implemented by its regulations.

5. Section 403(i)(1)—Common or Usual Name

11. One comment stated that the language of the IOM report contradicts IOM's conclusion that section 403(i)(1) of the act is adequately being implemented. The comment stated that the fact that the food industry continues to develop new foods for which no regulated common or usual name exists is evidence that section 403(i)(1) of the act is not adequately being implemented. The comment noted that the areas examined by IOM, i.e., bottled water, honey, fish, oriental noodles, Vidalia onions, and wild rice, are indicative of the fact that State standards offer more consumer protection than Federal standards.

The agency disagrees with the comment. The general regulation for common or usual names (§ 102.5 (21 CFR 102.5)) provides general principles that direct how to name any new food for which an individualized common or usual name regulation or standard of identity does not exist. Section 102.5 provides that:

The common or usual name of any new nonstandardized food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible the basic nature of the food of its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name.

In addition, § 102.5 requires that "each class or subclass of food shall be given its own common or usual name that states in clear terms, what it is in a way that distinguishes it from different foods." Section 102.5 also includes percentage labeling requirements for characterizing ingredients in certain foods. It provides that a common or usual name of a food may be established by regulation in 21 CFR part 102, Subpart B (Requirements for Specific Nonstandardized Foods), in 21 CFR part 104 (Nutritional Quality Guidelines for Foods), in a standard of identity regulation (21 CFR part 131 through 169), or in other regulations in Chapter I of Title 21 of the Code of Federal Regulations. It also states that a common or usual name of a food may be established by common usage.

The agency disagrees with the comment's statement that the specific

common or usual name examples cited in the comment are indicative that State standards are stronger than Federal standards. The IOM report identifies several foods, including the six mentioned in the comment, for which States had common or usual name requirements but for which there were no Federal requirements. FDA finds, as did IOM, that each of IOM's examples represents a situation that either is not subject to section 403A of the act or calls for a state petition for exemption from preemption under section 403A(b), and that these examples do not demonstrate that the requirements of FDA's regulations do not adequately implement section 403(i)(1) of the act.

The agency notes that of the products cited by the comment, only three would be candidates for a common or usual name regulation. Wild rice, Vidalia onions, and fish. With respect to wild rice, IOM did state in its report that there was a potential for consumer fraud through substitution and blending of the more expensive wild rice with other cheaper rice products. However, the agency has no data, nor was any submitted, to confirm that this in fact is the situation in the marketplace. Moreover, the agency does not believe establishing a specific common or usual name regulation for wild rice would necessarily give the consumer any more protection than is currently provided by §102.5 While the agency is not persuaded that there is a consumer fraud problem with wild rice, it would certainly entertain a citizen petition to establish a specific common or usual name regulation if a proper case is presented that demonstrates that there is a problem and a regulation is needed.

IOM also concluded that the Georgia State requirement for Vidalia onions appears to be predominantly protectionist in that no specific justification is provided for limiting the source to the defined producing locality. The agency concurs with IOM'S assessment and, therefore, concludes that a specialized Federal common or usual name regulation for this product is not necessary. Again, while FDA believes that § 102.5 adequately provides for the naming of this product, it would have no objection to the State of Georgia or any other group or industry submitting a citizen petition to FDA to establish a specific common or usual name regulation for Vidalia onion based on measurable geographical, botanical, or quality criteria that differentiates it from other varieties or species of onion.

With respect to fish, FDA has issued "The Fish List FDA Guide to Acceptable Market Names for Food Fish Sold in

Interstate Commerce 1988" to provide acceptable market, scientific, and common names for a wide range of common species. The agency believes, as did IOM, that The Fish List provides order to the marketplace. FDA also has Compliance Policy Guides (CPG's) for "red snapper" and for surimi-based (minced fish) imitation crab and other fish substitutes (CPG 7108.04 and 7108.16, respectively). The agency believes that The Fish List and the various CPG's more than adequately protect the consumer from fraud, while establishing specific common or usual name regulations for the many species of fish would be beyond the agency's resources and would not result in an appreciable reduction in consumer fraud. Anyone who believes a specific common or usual name regulation is needed for a particular species of fish may, of course, submit a citizen petition with appropriate justification as to why such action is warranted.

Bottled water, honey, and oriental noodles were also cited by the comment as products examined by IOM. Oriental noodles have compositional requirements, and, therefore, any regulations promulgated by FDA for this product would be in the form of a standard of identity regulation. Food standards are promulgated under the authority of section 401 and 403 (g) of the act, not section 403(i)(1). The agency further notes that it has issued a compliance policy guide for oriental noodles (CPG 7102.02: Chow Mein Noodles, Chinese noodles, and other Oriental Noodles; Labeling). The agency believes that the CPG for oriental noodles more than adequately protects the public from consumer fraud. Again, the agency would not object to any interested persons submitting a citizen petition to establish a standard of identity for oriental noodles. The agency notes that it is currently considering a citizen petition from the International Bottled Water Association requesting that FDA regulate bottled water. The agency hopes to take action on this petition by the end of this year.

Thus, FDA concludes that it does have a strong and adequate regulatory system in place to implement section 403(i)(1) of the act. Therefore, the agency accepts IOM'S recommendation and rejects the comment on this point.

6. Section 403 (k)—Declaration That the Product Contains Artificial Flavoring, Coloring, or Preservatives

12. One comment argued that section 403(k) of the act is not adequately being implemented because there are several areas where FDA's current regulations fall short. As examples the comment

noted that current regulations: (1) Do not require all artificial flavorings in foods to be specifically identified on the label by their common or usual name (the comment stated that artificial flavorings can be listed as "flavorings") (2) do not give consumers that are sensitive to monosodiumglutamate (MSG) or sulfites sufficient label information to be able to avoid these substances, and (3) do not require labeling to reflect the percentage of each type of ingredient (e.g., the term "natural and artificial flavoring" can be used for a product which has 5 percent artificial and 95 percent natural flavoring and vice versa) when both natural and artificial coloring and flavoring are used in a food.

The agency disagrees with the comment. The premise of the comment is based upon a faulty interpretation of the requirement of section 403 (k) of the act, of the agency's implementation of those requirements, and of IOM's report. The issues being raised by this comment would require fundamental statutory changes.

With regard to the first point, although they are separate requirements, section 403(i)(2) and (k) of the act must be read together. Section 403(i)(2) of the act requires the listing of the ingredients of a food by their common or usual names except that spices, flavorings, and color additives not required to be certified under section 706(c) of the act may be designated as spices, flavorings, and colorings without naming each (see also section 403(g)). Section 403(k) of the act provides that a food shall be deemed to be misbranded if it bears or contains any artificial flavorings unless it bears labeling stating that fact. FDA, has implemented and amplified the requirements of section 403(k) of the act in § 101.22(h), which provides that the label of a food to which a flavor is added shall declare the flavor in the statement of ingredients as "artificial flavor" or "natural flavor" or any combination thereof, as the case may be.

Thus, contrary to the comment's assertion, FDA does not have the legal authority to require that artificial flavorings be listed by their common or usual name. However, again contrary to what the comment asserted, FDA has required that artificial flavorings be designated by the term "artificial flavoring."

The agency notes that the comment's concerns about the need for sensitive individuals to have sufficient label information to be able to avoid substances such as MSG and sulfites and the lack of percentage labeling of artificial and natural flavorings when both are used in food are not germane

to whether section 403(k) of the act is adequately being implemented. To the extent that MSG, sulfites, or other substances that cause food sensitivities are flavorings, section 403(k) of the act would not require that they be declared in a way that would permit consumers to avoid them. FDA regulations do require that sulfites that are present in detectable amounts are declared on the food label (see § 100.100(a)(4) and the document on ingredient labeling published elsewhere in this issue of the **Federal Register**), however, FDA adopted this requirement under other provisions of the act. Similarly, percentage labeling requirements are outside the scope of section 403(k) of the act, which requires only that the presence of artificial flavorings (or artificial colors or chemical preservatives) be declared on the label Section 101.22(h)(1) of FDA's regulations set forth how the addition of both artificial and natural flavorings to a food is to be declared. Therefore, the agency rejects the comment on this point.

Having considered the comments, the IOM report and other available Information, FDA finds that section 403(k) of the act-is being adequately implemented.

D. Procedural Issues

13. One comment argued that the agency's failure to present more than a conclusory acceptance of IOM's recommendations did not provide the agency's views on the decision as to which sections were adequately being implemented.

The agency disagrees. The agency explicitly stated its tentative conclusions as to those sections that were adequately being implemented, and those that were not, were based on the recommendations of IOM and all of the information that IOM supplied to the agency as a result of the contract between FDA and IOM (57 FR 33283 at 33285). The July 28, 1992, proposal announcing the proposed lists discussed in detail the approach taken by IOM and the criteria that it used to determine adequate implementation. The notice summarized the basis for IOM'S recommendations, with respect to each section of the act (57 FR 33283 at 33284 through 33285). All the comments and other information considered by IOM, along with its draft final manuscript and final report, were placed on public display for all interested persons to review.

FDA's presumptive tentative acceptance of IOM's recommendations was fully consistent with the 1990 amendments and with the

Administrative Procedure Act. Section 6(b)(3)(A) of the 1990 amendments directs the agency to publish the proposed lists as determined under the contract with a public or nonprofit private entity, which turned out to be IOM. This is exactly what the agency did. Moreover, § 10.40(b) (21 CFR 10.40(b)), FDA's regulation that implements the Administrative Procedure Act on informal rulemaking, states that the proposal shall act out the terms or substance of the proposed action and summarize the facts and policy that underlie it. Again, the July 28, 1992, proposal fully complies.

Thus, the agency finds that it provided adequate notice for all persons interested in this rulemaking as to the basis for its tentative determinations of adequacy of implementation.

III. Economic Impact

FDA has examined the economic implications of the final lists as required by Executive Orders 12291 and 12612 and the Regulatory Flexibility Act, Executive Order 12291 compels agencies to use cost-benefit analysis when making decisions, and Executive Order 12612 requires Federal agencies to ensure that Federal solutions, rather than State or local solutions, are necessary. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. The agency finds that this final rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (Pub L. 96-354), FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses. Finally, because these lists implement a statute that provides for preemption of State and local laws in specified circumstances, FDA finds that there is no substantial federalism issue that would require an analysis under Executive Order 12612.

A. Alternatives

The primary alternatives available to FDA were as follows:

1. Accept recommendation of IOM report
2. Reject recommendation of IOM report

B. Costs

1. Accept Recommendation of IOM Report

By accepting the recommendation of the IOM report, FDA is legally required to publish regulations that ensure that section 403(d) of the act is adequately implemented. The compliance costs imposed by FDA's acceptance of this

legal obligation depend on the regulations that FDA promulgates to fulfill this obligation. One possible regulation that FDA might promulgate simply repeats the language of section 403(d) of the act. The compliance cost of this regulation would be zero because section 403(d) is already legally binding on food package manufacturers. If more restrictive regulations are promulgated, then compliance costs may occur. Potential compliance costs to industry include designing and manufacturing new packages. FDA has estimated the cost of implementing the regulations in the proposal on misleading containers that is published elsewhere in this issue of the **Federal Register**.

2. Reject Recommendation of IOM Report

If FDA had rejected the recommendation of the IOM report, then FDA could have made one of the following decisions: (1) Find that all sections of the act defining circumstances in which a food is misbranded are adequately implemented, or (2) find that one or more sections of the act defining circumstances in which a food is misbranded other than section 403(d) are not adequately being implemented.

If all relevant sections of the act had been found to be adequately implemented, then compliance costs would have been zero. If one or more sections of the act defining circumstances in which a food is misbranded other than section 403(d) had been found to be not adequately implemented, then compliance costs may have occurred. One possible regulation that FDA might have promulgated in the latter case would have simply repeated the language of the relevant sections of the act. The compliance cost of this regulation would have been zero because these sections of the act are already legally binding on food package manufacturers. If more restrictive regulations are promulgated, then some compliance costs may be incurred.

C. Benefits

1. Accept Recommendation of IOM Report

By accepting the recommendation of the IOM report, FDA is legally required to publish regulations that ensure that section 403(d) of the act is adequately implemented. One possible regulation that FDA might promulgate simply repeats the language of section 403(d) of the act. The benefit of this regulation would be zero because section 403(d) of the act is already legally binding on

food package manufacturers. If more restrictive regulations are promulgated, then there may be positive benefits. The potential benefit of more restrictive regulations would be a reduction in consumer dissatisfaction with the fill of food containers. FDA has estimated the benefits of implementing regulations in the proposal on misleading containers that is published elsewhere in this issue of the **Federal Register**.

2. Reject Recommendation of IOM Report

If FDA had rejected the recommendation of the IOM report, then FDA could have made one of the following decisions: (1) Find that all sections of the act defining circumstances in which a food is misbranded are adequately implemented, or (2) find that one or more sections of the act defining circumstances in which a food is misbranded other than section 403(d) of the act are not adequately being implemented.

If all relevant sections of the act had been found to be adequately implemented, then benefits would have been zero. If one or more sections of the act defining circumstances in which a food is misbranded other than section 403(d) had been found to be not adequately implemented, then there may have been positive benefits. One possible type of regulation that FDA might have promulgated in this case would have simply repeated the language of the relevant section of the act. The benefit of this type of regulation would have been zero because these sections of the act are already legally binding on food package manufacturers. Thus the benefits of this alternative would have been estimated to be zero. If more restrictive regulations had been promulgated, then there may have been positive benefits.

D. Conclusion

In accordance with Executive Order 12291, the agency has analyzed the economic effects of this proposed rule and has determined that this rule, if promulgated, will not be a major rule as defined by that order.

In accordance with the Regulatory Flexibility Act, the agency has considered the effect that this regulation would have on small entities including small businesses and has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

The costs and benefits of this final rule depend on the regulations that FDA produces in response to the requirement that it promulgate regulations ensuring

the adequate implementation of sections of the act that it finds are not adequately being implemented. The costs and benefits of those regulations will be zero if those regulations simply repeat the language of the relevant sections of the act. As noted above, the costs and benefits of implementing regulations are considered in the proposal on misleading containers.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Final lists

Based on its review of the IOM report, the comments to the July 28, 1992 proposal, and other available information, the agency is announcing its conclusions related to the adequacy of Federal implementation of sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the act. FDA finds that the following sections are adequately implemented by FDA regulations: sections 403(b), 403(f), 403(h), 403(i)(1), and 403(k) of the act. Based upon the same considerations, FDA finds that section 403(d) of the act on misleading containers is not adequately being implemented by FDA regulations.

Having made these findings, FDA advises that section 403A(a)(3) of the act and section 6(b)(3)(B) of the 1990 amendments provide that no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce any requirement for the labeling of food of the type required by sections 403(b), 403(f), 403(h), 403(i)(1), or 403(k) of the act that is not identical to the requirement of such section, effective February 5, 1993.

Published elsewhere in this issue of the **Federal Register** is a proposal entitled "Misleading Containers; Nonfunctional Slack-Fill," in which FDA is proposing revisions of its regulations to ensure adequate implementation of section 403(d) of the act. Upon the effective date of the final regulations based upon that proposal, no State or local subdivision of a State may establish or continue in effect any requirement that is not identical to the requirements of section 403(d) of the act and regulations issued thereunder. If the agency does not issue final regulations in response to the proposal by May 8, 1993, the proposed regulations will be

considered the final regulations under the 1990 amendments, and preemption will become effective on the effective date of the rules that, on May 8, 1993, are considered final rules.

Dated: November 5, 1992.

David A. Kessler,

Commissioner of Food and Drugs

Louis W. Sullivan,

Secretary of Health and Human Services

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