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Wednesday
January 6, 1993

Part IV

Department of
Health and Human
Services

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Food and Drug Administration

21 CFR Part 1, et al.
Food Labeling; General Provisions;
Nutrition and Labeling; Label Format; Nutrient
content Claims; Health Claims; Ingredient
Labeling; State and Local Requirements;
and Exemptions; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5, 20,100,101,105, and 130

[Docket No. 92N-0440]

Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; opportunity for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is revoking the regulations implementing section 403(q) and (r) of the Federal Food, Drug, and Cosmetic Act (the act), and the lists implementing section 6 of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), that were considered final by operation of law as of November 8, 1992 (hereinafter referred to as the November 8 regulations). Elsewhere in this issue of the **Federal Register**, FDA is adopting final rules based on public comment to replace the November 8 regulations. FDA is taking this action to ensure that the final regulations that implement the 1990 amendments are those based on full public comment, and that those regulations are put in place without delay.

DATES: Effective January 6, 1993. Comments by February 5, 1993.

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

FOR FURTHER INFORMATION CONTACT:

Frank E. Scarbrough, Center for Food Safety and Applied Nutrition (HFS-150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4561.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, President Bush signed the 1990 amendments into law. Sections 2, 3, and 6 of the 1990 amendments gave FDA 24 months from the date of their enactment to promulgate final rules implementing those sections. In response, FDA published proposals on November 27, 1991 (56 FR 60366 through 60878) and July 28, 1992 (57 FR 33283).

Sections 2(b)(2) and 3(b)(2) of the 1990 amendments provided that, if final

rules to implement section 403(q) and (r) of the act, respectively, were not promulgated by November 8, 1992, then the regulations proposed to implement these sections of the act were to be considered as final regulations. There are similar provisions in section 6(b)(3)(D) of the 1990 amendments.

The 24-month period established by the 1990 amendments expired on Sunday, November 8, 1992, without the issuance of final rules implementing section 403(q) and (r) of the act or section 6 of the 1990 amendments. Thus, on November 8, 1992, the proposed regulations implementing those sections of the act and section 6 of the 1990 amendments were considered final regulations by operation of law. Under sections 2(b)(2) and 3(b)(2) of the 1990 amendments, FDA was directed to promptly publish in the **Federal Register** notice of the new status of the proposed regulations. FDA published that notice on November 27, 1992 (57 FR 56347).

II. The Revocation

The triggering of the mechanism established in sections 2(b)(2), 3(b)(2), and 6(b)(3) of the 1990 amendments did not toll the rulemakings instituted on November 27, 1991, and July 28, 1992, in response to sections 2, 3, and 6 of the 1990 amendments. Elsewhere in this issue of the **Federal Register**, FDA is publishing the final rules that are the culmination of those rulemakings. FDA has concluded that the final rules based on public comment should replace the November 8 regulations.

Because the agency is completing the rulemaking process begun in 1991, it is necessary to revoke the November 8 regulations so that only the rules that have had the benefit of full notice-and-comment procedures are in effect and provide a basis on which industry can begin to conform its food labels to the new requirements. This revocation does not constitute a reversal of the agency's former views as expressed in the November 27, 1991, and July 28, 1992, proposals and in the November regulations, except to the extent that any changes, in accordance with the Administrative Procedure Act (5 U.S.C. 553(b)), are a logical outgrowth of the proposals. To the extent that differences exist between the November 8 regulations and the new final rules, a reasoned analysis for the changes is supplied in the preambles to the final rules published elsewhere in this issue of the **Federal Register**.

The legislative history of the 1990 amendments states that, if the deadline for publishing final rules based on public comment was not met, there

would be good cause to consider the proposed regulations as final regulations because of the importance of mandatory nutrition labeling, rules on claims, and a unified system of regulations on misbranding. The legislative history also pointed to the fact that Congress expected the agency to have received public input prior to issuing the proposed regulations (H. Rept. 101-538, 101st Cong., 2d sess. 18-19 (1990)). The November 8 regulations were to be considered final rules to ensure that some rules would be in place without undue delay to implement the statutory requirements of the 1990 amendments.

Congress contemplated that, if the agency did not issue final rules based on public comment by the specified date (H. Rept. 101-538, supra, 18), and the provisions of sections 2(b)(2), 3(b)(2), and 6(b)(3)(D) of the 1990 amendments were triggered, then the consideration of the proposed rules as final rules without notice and comment should occur and would be justified. This so-called "hammer" provision had an overriding purpose: to motivate FDA and all parties involved in these rules to resolve expeditiously the many issues raised in them, rather than become mired indefinitely in their complexity. FDA believes the hammer has fully achieved its important purpose. It has encouraged prompt resolution of outstanding issues and led to agreement on final rules that represent substantial improvement over the proposed rules and that will be in place sufficiently before the date the statute must be applied to allow full industry compliance.

There is no indication in the legislative history of the 1990 amendments that Congress intended FDA to disregard the comments that it had received on the November 27, 1991, and July 28, 1992, proposals once the "hammer" had fallen and the November 8 regulations were considered final, or that Congress intended the triggering of the mechanism in sections 2(b)(2), 3(b)(2), and 6(b)(3)(D) of the 1990 amendments to prevent FDA from putting in place final regulations based on public comments as quickly as possible. While the proposals to implement the 1990 amendments may have had the benefit of general public comment on food labeling issues, they are no substitute for final rules based on the extensive rulemaking record developed in response to those proposals. In response to the public comments on the proposals, FDA has improved the regulations in numerous respects, better achieving the goals of the 1990 amendments, to the benefit of both industry and consumers.

Revocation of the November 8 regulations will eliminate any ambiguity as to which final regulations are controlling. Thus, for the reasons set forth above, FDA believes that this revocation is fully consistent with the 1990 amendments.

This revocation is also fully consistent with the requirements of the Administrative Procedure Act. The Administrative Procedure Act provides that the agency may revoke a regulation without notice-and-comment procedures "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." FDA finds that there is good cause for dispensing with notice-and-comment procedures in revoking the November 8 regulations.

First, notice-and-comment rulemaking on the revocation of the November 8 regulations is impracticable. Very little time remains before the provisions added by the 1990 amendments and implemented by the November 8 regulations go into effect. The new provisions of the act on health claims are effective on May 8, 1993, without any possibility of extension. Under those provisions, foods are automatically misbranded if health claims are made on their labels that do not meet the requirements of FDA's regulations.

In the final rules published elsewhere in this issue of the **Federal Register**, FDA is exercising the statutory flexibility granted in section 10(a)(3)(B) of the 1990 amendments to extend the date on which it will apply the new provisions on nutrition labeling and nutrient content claims to May 8, 1994. Comments have shown that this additional time for compliance with the final regulations is necessary to prevent undue economic hardship to industry. Even a minimal prior notice-and-comment period on this revocation would be likely to delay issuance of any final rules for at least several months. This delay would reduce significantly the amount of time industry is permitted under the statute to come into compliance with the nutrition labeling and nutrient content claims rules. That compliance cannot begin until the final rules on which the agency intends to rely in enforcing the amendments are in place. Use of notice-and-comment procedures to revoke the November 8 regulations and to replace them with new final rules would thus risk causing the very harm Congress attempted to prevent in permitting this extension.

Secondly, engaging in notice-and-comment rulemaking on the revocation of the November 8 regulations would be contrary to the public interest. The delay caused by receiving and responding to comments on the revocation would increase confusion and could lead to substantial hardship and expense to industry, which would face the possibility of having to label its products to comply with the November 8 regulations and then having to relabel them to comply with any new final rules that the agency eventually issued after the comment period. Revoking the November 8 regulations without notice and comment allows the agency to replace them immediately with final rules based on extensive public comment and thus to provide certainty to industry as to the regulatory requirements with which it must comply.

There is a strong interest in ensuring continuity of regulation, particularly where the purpose of the regulations is to provide information to consumers that they can understand and on which they can rely. A situation in which labels appear that comply with the November 8 regulations, only to be replaced by labels that comply with any final rules that the agency might ultimately issue, would be inconsistent with this goal. Rather, it would contribute to consumer confusion, which is precisely what Congress was trying to prevent in enacting the 1990 amendments to reform the food label.

The agency's final rules implementing the 1990 amendments need to be the gold standard for the food marketplace. Based as they are on public comment, scientific evidence, and sound public policy, the final rules issued today are the culmination of the Department of Health and Human Services' efforts, begun in August 1989, and reinforced in 1990 by the Administration and Congress, to reform the food label.

Finally, it is in the public interest and consistent with the purposes of the Administrative Procedure Act to have in place as quickly as possible final rules that are the product of a full rulemaking procedure. As stated above, Congress included sections 2(b)(2), 3(b)(2), and 6(b)(3) in the 1990 amendments because of the importance of having final regulations in place implementing the 1990 amendments without undue delay. H. Rept. 101-538, supra, 18. Today's action is consistent with that goal, because final rules implementing section 403(q) and (r) will be in place. By revoking the November 8 regulations in a manner consistent with the Administrative Procedure Act, FDA is giving full recognition to the effect of

sections 2(b)(2), 3(b)(2), and 6(b)(3) of the 1990 amendments. The rules that will be in place as a result of today's action have had the benefit of full public comment. Those comments established the existence of problems with the proposals, and FDA has fully addressed those problems in the final rules. (See the final rules published elsewhere in this issue of the Federal Register.)

Considering the factual situation as a whole, there is good cause for waiving notice and comment. FDA has been, diligent in arriving at final rules. In the past year, FDA has reviewed over 40,000 comments, held three public hearings, and produced final rules in more than 20 separate proceedings. There has been full notice-and-comment rulemaking on the final rules that FDA is issuing today, and interested persons have had ample opportunity to comment on all substantive issues addressed in those rules. However, circumstances outside FDA's control prevented it from issuing those final rules by the statutory deadline. In light of this, the agency is acting responsibly and reasonably in dealing with the unique situation it faces. The agency's prompt action to withdraw the November 8 regulations is necessary to facilitate the enormous transformation of the food label that will occur over the coming months. Moreover, no hardship will result from replacing the November 8 regulations now, because not enough time has passed since November 8 to permit significant action in reliance on the November 8 regulations.

Therefore, FDA concludes that there is good cause for withdrawing the November 8 regulations without notice and comment.

Consistent with its own procedural regulations, however, FDA is providing an opportunity for comment on its decision to revoke the November 8 regulations. Under § 10.40(e)(1) (21 CFR 10.40(e)(1)), FDA may issue a regulation without notice and public procedures when the agency determines for good cause that they are impracticable, unnecessary, or contrary to the public interest. In such a situation, the FDA procedural regulations require that the notice promulgating the regulation state the reasons for the determination, and provide an opportunity for comment to determine whether the regulation should subsequently be modified or revoked. This notice complies with these procedural requirements. Given the present unique circumstances, however, FDA finds under § 10.40(b)(2) that there is good cause to limit the comment period to 30 days.

FDA also finds, based on the reasons discussed above, that there is good cause to issue this revocation effective immediately (5 U.S.C. 553(d)(3)). A delayed effective date would be contrary to the public interest in minimizing regulatory uncertainty: it would create unnecessary confusion if these rules remained in effect for 30 days after the issuance of the final rules based on notice and comment. Moreover, this revocation of regulations that are not yet effective will not impose any behavioral changes on regulated industry, unlike the promulgation of a normative rule. Thus, a delayed effective date for this final rule would be unnecessary, impracticable, and contrary to the public interest.

After carefully considering the provisions of the 1990 amendments and their legislative history, FDA believes that, in this final rule and in the other final rules published today, it has taken the appropriate steps to resolve any questions created by the hammer. FDA is taking a course that recognizes Congress' desire to have final regulations in place by November 8, 1992, but that also recognizes, as discussed above, that Congress ultimately would not want to undercut the benefits of notice-and-comment rulemaking. The agency considered various alternate courses of action but rejected them because they were inconsistent with the 1990 amendments, the amendments' legislative history, the relevant facts, or the urgency of the current situation.

One alternative would have been to propose to revoke the November 8 regulations and to propose rules to replace them. This course was rejected because it would create too much uncertainty for industry, which would then have been compelled to begin complying with section 403(r)(1)(B) of the act on May 8, 1993, and with requirements on nutrition labeling and nutrient content claims by May 8, 1994, and because this course of action gives no effect to the extensive rulemaking that FDA has conducted for the last 12 months.

A second course would have been to term the final rules published today "interim rules," with additional opportunity for comment and a commitment to publish "true" final rules based on further comment. The agency has concluded that there would be little gain from such a course. Calling the rules "interim rules" would only create confusion and could induce industry to postpone action to comply with the new regulations. Also, although the comment period on the November 27, 1991, proposals closed on

February 25, 1992, FDA continued to receive and consider comments well into the early fall. FDA believes that, since that time, no new information has become available that would change the agency's regulatory approach. If such information exists, FDA's procedural regulations provide ways for bringing it to the agency's attention, e.g., a petition under 21 CFR 10.30.

A third course would be simply to leave the November 8 regulations in place. FDA has concluded that this course of action would make little sense. It would be unfair to both industry and consumers to forego promulgating the best regulations possible. The agency thus believes that, in publishing the new final rules today, it is acting in the best interests of industry and consumers.

The agency therefore urges all affected manufacturers, packers, and distributors to begin to act in accordance with the final rules published today. The agency has received numerous comments about how much work will be necessary to comply with the new regulations, and, in response, FDA is announcing elsewhere in this issue of the **Federal Register** that it is delaying until May 8, 1994, the application of section 403(q) and (r)(2) of the act. However, if there is to be compliance by the application date, work must begin now. The final rules published today establish the requirements that must be met.

III. Additional Comments

The final rules that FDA is issuing today are the product of notice-and-comment procedures, and no further such procedures are required. The Administrative Procedure Act provides for notice and opportunity for public comment on proposed agency rules to ensure meaningful public input into agency rules that affect the public. Public comment is not an end in itself. FDA believes that it has fulfilled any possible purpose of this requirement. The agency has provided three prior opportunities for public comment on food labeling reform: the 1989 advance notice of proposed rulemaking, proposed rules in 1990, and proposed rules implementing the 1990 amendments in 1991 and 1992. While additional comments are always possible, the agency believes the Administrative Procedure Act in no way requires an additional opportunity for them. Now, the public interest requires finality and expeditious actual reform of the label—to the benefit of both industry and consumers. Recognizing, however, that some people may argue that there is a technical requirement for further rulemaking procedures, FDA finds that

there is also good cause to proceed without them. For the reasons discussed elsewhere in this document, and in light of the extensive rulemaking procedures that have already been followed, further notice and comment would be unnecessary/impracticable, and contrary to the public interest.

The agency firmly believes that all the final rules it is publishing today, including those superseding the November 8 regulations, are the logical outgrowth of the November 27, 1991, and July 28, 1992, proposals and are fully supported by the administrative record that has been developed. Although the agency does not believe that any public purpose would be served by reopening for further comment at this time the issues addressed in that rulemaking, FDA recognizes that in any rulemaking of this size there will be technical issues in specific provisions. Therefore, the agency is providing 30 days for comment on these final rules on such issues. FDA is not interested in receiving comments that it has already received and considered. Interested persons are urged to limit their comments to technical matters or technical unintended consequences in specific provisions if not raised in earlier comments, in order to assure consideration of any comments, interested persons must certify that their comments are so limited. Comments should be submitted to the specific docket of the final rule being commented on. If the comments identify any technical provision of the final rules that FDA agrees should be changed, FDA will take action to modify that Provision. This approach will enable FDA to quickly address any unintended effects of the final rules, yet not delay the finality that FDA believes is imperative for both industry and consumers.

IV. Opportunity for Comments

Under §10.40(e), an opportunity for comment on this final rule is being provided. Interested persons may, on or before February 5, 1993, submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Therefore, the regulations that were considered final by operation of law on November 8, 1992, as announced in the

Federal Register of November 27, 1992
(57 PR 56347), are hereby revoked.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drug.

Louis W. Sullivan,

Secretary of Health and Human Services.

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