

ensure that it would be given effect without undue delay. In the 1994 DSHEA, Congress, while embracing most of what FDA has done under the 1990 amendments with respect to dietary supplements, sought to provide for the inclusion of additional information on the nutrition label and to provide additional flexibility in how that information is presented. The dietary supplement industry is left facing an applicability date for FDA's nutrition labeling and nutrient content claim regulations for dietary supplements of July 1, 1995, without complete guidance on how the nutrition label is ultimately to be presented on these products. As for consumers, they are currently provided with nutrition information on many, but by no means all, dietary supplements, but that information is not being presented in a form that is consistent with the "Nutrition Facts" panel that appears on conventional foods.

Having considered these factors, FDA advises that, while the nutrition labeling and nutrient content claim regulations implementing the 1990 amendments for dietary supplements will go into effect on July 1, 1995, it does not intend to enforce those regulations until it has modified them to reflect the 1994 DSHEA, and until after dietary supplement manufacturers are required to label their products in accordance with the 1994 DSHEA; that is, not until after December 31, 1996.

FDA considers this course of action appropriate for several reasons. First, FDA recognizes the merit in the dietary supplement industry's argument that it should not be required to relabel its products until it has a full understanding of what its alternatives and obligations are. Enforcing the nutrition labeling and nutrient content claims regulations on July 1, 1995, would require dietary supplement manufacturers to choose between relabeling their products twice, the first time to come into compliance and the second to take advantage of the flexibility provided by the new law, or foregoing that flexibility. To force dietary supplement manufacturers to make such a choice would be a result that the agency does not believe Congress contemplated or would have intended in enacting the 1994 DSHEA.

The 1994 DSHEA provides for flexibility in the dietary ingredients that can be included in the "Nutrition Facts" box and in the presentation of ingredient information. FDA, pursuant to the 1994 DSHEA, is at work on regulations that define this flexibility. FDA agrees that industry should have an opportunity to take advantage of this

flexibility without being forced to relabel twice to do so. FDA acknowledges that it will not be possible for the agency to have its regulations in place, nor for the industry to have adequate time to design its labeling in accordance with these regulations, by July of this year. Thus, the interests of industry and the policies embodied in the 1994 DSHEA will be advanced if FDA declines to enforce the nutrition labeling and nutrient content claim regulations that apply to dietary supplements until after December 31, 1996, when they will be fully modified to reflect the 1994 DSHEA.

While the purposes of the 1990 amendments will not be as clearly advanced by such a course of action, they will also not be contravened. Implementation of the 1994 DSHEA will move FDA forward toward its goal of full implementation of the 1990 amendments. Moreover, while Congress sought to rule out undue delay in implementation of the 1990 amendments, a delay caused by implementation of another law enacted by Congress can hardly be considered "undue."

Finally, it is true that consumers face an additional delay before dietary supplements bear nutrition information that is as consistent as possible, both in content and presentation, with that on other foods, and until there is full compliance by dietary supplements with the nutrient content claim provisions of the act. These facts are mitigated, however, by the fact that there is information listing nutrients and their levels on many dietary supplements, and that many dietary supplements do not bear nutrient content claims.

Thus, having fully considered these factors, the agency advises that it does not intend to enforce the nutrition labeling and nutrient content claims regulations that apply to dietary supplements until after December 31, 1996. The agency is at work developing a proposal that implements the labeling provisions of the 1994 DSHEA and expects to publish it in the near future.

III. References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Cordaro, John, President, Council for Responsible Nutrition, letter to David A. Kessler, Commissioner, FDA, December 7, 1994.

2. Shank, Fred, R., Director, Center for Food Safety and Applied Nutrition, FDA, letter to John B. Cordaro, President, Council for Responsible Nutrition, January 30, 1995.

Dated: February 6, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 226

Administration of Assistance Awards to U.S. Non-Governmental Organizations

AGENCY: Agency for International Development (USAID).

ACTION: Correction to interim final rule.

SUMMARY: This document contains a correction to the interim final rule which was published Thursday, January 19, 1995 (60 FR 3743). The rule relates to the administration of assistance awards to U.S. Non-Governmental Organizations.

EFFECTIVE DATE: February 9, 1995.

FOR FURTHER INFORMATION CONTACT: Diana Joan Esposito, Office of Procurement, Procurement Policy and Evaluation (M/OP/P), USAID, SA-14 Rm. 1600I, 320 21st Street, Washington, DC 20523. Telephone 703 875-1529, Fax 703-875-1243.

SUPPLEMENTARY INFORMATION:

Background

On January 19, 1995, USAID issued an interim final rule at 22 CFR part 226 which implemented Office of Management and Budget (OMB) Circular A-110.

Need for Correction

As published, the preamble refers to a change that was not implemented in the interim final rule.

Correction of Publication

Accordingly, the publication on January 19, 1995 of the interim final rule, is corrected as follows:

Preamble [Corrected]

On page 3744, in the first column, at the paragraph beginning "Section 226.22(l) is revised to provide * * *" is corrected to read: "Section 226.22(l) is revised to provide that USAID may authorize recipients to retain all interest earned in accordance with USAID's statutory authority." The statement in the preamble that interest earned will be remitted to USAID has been deleted.