

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98N-0044]

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Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Partial Stay of Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; partial stay of compliance.

SUMMARY: The Food and Drug Administration (FDA) is announcing a partial stay of compliance for the final rule defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body for certain dietary supplement products. Dietary supplement products that were labeled, or for which labeling had been printed, on or before January 6, 2000, the publication date of the final rule, are eligible for the stay. This action is in response to two petitions for stay and reconsideration.

DATES: This rule is effective *[insert date 30 days after date of publication in the Federal Register]*. Submit written comments by *[insert date 30 days after date of publication in the Federal Register]*. Submit written comments on the information collection provisions of this final rule by *[insert date 10 days after date of publication in the Federal Register]*. Notifications of products that are eligible for the stay of compliance may be submitted to FDA at any time following the effective date of this rule; it is to manufacturers' advantage to submit such notifications as soon as possible, as only products for which FDA has received a notification qualify for the stay.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit written comments on the information collection provisions of this final rule to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), 725 K St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. Send notifications of products that are eligible for the stay of compliance to Food and Drug Administration, Office of Nutritional Products, Labeling, and Dietary Supplements, Division of Compliance and Enforcement (HFS-810), 200 C St. SW., Washington, DC 20204.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4605.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of January 6, 2000 (65 FR 1000), FDA published a final rule entitled “Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body” (hereinafter referred to as “the final rule”). In the final rule, FDA established regulations to define the types of statements that may be made without prior FDA review about the effects of dietary supplements on the structure or function of the body (structure/function claims), and to distinguish these claims from claims that a product treats, prevents, cures, diagnoses, or mitigates disease (disease claims).

In the preamble to the final rule, FDA stated that the final rule would become effective on February 7, 2000, approximately 30 days after publication. FDA also stated that any product that is marketed for the first time after publication of the final rule, and any new claims made for an existing product for the first time after the publication of the final rule, would be expected to be in compliance as of the effective date, February 7, 2000. However, small businesses that marketed a product as of January 6, 2000, the date of publication of the final rule, would have

an additional 17 months (until July 7, 2001) to bring existing claims (i.e., claims already in the product's labeling on January 6, 2000) for those products into compliance. For all other products that were on the market as of January 6, 2000, FDA allowed an additional 11 months beyond the effective date (until January 7, 2001) to bring existing claims for those products into compliance.

II. Petitions for Reconsideration and Stay of Action

FDA received one petition under § 10.35 (21 CFR 10.35) for stay of the 30-day effective date and one petition under 21 CFR 10.33 for stay and reconsideration of part of the implementation plan in the final rule. A petition for stay submitted jointly by the Council for Responsible Nutrition (CRN) and the Consumer Healthcare Products Association (CHPA) (Docket No. 99N-0044/PSA1) (Ref. 1) (hereinafter referred to as the "joint petition") requested that FDA stay its 30-day effective date for "pipeline" products, i.e., products that were labeled, or for which labeling had been printed, but that had not yet been marketed when the final rule was published on January 6, 2000. The joint petition requested that such products be given the 11 or 17 months for compliance afforded to products that were being marketed as of the publication date of the final rule. The joint petition stated that in the nearly 2 years between publication of the proposed and final rules, dietary supplement manufacturers and distributors had relied on the criteria and examples of acceptable structure/function claims in the proposed rule to develop marketing strategies, manufacture products, and design and produce labeling. The petition stated that in many cases, this reliance had involved a significant investment of resources.

The joint petition further stated that the implementation of the final rule will involve, among other things, package redesign, redesign of websites and promotional literature, and sometimes, new packaging equipment. The joint petition argued that the short implementation period (30 days for products not yet marketed) would not provide a long enough transition period to enable "pipeline" products to be brought into compliance. Moreover, the joint petition asserted that giving such products the same transition compliance period as products that had actually been marketed

by January 6, 2000, would provide a fair and reasonable implementation plan for firms that had invested energy and resources, in good faith, developing a new product with labeling bearing claims based on the proposed rule, but that narrowly missed marketing the product by January 6, 2000.

The petition for stay and reconsideration was submitted by the American Herbal Products Association (Docket No. 98N-0044/PRC4) (Ref. 2) (hereinafter referred to as the "AHPA petition"). The AHPA petition requested that FDA reconsider two provisions of the final rule, one of which was the implementation plan. This notice will address only the request in the AHPA petition that concerns the implementation plan in the final rule; the other part of the AHPA petition will be addressed separately at a later time.

The AHPA petition requested two actions by FDA concerning the implementation plan. First, the AHPA petition requested that FDA treat certain products labeled before the February 7, 2000, effective date the same way as products marketed before the publication of the final rule on January 6, 2000. Specifically, the petition requested that FDA allow any product labeled before the February 7, 2000, effective date to be marketed during the 11-month or 17-month transition compliance period, provided that a notification has been submitted to FDA as required by section 403 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(6)), that FDA has not objected to the notification, and that the product bears the required disclaimer. Second, the AHPA petition requested that products subject to the transition compliance period be allowed to be shipped after that period has ended, provided that the label had been affixed to the product prior to the applicable 11-month or 17-month compliance date.

The AHPA petition stated that the requested relief is necessary for two reasons. First, the AHPA petition asserted that the 30-day effective date does not provide enough time to relabel products that were in the pipeline, but were not marketed, before the publication of the final rule. The AHPA petition also stated that products labeled at any point during the 11-month or 17-month transition period should be allowed to be marketed even after the applicable compliance date to reduce the costs of the rule by eliminating the need to relabel or destroy inventory not

marketed by the end of the transition period. The AHPA petition further stated that there is no basis to distinguish the implementation scheme for the final rule from that used to implement the dietary supplement nutrition labeling final regulations published in the **Federal Register** of September 23, 1997 (62 FR 49826 at 49842), which provided that any product labeled before the effective date did not have to be relabeled to comply after the effective date.

III. Response to Petitions

FDA has fully evaluated the two petitions for stay and reconsideration of the implementation plan in the final rule. FDA agrees that there may be manufacturers who, relying on the criteria and examples of acceptable structure/function claims in the proposed rule, produced labeling with claims that would have been considered structure/function claims under the proposed rule, but that are classified as disease claims under the final rule. We also agree that the 30-day effective date of the final rule may not have provided a long enough transition period to enable products close to being marketed when the final rule was published to be brought into compliance. Therefore, FDA is announcing a stay of compliance for a limited class of products. Products that were labeled no later than the publication date of the final rule, January 6, 2000, or for which labeling had been printed by that date (hereinafter referred to as "eligible products") will be eligible for the stay.

To prevent the partial stay from becoming effectively a blanket stay of the 30-day effective date for all products, FDA is requiring that any firm wishing to take advantage of the stay notify FDA of that fact before it markets its eligible products. The notification must: (1) Include the name and complete address of the firm submitting it; (2) identify the eligible products; (3) provide documentation that the eligible products were in fact labeled no later than January 6, 2000, or that labeling for the products had been printed by that date; and (4) include a certification, signed by a responsible individual, that the products are eligible for the stay. The eligible products must be described with sufficient specificity to enable FDA to identify them in the marketplace and distinguish them from other products (including other lots of the same product) that do not qualify

for the stay. For example, the identification might consist of the name of the product and a unique identifier code, such as a product identification or lot code that the manufacturer uses to track its products.

FDA believes that the notification requirement is necessary for effective enforcement of the final rule. Without the notification, the agency would be unable to verify whether individual products are eligible for the stay and therefore would not be able to determine which products in the marketplace bear violative claims and are subject to enforcement action.

Firms must send the required notification to: Food and Drug Administration, Office of Nutritional Products, Labeling, and Dietary Supplements, Division of Compliance and Enforcement (HFS-810), 200 C St. SW., Washington, DC 20204. Notifications may be submitted at any time after the effective date of this final rule. It is to a manufacturers' advantage to submit such notifications as soon as possible, as only products for which FDA has received a notification qualify for the partial stay of compliance.

Small businesses that have eligible products and that submit the required notification to FDA will have 17 months after the effective date of the final rule (until July 7, 2001) to bring their eligible products into compliance, and other firms will have 11 months after the effective date of the final rule (until January 7, 2001) to bring their eligible products into compliance. We believe that this action provides a fair and reasonable implementation plan for firms that made a substantial investment in products that narrowly missed being marketed by the publication date of the final rule.

We are not granting the request in the AHPA petition that FDA allow products labeled before the 11-month or 17-month compliance date to be shipped after that date. In the preamble to the final rule (65 FR 1000 at 1044), FDA concluded that the compliance periods of 11 and 17 months following the effective date of the final rule were reasonable and fair. The agency stated that these compliance periods, uniformly applied, are sufficiently long and that an extension of the time to comply is not needed. The purpose of the compliance period is to give firms time to

develop new labels that comply with the requirements of the act and regulation and to ensure a level playing field for all firms marketing dietary supplements. We find no basis to permit some firms to continue to market products with claims that violate the act and that may give them a competitive advantage over products marketed by firms that have made the investment in time and expense to meet the applicable compliance dates.

Moreover, granting AHPA's request would create an incentive for manufacturers to perpetuate existing claims that are defined as disease claims under the final rule and, in fact, to label as many products as possible with such claims between now and the applicable compliance date. FDA believes that creating such an incentive would be unwise and that the agency should maintain the policy in the final rule, which was designed to encourage manufacturers to change their labeling in accordance with the final rule as quickly as possible, but no later than the applicable compliance date. Having a date by which all products must comply will reduce consumer confusion and greatly simplify enforcement, as after that date the agency will be able to take action against any product that bears unapproved disease claims, without also having to determine when the product was labeled.

We disagree that the basis for the effective date of the September 23, 1997, final rule implementing the nutrition labeling requirements for dietary supplements is relevant to the current rulemaking. In deciding to base the effective date of the September 23, 1997, final rule on the date of labeling, rather than the date of marketing, FDA relied on language in section 7 of the Dietary Supplement Health and Education Act of 1994 (DSHEA). Section 7 of DSHEA states that dietary supplements "may be labeled after the date of the enactment of this Act in accordance with the amendments made by this section, and shall be labeled after December 31, 1996, in accordance with such amendments." The final rule implements section 6 of DSHEA, which does not contain the same language as section 7 and is not subject to section 7. Therefore, the fact that FDA allowed products labeled before the effective date of the September 23, 1997, final rule to be marketed after the effective date of that rule does not compel that the same approach be

taken to implement the final rule. For the reasons discussed above, namely, to encourage prompt implementation of the rule and ensure a level playing field after the compliance date, the agency is not staying the compliance dates in the implementation plan for products labeled on or before the appropriate compliance date. Consistent with the implementation plan in the final rule (65 FR 1000 at 1044), all products in interstate commerce that are subject to the final rule must be in compliance with the act and regulations by July 7, 2001 (for products marketed by small businesses), or January 7, 2001 (for other products).

Under § 10.35(a) and (d)(1), FDA may stay the effective date of a rule, or any other administrative action, upon a finding that the stay is in the public interest. FDA finds that this partial stay of compliance is in the public interest because it will allow a fair and reasonable transition compliance period for firms that made a substantial investment in dietary supplement products that were close to marketing when the final rule was published.

The Administrative Procedure Act and FDA regulations provide that the agency may issue a regulation without notice and comment procedures when the agency for good cause finds that such procedures are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 553(b)(3)(B); 21 CFR 10.40(e)(1)). Because this final rule is a stay of compliance, FDA finds that there is good cause to dispense with notice and comment procedures. Notice and comment procedures are unnecessary because this final rule does not change the substantive requirements of the final rule, only the date on which compliance with those requirements is expected for a limited class of products. Further, notice and comment procedures are not in the public interest because the final rule has already become effective, and therefore a prompt response to the petitions for stay and reconsideration is important.

IV. Analysis of Impacts

The economic impact of the final rule was discussed in the **Federal Register** (65 FR 1000 at 1044 through 1049). A partial stay of compliance for the final rule will provide additional time for companies to relabel products and will reduce label obsolescence, as there will be additional

time to use up more existing labeling. Although this rule granting a partial stay of compliance will impose some small administrative costs on those industry members that wish to take advantage of it, these costs are expected to be much smaller than the savings that will be realized from reduced inventory losses. Thus, this final rule granting a partial stay of compliance should reduce the economic impact on industry.

FDA has examined the impacts of this final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612) and the Unfunded Mandates Reform Act. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. This final rule provides a stay of compliance, which will allow manufacturers additional time to use up existing product labeling. Accordingly, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation).

The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this rule, because this rule is not expected to result in expenditures that would exceed \$100 million, adjusted for inflation, in any one year. The current inflation-adjusted statutory threshold is \$110 million.

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Notification of Products Eligible for a Stay of the Effective Date of FDA's Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body

Description: Under sections 301, 403(r)(1)(B) and (r)(6), and 505(a) of the act (21 U.S.C. 331, 343(r)(1)(B) and (r)(6)), and 355(a)) FDA is responsible for preventing distribution in interstate commerce of products marketed as dietary supplements with claims about the effect of the product on a disease, unless the claim is an authorized health claim. Section 701(a) of the act (21 U.S.C. 371(a)) gives FDA the authority to issue regulations for the efficient enforcement of the act. In

the final rule (65 FR 1000), FDA published a regulation that defined the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. In the preamble to the final rule, the agency stated that the final rule would become effective on February 7, 2000, approximately 30 days after the date of the final rule's publication in the **Federal Register**. The final rule further provided that any product that is marketed for the first time after publication of the final rule, and any new claims made for an existing product for the first time after the publication of the final rule, would have to be in compliance as of the effective date.

In response to two petitions asking the agency to stay and/or reconsider the 30-day effective date for the final rule, FDA is granting a partial stay of compliance with the rule for those dietary supplement products that were labeled or for which labeling had been printed on or before January 6, 2000, the publication date of the final rule. A manufacturer that wishes to market products that are eligible for the stay would have to notify FDA of the identity of its eligible products; provide documentation that the products were labeled by January 6, 2000, or that labeling for the products had been printed by that date; and certify that the products that are the subject of the notification meet the eligibility criteria.

Information that is required in the notification includes: (1) The name and complete address of the firm submitting the notification; (2) a description of the products that are the subject of the notification. The description must be sufficient to enable FDA to identify the firm's qualifying products in the marketplace and distinguish them from other products (including other lots of the same product) that are not eligible for the stay. For example, the description might consist of the name of the product and a unique identifier code (such as a product identification or lot code that the manufacturer uses to track its products); (3) documentation that the products were labeled by January 6, 2000, or that the labeling for the products had been printed by that date (for example, purchase records from a label manufacturer or production records that showed that the products

had been labeled by January 6, 2000); and (4) a certification, signed by a responsible individual, that the products are eligible for the stay.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
48	1	48	2	96

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the number of firms that may have products that are eligible for the stay. In the final rule (65 FR 1000 at 1047), FDA estimated that 1,000 firms manufacture dietary supplement products that would be covered by the final rule. FDA also estimated that approximately 4.81 percent of the 17,400 dietary supplement products currently being marketed with structure/function claims would be required to change their labels because of the requirements in the final rule (65 FR 1000 at 1046). Therefore, assuming that products affected by the final rule are uniformly distributed throughout the industry, approximately 48 firms (4.8 percent of 1,000 firms) may have products affected by the partial stay of compliance.

The notification burden would consist of the preparation of the letter notifying FDA and accompanying documentation that the products were labeled before January 6, 2000, or that the labeling had been printed by that date. FDA believes this burden will be small since firms already have the information needed to describe their own products with specificity. With respect to the supporting documentation, the firm would already have identified the relevant documents as part of ascertaining which products are eligible for the stay. Therefore, the firm would only need to reproduce the relevant documents to accompany the notification. The notification is a one-time action, and all of a firm's eligible products can be listed in a single notification. Therefore, FDA anticipates receiving only one notification per firm.

The information collection provisions of this final rule have been submitted to OMB for review. Interested persons may send comments regarding information collection by *[insert date 10 days after date of publication in the Federal Register]*, to the Office of Information and

Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FDA has requested expedited processing of this information collection request under section 3507(j) of the PRA and 5 CFR 1320.13. The information to be collected under this final rule is needed before clearance could be obtained under the normal PRA clearance time periods. Further, the use of normal PRA clearance procedures is impracticable and would be likely to prevent or disrupt the collection of information because the compliance periods during which products that qualify for the partial stay may be marketed without relabeling would have ended or would be close to ending.

Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the final rule by [*insert date 30 days after date of publication in the **Federal Register***], except that comments regarding information collection are to be submitted to OMB (address above) by [*insert date 10 days after date of publication in the **Federal Register***]. 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Council for Responsible Nutrition and Consumer Healthcare Products Association, Petition for Stay of Action, February 7, 2000.

2. American Herbal Products Association, Petition for Reconsideration and Petition for Stay of Action, February 7, 2000.

Dated: 9/21/00
September 21, 2000.



William K. Hubbard
Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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