



SEP 25 2000

James H. Skiles
Vice President and General Counsel
Grocery Manufacturers of America
1010 Wisconsin Ave., NW, Ninth Floor
Washington, DC 20007

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Re: Docket No. 00N-0506/PRC1

Dear Mr. Skiles:

This letter responds to your petition for reconsideration (PRC) and stay dated February 7, 2000. In that petition, you request that the Food and Drug Administration (FDA) reconsider its determination that implied disease claims are outside the scope of structure/function claims permitted under section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act). You also request that FDA stay the effective date of that portion of the final rule on Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body (65 FR 1000, Jan. 6, 2000) that states that implied disease claims are not structure/function claims. FDA reaffirms its prior decision regarding implied disease claims and denies your request for a stay for the reasons set forth below.

I. Your Request for Reconsideration

FDA will reconsider an Agency action using the criteria found at 21 CFR 10.33. Section 10.33(d) provides that:

The Commissioner shall grant a petition for reconsideration in any proceeding if the Commissioner determines all of the following apply:

- (1) The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.
- (2) The petitioner's position is not frivolous and is being pursued in good faith.
- (3) The petitioner has demonstrated sound public policy grounds supporting reconsideration.
- (4) Reconsideration is not outweighed by public health or other public interests.

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The Agency does not dispute your statement (PRC at 10) that your petition is not frivolous and is being pursued in good faith (criterion #2 above). Nevertheless, FDA has determined that your petition does not meet the remaining three reconsideration criteria.

A. FDA fully and adequately considered all relevant information and views contained in the administrative record.

The Agency has determined that you did not demonstrate that any relevant information was inadequately considered in the Agency's decision to include implied disease claims within the definition of disease claims.

You argue that FDA did not adequately consider your comments on the proposed rule (PRC at 5). In those comments and in your petition for reconsideration, you argue that the Act must be read to include implied disease claims within the scope of structure/function claims authorized by section 403(r)(6) (see PRC at 4-8).

FDA took a number of steps to ensure that it carefully considered all relevant information and views on whether implied disease claims are disease claims, including your comments. In the *Federal Register* of July 8, 1999 (64 FR 36824), FDA announced a public meeting to be held on August 4, 1999, at which representatives of the dietary supplement industry, consumer groups, and health professionals were asked to address three major issues raised by the comments. One of those three specific issues was whether to permit implied disease claims to be considered structure/function claims. The July 8, 1999, notice also reopened the comment period for the proposed rule until August 4, 1999, to receive additional written comments on these issues. Many of these comments took a position contrary to the position you advocate.

After the public meeting and in response to the oral and written comments received, FDA published a detailed discussion of the implied claims issue in the preamble to the final rule. In that discussion, FDA summarized the comments received, responded to those comments, and stated the reasons why it would treat implied disease claims as disease claims (see, e.g., 65 FR 1000 at 1011-30, 1037). FDA responded specifically (65 FR 1000 at 1013-15) to your arguments regarding the statutory construction of section 403(r)(6) of the Act (see PRC at 4-6, 10) and its legislative history (see PRC at 7). You characterize this detailed response to your comments as "inadequate" (see, e.g., PRC at 5, 7, 10). In fact, it appears that you simply disagree with FDA's position and rationale as stated.¹

You request that if FDA finds that implied disease claims are disease claims, FDA state that only implied claims for which there is a direct causal relationship between the structure or function parameter in the claim and a known disease be considered disease claims (PRC at 3). You made this identical request in your comments on the proposed rule, and FDA responded to your

¹ For example, you argue that an article is a drug under section 201(g)(1)(B) of the Act only if "express disease claims" are made for the article (PRC at 4-5, 7-8). FDA unequivocally disagrees with your position, and provided an in-depth explanation as to why in the preamble of the final rule (65 FR 1000 at 1014, 1037).

comment in the preamble to the final rule (65 FR 1000 at 1015). As explained there, FDA considered your comment and others like it "but does not believe that any of them have provided a principle that distinguishes between claims that consumers will understand as disease claims and those that will not be understood as disease claims."

B. You have not demonstrated sound public policy grounds supporting reconsideration.

You argue that FDA does not have the legal authority to state that implied disease claims are not structure/function claims (PRC at 1). You note that there is pending litigation concerning FDA's authority to determine the breadth of its own drug jurisdiction and the First Amendment limitations imposed on FDA authority to prohibit commercial speech that is not false or misleading (PRC at 10-11).

FDA is routinely responsible for responding to challenges regarding the scope of its authority and its implementation of the statutes with which it is charged. Pending litigation is not a sound public policy ground on which FDA will generally rest reconsideration of its actions. In any case, FDA addressed in the preamble to the final rule the litigation you appear to reference (see PRC at 8, n. 10). The Agency explained there why the rule does not depend on resolution of any issue before the courts in those cases (65 FR 1000 at 1036-40).

C. FDA continues to find that reconsideration is outweighed by public health or other public interests.

You argue that a stay will facilitate the dissemination of truthful and nonmisleading information about the effects of foods on the structures and functions of the human body and thus promote the public health and the public interest (PRC at 11).

As FDA stated in the preamble to the final rule, the fact that labeling is truthful does not necessarily mean that it falls within the scope of claims authorized by section 403(r)(6) of the Act. For example, the Agency believes that there are many dietary ingredients that could be shown to treat or prevent diseases and for which it could thus be truthful to state that the product treats or prevents a specific disease. Under the Act, however, if a manufacturer wants to explicitly or implicitly label its product to treat or prevent disease, it must do so under the drug approval provisions or the health claim provisions of the Act. It may not do so under section 403(r)(6) of the Act. In drafting section 403(r)(6) of the Act to exclude disease claims, Congress made a judgment that the public health will be served by requiring premarket review of such claims (65 FR 1000 at 1023).

Because you have not met all of the criteria found in § 10.33(d), your petition for reconsideration is denied.

II. Your Request for a Stay

You have also requested that FDA stay the effective date of those provisions of FDA's final rule that exclude implied disease claims from the scope of structure/function claims permitted under section 403(r)(6). Pursuant to 21 CFR 10.35(e), FDA may stay an action if it is in the public interest and in the interest of justice to do so and shall stay an action if all of the following apply:

- (1) The petitioner will otherwise suffer irreparable injury,
- (2) The petitioner's case is not frivolous and is being pursued in good faith,
- (3) The petitioner has demonstrated sound public policy grounds supporting the stay, and
- (4) The delay resulting from the stay is not outweighed by public health or other interests.

For the same reasons discussed above with respect to your petition for reconsideration, FDA believes that no sound public policy grounds exist to support a stay, and that staying the effective date of the implied claims provisions of the final rule would not be in the public interest. While we accept the fact that your requests have been made in good faith, we do not accept the representation that your members will suffer irreparable injury without a stay. You assert that the final rule is "tantamount to a ban on their commercial speech." However, FDA has explained in-depth in the preamble that the final rule is consistent with the First Amendment (65 FR 1000 at 1037-43). Your request for a stay is therefore denied.

Sincerely yours,



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