Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98N–0044]

RIN 0910–AA59

Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to solicit additional comments on three particularly controversial issues raised by FDA's proposed rule on statements made for dietary supplements concerning the effect of the product on the structure or function of the body (''structure/function claims''). This meeting is intended to provide the public an additional opportunity to provide focused comment on these issues in a manner that will assist FDA in evaluating appropriate policies and approaches. FDA is also reopening, until August 4, 1999, the comment period for the proposed rule, to allow interested persons to comment on the issues raised in this document.

DATES: The meeting will be held on August 4, 1999, from 8 a.m. to 6 p.m. Submit written comments on or before August 4, 1999.

ADDRESSES: The meeting will be held at the Jefferson Auditorium, U.S. Department of Agriculture, 1400 Independence Ave. SW., Washington, DC. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, or via e-mail to ''FDADockets@oc.fda.gov''. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Lisa Barclay, Office of Policy, Planning, and Legislation (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of April 29, 1998 (63 FR 23624), FDA published a proposed rule on the types of claims that could be made for dietary supplements without prior authorization by FDA. Under Federal Food, Drug, and Cosmetic Act (the act), as amended by the Dietary Supplement Health and Education Act of 1994 (DSHEA), a dietary supplement may carry a statement that describes ''the role of a nutrient or dietary ingredient intended to affect the structure or function in humans'' or that ''characterizes the documented mechanism by which [the supplement] acts to maintain such structure or function.'' These types of claims are referred to as structure/function claims. However, a permitted structure/function statement ''may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.'' These types of claims are referred to as ''disease claims.''

In the April 29, 1998, proposal, FDA stated its belief that the line between structure/function claims and disease claims was not always clear and that clarifying criteria were needed. The proposed rule was intended to help identify disease claims; claims that did not qualify as disease claims would be considered acceptable structure/function claims. The proposal contained a definition of ''disease,'' based upon current definitions of the term in medical and legal dictionaries. This definition differed from a definition of ''disease or health-related condition'' already found in FDA's regulations implementing the health claims provisions of the Nutrition Labeling and Education Act (NLEA). FDA proposed to conform the definition of ''disease or health-related condition'' in the health claims regulation to the proposed new definition of ''disease.'' The proposal also contained 10 criteria for identifying disease claims.

FDA received over 100,000 comments on the proposed rule. Most of the comments objected to the proposed definition of disease or to some or all of the criteria for identifying disease claims. Although the comments raised many issues, three issues received particular attention: (1) Whether FDA should retain the definition of ''disease or health-related condition'' issued for NLEA health claims, rather than issue a new definition of ''disease''; (2) whether certain common conditions associated with natural states, such as hot flashes associated with menopause, or premenstrual syndrome associated with the menstrual cycle, should be considered ''diseases''; and (3) whether dietary supplements may carry implied disease claims. Because of the degree of controversy surrounding these issues, FDA believes that further public discussion focused on the three issues would be useful. FDA is therefore holding a public meeting to obtain further input on how to develop appropriate rules or policies that are consistent with the intent of DSHEA and with protection of the public health.

II. Scope of Discussion

The scope of the meeting will be limited to the three issues discussed in this notice. A brief discussion of each of the issues with specific questions on which FDA would like input follows.

A. Definition of Disease

In 1993, FDA issued regulations implementing the health claims provisions of NLEA. NLEA requires food manufacturers, including dietary supplement manufacturers, to obtain prior FDA authorization for any labeling statement that characterizes the relationship between a nutrient in the food to a ''disease or a health-related condition'' (section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)). The phrase ''disease or health-related condition'' was defined in those regulations as: damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition * * * § 101.14(a)(6) (21 CFR 101.14(a)(6)).

In the proposed rule on structure/function claims, FDA proposed a new definition of ''disease'':

any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms, including laboratory or clinical measurements that are characteristic of a disease.

FDA's proposed definition of disease was based on current medical and legal definitions of the term. FDA stated in the preamble to the proposed rule that the agency did not want to make use of the older health claims definition of ''disease or health-related condition'' because its use of the term ''damage'' could be interpreted to limit the definition to serious or long-term diseases, and might exclude conditions that are medically understood to be diseases, such as depression or migraine headaches.

A very large percentage of the comments received on the proposal objected to the new definition of disease. Among the principal objections were that: (1) The new definition is too broad, sweeping in many minor deviations or abnormalities that are not diseases; and (2) Congress should be presumed to have been aware of the 1993 definition of ''disease or health-related condition'' and to have intended FDA to use that definition. Almost all of the comments from the dietary supplement industry and from individuals recommended that FDA return to the 1993 definition. Comments from health professional groups tended to support the new definition of disease as more consistent than the NLEA definition with a medical understanding of disease.

FDA seeks further input on the appropriate definition of disease. To help focus comments on this issue for the public meeting, the agency seeks input on the following questions: (1) What are the consequences, with respect to the range of permissible structure/function claims, of adopting: (a) The 1993 definition in § 101.14(a)(6), or (b) the definition in the proposed rule? (2) If FDA were to retain the 1993 definition, does the reference to ''damage'' exclude any conditions that are medically understood to be diseases? Please provide examples. (3) If it does not exclude any such conditions, is the 1993 definition otherwise consistent with current medical definitions of disease? (4) If it does exclude conditions that are medically understood to be diseases, could it be revised in a way that would include such conditions?

B. Common Conditions Associated With Natural States

The proposed rule stated that natural states such as aging, menopause, pregnancy, and the menstrual cycle, were not themselves diseases, but could be associated with abnormal conditions that were diseases. FDA proposed to treat as a disease claim a statement that a product had an effect on a condition associated with a natural state if the condition presented ''a characteristic set of signs or symptoms recognizable to health care professionals or consumers'' as an ''abnormality'' (see proposed § 101.93(g)(2)(iii)). FDA provided as examples of such abnormal conditions the following: Toxemia of pregnancy, premenstrual syndrome, hot flashes, and presbyopia, decreased sexual function; and Alzheimer's disease associated with aging.

Many comments strongly objected to classifying common conditions associated with natural states as diseases. While no one argued that toxemia of pregnancy or Alzheimer's disease are not diseases, a very large number of comments contended that premenstrual syndrome, hot flashes, and decreased sexual function associated with aging are so common that they should be considered neither abnormal nor diseases.

To help focus comments on this issue for the public meeting, FDA seeks input on the following questions: (1) If FDA were to treat some conditions associated with natural states as diseases (e.g., toxemia of pregnancy and Alzheimer's disease) but not others (e.g., hot flashes, common symptoms associated with the menstrual cycle, and decreased sexual function associated with aging), what would be an appropriate principle for distinguishing the two groups? (2) For example, would it be appropriate to consider the severity of the health consequences if the condition were to go without effective treatment? (3) If so, how should ''severity'' be defined?

C. Implied Disease Claims

FDA proposed to treat both express and implied disease claims as disease claims that could not be made for dietary supplements without prior FDA review (either as health claims or as drug claims). Many comments objected, arguing that Congress intended to include implied disease claims within the category of structure/function claims that do not require prior FDA review.

Most of the comments contended that Congress intended to prohibit only express disease claims, which, according to the comments, are limited to claims that explicitly refer to a specific disease. For example, ''for the treatment of lung cancer'' would be an express disease claim because it uses the term ''cancer.'' According to the comments, implied disease claims are those that do not explicitly mention a specific disease. Implied disease claims may, however, refer to identifiable characteristics of a disease from which the disease itself may be inferred. There are many possible ways to imply treatment or prevention of disease, from listing the characteristic signs and symptoms of the disease to providing images of people suffering from the disease. As defined by the comments, the last 9 of the 10 criteria proposed by FDA for identifying disease claims could be considered methods of implying disease treatment or prevention.

Many comments argued with particular energy that dietary supplements should be allowed to claim to alleviate the characteristic signs or symptoms of a disease. Few comments offered examples of the types of implied disease claims they believed should be permitted. Applying the principle that dietary supplement labeling should be allowed to list the signs and symptoms of a disease, ''shrinks tumors of the lung'' or ''prevents development of malignant tumors'' would be permitted claims because they refer to the remedial effect of a product on a defining symptom of cancer, but do not mention the name of the disease itself. Similarly, while ''treatment of epilepsy'' would be prohibited as an express disease claim, ''prevention of seizures'' would be acceptable as an implied disease claim. ''Treatment of hay fever'' would be prohibited as an express disease claim, while ''relief of sneezing, runny nose, and itchy watery eyes caused by exposure to pollen or other allergens'' would be permitted as an implied disease claim.

The comments argued that Congress' intent to permit implied disease claims can be seen in at least three provisions of DSHEA. First, the Findings section of DHSEA refers to the relationship between dietary supplements and disease prevention. Second, section 403(r)(6) of the act states that structure/function statements may not ''claim'' to treat or prevent disease, and this term should be read to refer only to express claims. Third, DSHEA requires structure/function claims to be accompanied by a disclaimer that ''this product is not intended to diagnose, treat, cure, or prevent any disease.'' According to the comments, Congress understood that specific disease treatment or prevention effects can also be described as effects on the structure

or function of the body, and resolved the tension by requiring the disclaimer. Many comments also argued generally that DSHEA was intended to promote the free-flow of truthful information about dietary supplements, and that prohibiting implied disease claims is contrary to this legislative goal.

FDA had proposed to treat both express and implied claims as disease claims on two grounds. First, the agency has always exercised authority over both express and implied claims under section 201(g)(1)(B) of the act (21 U.S.C. 321(g)(1)(B)) , and believed that Congress would have explicitly authorized implied claims if it intended to change the agency's longstanding interpretation of the statute. The sections of DSHEA cited by the comments do not contain such an express authorization. Second, FDA believed that most disease treatment or prevention claims, including claims about serious and life-threatening diseases, can be described in a manner that will be easily understood by consumers without express reference to the name of the disease (e.g., ''shrinks tumors of the lung''). If dietary supplements were permitted to make implied disease claims, the burden would be on consumers to evaluate the validity of claims about dietary supplements marketed for serious and life-threatening diseases. In addition, dietary supplements could be given an unfair advantage over prescription and over-the-counter drugs in the marketplace that are required to establish their safety and effectiveness for disease treatment and prevention.

In the proposed rule, FDA asked for comment on a specific type of implied disease claim: A claim that a dietary supplement prevents or treats abnormal or unhealthy conditions or clinical measurements that are not themselves diseases but are markers of, or risk factors for, diseases, e.g., ''lowers cholesterol.'' FDA proposed to treat such claims as disease claims, but to permit claims that a product maintains healthy function, e.g., ''helps maintain a healthy cholesterol level.'' Most of the comments argued that consumers do not perceive a distinction between claims that a product treats or prevents abnormal function, and claims that the product maintains healthy function. Comments from dietary supplement manufacturers and some consumer groups argued that both types of claims should be permitted, while comments from health professional groups, groups devoted to specific diseases, and other consumer groups tended to argue that neither type of claim should be permitted.

FDA seeks further input on whether dietary supplements should be permitted to carry implied disease claims without prior review, either as health claims or as drug claims. To help focus comments on this issue for the public meeting, the agency seeks input on the following questions: (1) If such claims should be permitted, how should FDA correctly draw the line between what constitutes a prohibited express claim and what constitutes a permitted implied claim? (2) If such claims should be permitted, what are representative examples of the types of implied disease claims that should be permitted without prior review? (3) Are the examples mentioned in this notice appropriate structure/function claims? (4) Is a claim that a product ''maintains healthy function'' an implied disease claim in all cases? If not, under what circumstances is such a claim not an implied disease claim?

III. Registration and Requests to Make Oral Presentations

If you would like to attend the meeting, you must register with the contact person (address above) by July 16, 1999, by providing your name, title, business affiliation, address, telephone, and fax number. To expedite processing, registration information may also be faxed to 301–594–6777. If you need special accommodations due to disability, please inform the contact person when you register.

FDA intends to invite representatives from industry, health professional groups, and consumer groups to participate in panel discussions on the three issues discussed previously during the first portion of the meeting. Presentations by members of the public will be permitted during the second portion of the meeting, as time permits. If, in addition to attending, you wish to make an oral presentation during the meeting, when you register to attend you must so inform the contact person and submit: (1) A brief written statement of the general nature of the arguments you wish to present, (2) the names and addresses of the persons who will give the presentation, and (3) an indication of the approximate time that you request to make your presentation. Depending upon the number of people who register to make presentations, we may have to limit the time allotted for each presentation. We anticipate that, if time permits, those attending the meeting will have the opportunity to ask questions during the meeting.

IV. Comments

Interested persons may, on or before August 4, 1999, submit written comments to the Dockets Management Branch (address above). You may also send comments to the Dockets Management Branch via e-mail to ''FDADockets@oc.fda.gov''. You should annotate and organize your comments to identify the specific issues to which they refer. You must submit two copies of comments, identified with the docket number found in brackets in the heading of this document, except that you may submit one copy if you are an individual. You may review received comments in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

You may request transcripts of the meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. You may also examine the transcript of the meeting at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA Website ''http://www.fda.gov''.

Dated: July 2, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 57, 72 and 75

RIN 1219–AA74; 1219–AB11

Diesel Particulate Matter Exposure of Underground Coal and Metal and Nonmetal Miners

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Proposed rules; corrections.

SUMMARY: This document corrects errors in the preamble discussions to the proposed rule on diesel particulate matter exposure of underground coal miners, and the proposed rule on diesel particulate matter exposure of underground metal and nonmetal miners. Specifically, this document corrects errors in the Diesel Emission Control Estimator formula in the proposed Appendix to Part V of both preambles; and corrects certain titles in proposed Figures V–1 through V–5 of