Availability of NPRM's

Any person may obtain a copy of the Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–230, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify Class E airspace at Manitowish, WI; this proposal would provide adequate Class E airspace for operators executing the GPS Runway 32 SIAP at Manitowish Waters Airport. Controlled airspace extending upward from 700 to 1200 feet AGL is needed to contain aircraft executing the approach. The intended affect of this action is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions. The area would be depicted on appropriate aeronautical charts thereby enabling pilots to circumnavigate the area or otherwise comply with IFR procedures. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore this, proposed regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL WI E5 Manitowish, WI [Revised]

Manitowish Waters Airport
(Lat. 46°07′19″ N, long. 89°52′56″ W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of the Manitowish Waters Airport and within 4 miles each side of the 141° bearing from the airport extending from the 7-mile radius to 9 miles southeast of the airport, excluding that airspace within the Minocqua-Woodruff Class E airspace.

* * * * *

Issued in Des Plaines, Illinois on February 27, 1997.

Maureen Woods,

Manager, Air Traffic Division.

[FR Doc. 97–6619 Filed 3–14–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 97N–0075]

Food Labeling; Timeframe for Final Rules Authorizing Use of Health Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to provide a timeframe in which it will issue final rules in rulemakings on health claims announcing whether it will authorize the use of the claim at issue. FDA is also providing for extensions of that timeframe for cause. The agency is issuing this proposal in response to a recent judicial decision.

DATES: Written comments by April 16, 1997. The agency is proposing that any final rule that may issue based on this proposal become effective 30 days after the date of its publication.

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

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5483.

SUPPLEMENTARY INFORMATION:

I. Background

Section 403(r) of the Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)), which was added by the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), provides for claims on the label and in the labeling of food that characterize the relationship of nutrients to a disease or health-related condition. In providing for these claims, called ''health claims,'' the act treats conventional foods differently than dietary supplements. For conventional foods, the act sets out the procedure and standard that FDA is to use in deciding whether to authorize health claims. For dietary supplements, the act states that health claims for these products are to be subject to a procedure and standard established by regulation of the Secretary of Health and Human Services (the Secretary), and by delegation FDA (section 403(r)(5)(D) of the act).

In January 1994, FDA completed a rulemaking to implement the health claim provisions of the act for dietary supplements. FDA decided to adopt the procedure and standard established in the act for health claims for conventional foods as the procedure and standard for dietary supplements (59 FR 395 at 405, January 4, 1994). Thus, health claims can be made for dietary supplements if FDA determines that the relationship between the substance and disease that are the subjects of the claim is scientifically valid, as well as truthful and not misleading. The standard that

FDA uses in determining scientific validity is set out in 21 CFR 101.14(c) of the agency's regulations, as well as in section 403(r)(3)(B)(i) of the act. It requires that the agency determine, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

People interested in having the agency authorize health claims about a particular nutrient-disease relationship may petition the agency to do so (see § 101.70 (21 CFR 101.70)). Under the procedure adopted by FDA, which parallels that in section 403(r)(4)(A)(i) of the act and, thus, applies to both conventional foods and dietary supplements, within 100 days of the date that it receives the petition, the agency will notify the petitioner by letter that the petition has either been filed for comprehensive review or denied. If the agency files the petition, within 90 days of filing, FDA will either deny it or advise the petitioner that a proposal to authorize the use of health claims about the subject substance/disease relationship will be published in the Federal Register. However, consistent with section 403(r)(4)(A)(i) of the act, FDA made no mention in its regulations of when a final rule on the health claim would be issued, even though it was asked to do so by a number of comments (59 FR 395 at 420).

In the wake of its adoption of the regulations on health claims for dietary supplements, FDA was sued several times by dietary supplement trade associations, manufacturers, retailers, and individuals, on the grounds that the agency regulations violate the First Amendment to the United States Constitution. One of these cases, *Nutritional Health Alliance* v. *Shalala,* 95 Civ. 4950 (RO) (S.D.N.Y.), was recently decided by Judge Richard Owen. In its decision, the District Court reviewed FDA's regulations under the four prong test, established in *Central Hudson Gas & Electric Corp.* v. *Public Service Commission of New York,* 447 U.S. 557 (1980) (*Central Hudson* test), for determining whether a particular regulation of commercial speech survives scrutiny under the First Amendment.

After finding that not all potential health claims are inherently misleading, and thus that such claims are entitled to some First Amendment protection (slip op. at 7), the court concluded that FDA's regulations were supported by a substantial governmental interest: ''preventing the spread of unsubstantiated health claims on labels so that consumers may not be deceived and follow unsound health practices; ensuring the reliability of scientific information disseminated in connection with the sale of dietary supplements; and protecting consumers from being induced to purchase products by misleading information on labels.'' (Slip op. at 8.) The court also found that FDA's regulation directly and materially advanced the substantial governmental interest. Thus, the court found no problem for FDA's regulations under the first three parts of the *Central Hudson* test.

However, under the fourth part of the test, that the regulation be narrowly tailored to advance the governmental interest, the court found a vulnerability. While the District Court found that the regulations did not cover more speech than necessary (slip op. at 8–9), it found that, once the agency had proposed to allow a particular health claim, the absence of a timeframe for the issuance of a final rule on whether a health claim would be authorized failed to meet *Central Hudson's* fourth prong and, thus, violated the First Amendment (slip op. at 9).

Accordingly, the court ordered FDA to establish a reasonable time limit for the issuance of a final rule for a health claim on dietary supplement labels. The court directed the agency to, within 90 days of the date of its order (January 31, 1997), submit such a regulation to the court for review of its reasonableness and for the entry of such further orders as may be appropriate (slip op. at 12).

While FDA does not agree with aspects of the court's opinion, it has decided that, on balance, given the general affirmance of the agency's regulations in the court's opinion, the most efficient course is to proceed to develop the regulation required by the court, to submit it to the court for review, and not to appeal at this time. Moreover, given the parallel procedures for dietary supplements and conventional foods, FDA has decided to propose to establish a timeframe for final rules on health claims for conventional foods as well as for dietary supplements.

II. The Proposal

A. Time for Review

FDA has carefully considered how much time to provide for itself between the issuance of a proposal to authorize a particular health claim and the issuance of a final rule. On the one hand, it is important that the agency establish a timeframe that it can reasonably expect to meet on a regular basis. On the other hand, the agency should not provide itself with so much time that authorization of a health claim will be unreasonably delayed.

In 1994, in rejecting comments that requested the establishment of such a timeframe, FDA expressed concern about various factors, including work priorities, the availability of personnel, and limitations on agency resources. It is significant to note that each of these factors has been a problem in the health claim rulemakings that FDA has completed since 1994. Thus, each of the above concerns continues to cause the agency to question its ability to set a timeframe to which it can reasonably expect, and can reasonably be expected, to adhere. This is particularly the case because FDA has no control over the number of petitions that are filed, and it is obligated to review and act on the petitions that it receives. Nonetheless, based on its experience since 1994 in issuing final rules on folic acid and neural tube defects, sugar alcohols and dental caries, and soluble fiber from whole oat products and coronary heart disease, FDA finds that it can delineate the steps involved in the production of a final rule and provide a reasonable estimate of how long each step is likely to take.

The steps in the production of a final rule include:

1. *A comment period*—FDA generally provides 75 days for comments on proposals. Because of the broad interest in health claims, however, FDA provided 90 days or more for comments in the sugar alcohols and oat bran and oatmeal rulemakings. To ensure that a final rule is issued as quickly as practicable, FDA intends to adhere to a 75-day limit on comment periods in future health claim rulemakings and to not consider comments that are received after the close of the comment period.

2. *Reviewing and responding to comments and developing a draft final rule*—The number of letters that FDA has received on health claim proposals issued in response to petitions has ranged from as high as approximately 1,500 letters, in response to the proposal on oatmeal and oat bran and the risk of coronary heart disease, to as few as 20 letters in response to the proposal on sugar alcohols and the risk of dental caries. The number of letters, however, understates the agency's task in developing a final rule because many letters comment on more than one issue. Thus, it is necessary for FDA to review the letters, catalogue all the comments,

group related comments together, and then formulate a response to each issue raised. This would seem to be a fairly straightforward process, given that FDA has already made a tentative determination to authorize the claim. In practice, however, this process has proven not to be a simple one.

In the oat proceeding, FDA received a large number of comments that requested that the agency authorize the claim for a substance not covered by its tentative determination, whole oat flour. In deciding how to respond to these requests, FDA had to balance the interest in a prompt decision against the value to the public health of taking the time to decide whether the important health information provided by the health claim could appropriately appear on a broader range of foods. To make this choice, development of the document had to be delayed while the agency evaluated the scientific evidence supporting the request and the import of that evidence. FDA ultimately chose to authorize the health claim on a broader range of foods, but the time involved in choosing this course added months to the time that it took FDA to develop the final rule.

In addition, limitations on the agency's resources and the competing priorities to which the agency is often subject can combine to cause interruptions in the development of a final rule. For example, the development of the final rule on sugar alcohols was interrupted on two occasions because of the filing of new health claim petitions and the agency's desire to conform to the statute's requirement that action be taken on petitions within 190 days. The same people who were charged with drafting the final rule also were responsible for drafting the responses to the new petitions. Thus, the development of the final rule on sugar alcohols was significantly delayed.

Moreover, in the development of final rules, FDA considers it important to obtain input from other parts of the Department of Health and Human Services (the Department) (such as from the National Institutes of Health or from the Centers for Disease Control and Prevention) and from other parts of the Federal Government (e.g. the U.S. Department of Agriculture) that have relevant expertise. There is a widespread expectation among the public, including the regulated industry, that FDA will solicit this input, and given the public health significance of the issues in a health claim proceeding, FDA considers it important that it do so. Yet, obtaining the input of the experts involved can add at least weeks to the process of developing a final rule because the scientists that are consulted have their own work, and FDA's request for review is in competition with that work. Moreover, there sometimes are disagreements among the scientists consulted, and these disagreements must be resolved before a final rule can issue.

For all these reasons, drafting a final rule involves much more than reading comments, summarizing them, and preparing answers. FDA tentatively concludes that, given the problems associated with this task, it is reasonable to provide 5 months (150 days) between the close of the comment period and the completion of a draft final rule that can be forwarded to the Commissioner of Food and Drugs (the Commissioner) for his or her signature.

3. *Review and endorsement by the Commissioner*—FDA tentatively finds that it is appropriate to allow 1 month (30 days) for clearance of the final rule for publication. Although the Commissioner has generally been delegated sign off authority under the act by the Secretary (21 CFR 5.10 of FDA's regulations), other factors, such as final legal and policy review, require that 30 days be provided for this aspect of the process.

For example, given the public health significance of health claims and the involvement of various parts of the Department in the development of health claim documents, there is continuing interest from the Office of the Secretary in health claim matters. Thus, time must be reserved to accommodate the Secretary, should he or she desire to review the final rule. In addition, under Executive Order 12866, the Office of Management and Budget (OMB) may choose to review a health claim final rule although it has generally not done so. Given the potential involvement of these other entities, FDA tentatively concludes that it is appropriate to reserve 1 month for the review and endorsement of any draft health claim final rule.

Taken together, these estimated timeframes total approximately 255 days. Based on these estimates, and the fact it is reasonable to allow 15 days for the inevitable slippage that occurs in the rulemaking process, FDA is proposing to adopt § 101.70(j)(4)(i), which states that within 270 days of the publication of the proposal, FDA will publish a final rule either authorizing the use of a health claim or explaining why it has decided not to authorize one.

FDA notes that the 270 days that it is proposing for production of a final rule is approximately 90 days less than the time that it took from proposal to final rule in both the whole oat products and sugar alcohols rulemakings. It is also 90 days less than the agency was granted by the 1990 amendments between the proposals and final rules on the 10 health claim topics that it was required to address. Nonetheless, FDA is committed, as it told the court (slip op. at 10), to issue final regulations as quickly as possible. Therefore, it is proposing to abide by a 9-month timeframe.

B. Extension of Time

In its opinion, the District Court recognized that FDA may receive information during the comment period that could require that the agency rethink whether to authorize a health claim. The court stated that such circumstances could be handled by an extension, founded on a showing of cause (slip op. at 10 n. 14).

Consistent with the court's statement, FDA is providing in proposed § 101.70(j)(4)(ii) that it could grant itself an extension beyond 270 days if cause exists to justify such an extension. For example, there may be circumstances in which the comments are of such volume (e.g., the soluble fiber from whole oats rulemaking) or the controversy surrounding an aspect of the health claim is so great (e.g., the folic acid rulemaking) that the agency simply finds that it cannot meet the 270 day deadline. In such cases, under proposed § 101.70(j)(4)(ii), FDA will publish notice of the extension in the Federal Register. The notice will explain the basis for the extension, the length of the extension, and the date by which the final rule will be published. The extension would be for no longer than necessary, and FDA would have to explain the length of the extension. FDA expects to grant itself such extensions only on rare occasions.

III. Analysis of Impacts

A. Economic Impact

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant

regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency is proposing only to provide firms with a timeframe in which they can expect health claim final rules to issue. Thus, in accordance with the Regulatory Flexibility Act, the agency certifies that this proposed 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.

B. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no reporting recordkeeping, labeling, or other third party disclosure requirements. Thus there are no ''information collection'' requirements necessitating clearance by OMB. However, to ensure the accuracy of this tentative conclusion, FDA is seeking comment on whether this proposed rule imposes any paperwork burden.

V. Effective Date

FDA is proposing to make the amendment to § 101.70, contained herein, effective 30 days after the publication of a final rule that may issue based on this proposal.

VI. Comments

Interested persons may, on or before April 16, 1997, submit to the Docket Management Branch (address above) written comments regarding this proposal. FDA is limiting the comment period to 30 days because it is necessary to do so if the agency is to comply with the District Court's order of January 31, 1997, that it establish a timeframe for issuance of final rules on health claims within 90 days of that order. FDA could not publish a final rule within that timeframe if it permitted the normal 75-day comment period.

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 my be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 101

Food Labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371).

2. Section 101.70 is amended by adding new paragraph (j)(4) to read as follows:

§ 101.70 Petitions for health claims.

* * * * *

(j) * * *

(4)(i) Within 270 days of the date of publication of the proposal, FDA will publish a final rule that either authorizes use of the health claim or explains why the agency has decided not to authorize one.

(ii) For cause, FDA may extend the period in which it will publish a final rule. FDA will publish notice of the extension in the Federal Register. The document will explain the basis for the extension, the length of the extension, and the date by which the final rule will be published.

Dated: March 4, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–6710 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG–208172–91]

RIN 1545–AU71

Basis Reduction Due to Discharge of Indebtedness; Hearing

AGENCY: Internal Revenue Service, Treasury.

ACTION: Proposed rule; change of date and location of public hearing.

SUMMARY: This document changes the date and location of the public hearing on the notice of proposed rulemaking relating to basis reduction due to discharge of indebtedness under sections 108 and 1017 of the Internal Revenue Code of 1986.

DATES: The public hearing is being held on Thursday, May 29, 1997, beginning at 10 a.m. Requests to speak and outlines of oral comments must be received by April 3, 1997.

ADDRESSES: The public hearing originally scheduled in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC is changed to the Commissioner's Conference Room, room 3313, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Evangelista Lee of the Regulations Unit, Assistant Chief Counsel (Corporate), (202) 622–7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and notice of public hearing appearing in the Federal Register on Tuesday, January 7, 1997, (62 FR 955) announced that a public hearing on proposed regulations relating to the basis reduction due to discharge of indebtedness under sections 108 and 1017 would be held on Thursday, April 24, 1997, beginning at 10 a.m. in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC and that requests to speak and outlines of oral comments should be received by Thursday, April 3, 1997.

The date and location of the public hearing has changed. The hearing is scheduled for Thursday, May 29, 1997, beginning at 10 a.m. in the Commissioner's Conference Room, room 3313, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. We must receive requests to speak and outlines of oral comments by Thursday, April 3, 1997. Because of the controlled access restrictions, attenders are not admitted beyond the lobby of the Internal Revenue Building until 9:45 a.m.

The Service will prepare an agenda showing the scheduling of the speakers after the outlines are received from the persons testifying and make copies available free of charge at the hearing.

Cynthia E. Grigsby,

Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 97–6674 Filed 3–14–97; 8:45 am]

BILLING CODE 4830–01–U