

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

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[Docket Nos. OOP-1275 and 00P-1276]

Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; notice of extension of period for issuance of final rule.

SUMMARY: The Food and Drug Administration (FDA) is extending to July 25, 2001, the period for issuance of a final rule in response to its interim final rule of September 8, 2000, entitled "Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease." FDA's regulations require the agency to issue a notice of such extension if it finds, for cause, that it is unable to issue a final rule within 270 days from the date of publication of the interim final rule. The complexity of the issues raised by the comments to the interim final rule and the lack of agency resources to complete the final rule within the specified 270 days have persuaded the agency of the need to extend the deadline to publish the final rule.

FOR FURTHER INFORMATION CONTACT: James E. Hoadley, Center for Food Safety and Applied Nutrition (HFS-832), 200 C St. SW., Washington, DC 20204, 202-205-5372.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 22, 1997 (62 FR 28230), FDA published a final rule amending § 101.70 (21 CFR 101.70) of its regulations to provide a timeframe in which it will issue, in rulemakings on health claims, final rules announcing whether it will authorize the use of the claim at issue and to provide for extensions of that timeframe for cause. In that final rule, FDA adopted § 101.70(j)(4)(i), which provides that within 270 days of the date of publication of a proposal to authorize a health claim, the agency will publish a final rule that either authorizes the use of a health claim or explains why the agency has decided not to authorize

one. FDA also adopted § 101.70(j)(4)(ii), which provides that, for cause, the agency may extend, no more than twice, the period in which it will publish a final rule and that each such extension will be for no more than 90 days. This regulation further requires that FDA publish a notice of any such extension in the **Federal Register**, and that it explain in that notice the basis for the extension, the length of the extension, and the date by which the final rule will be published (§ 101.70(j)(4)(ii)).

In the **Federal Register** of May 14, 1998 (63 FR 26717), FDA published a final rule that, in part, amended § 101.70 in response to section 302 of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 302 of FDAMA amended section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)(A)(i)) to provide, in part, that if FDA initiates rulemaking in response to a health claim petition, the agency must complete the rulemaking within 540 days of receipt of the petition. If FDA does not meet the 540-day deadline, FDAMA requires FDA to provide the relevant House and Senate legislative committees with the reasons for failing to do so. Accordingly, FDA amended § 101.70(j)(4)(ii) to state that any extensions of the final rule deadline in health claim rulemakings shall not cause the deadline to exceed 540 days from receipt of the petition. FDA noted that, depending upon how much time the agency uses to file a petition and publish a proposed rule in response to it, the agency may be limited to only one extension under § 101.70(j)(4)(ii), and the extension may be limited to fewer than 90 days (63 FR 267 17 at 26718).

In the **Federal Register** of September 8, 2000 (65 FR 54686), FDA published an interim final rule adding 21 CFR 101.83 to authorize the use, on food labels and in food labeling, of health claims on the association between plant sterol/stanol esters and reduced risk of coronary heart disease (CHD) (plant sterol/stanol esters interim final rule). The act, as amended by FDAMA, authorizes FDA to make proposed health claim regulations effective upon publication pending consideration of public comment and publication of a final regulation, if the agency determines that such action is necessary for public health reasons (see section 403(r)(7) of the act). The

legislative history of FDAMA indicates that such proposed regulations should be issued as interim final rules (H. Conf. Rept. 105-399, at 98 (1997)). Because the plant sterol/stanol esters interim final rule was issued under FDA's authority to make a proposed rule effective upon publication (see 65 FR 54685 at 54713), it was subject to the deadline for proposed rules in § 101.70(j)(3). Likewise, the final rule deadline in § 101.70(j)(4) applies to this rulemaking.

In the plant sterol/stanol esters interim final rule, the agency presented the rationale for a health claim on this food-disease relationship under the standard in section 403(r)(3)(B)(i) of the act and 21 CFR 101.14(c) of FDA's regulations. The agency concluded that, based on the totality of the publicly available scientific evidence, plant sterol/stanol esters may reduce the risk of CHD. The interim final rule specified the daily intake levels of plant sterol and stanol esters associated with reduced risk of CHD, the categories of foods eligible to bear the plant sterol/stanol esters health claim, and analytical methods for assessing compliance with qualifying criteria for the claim.

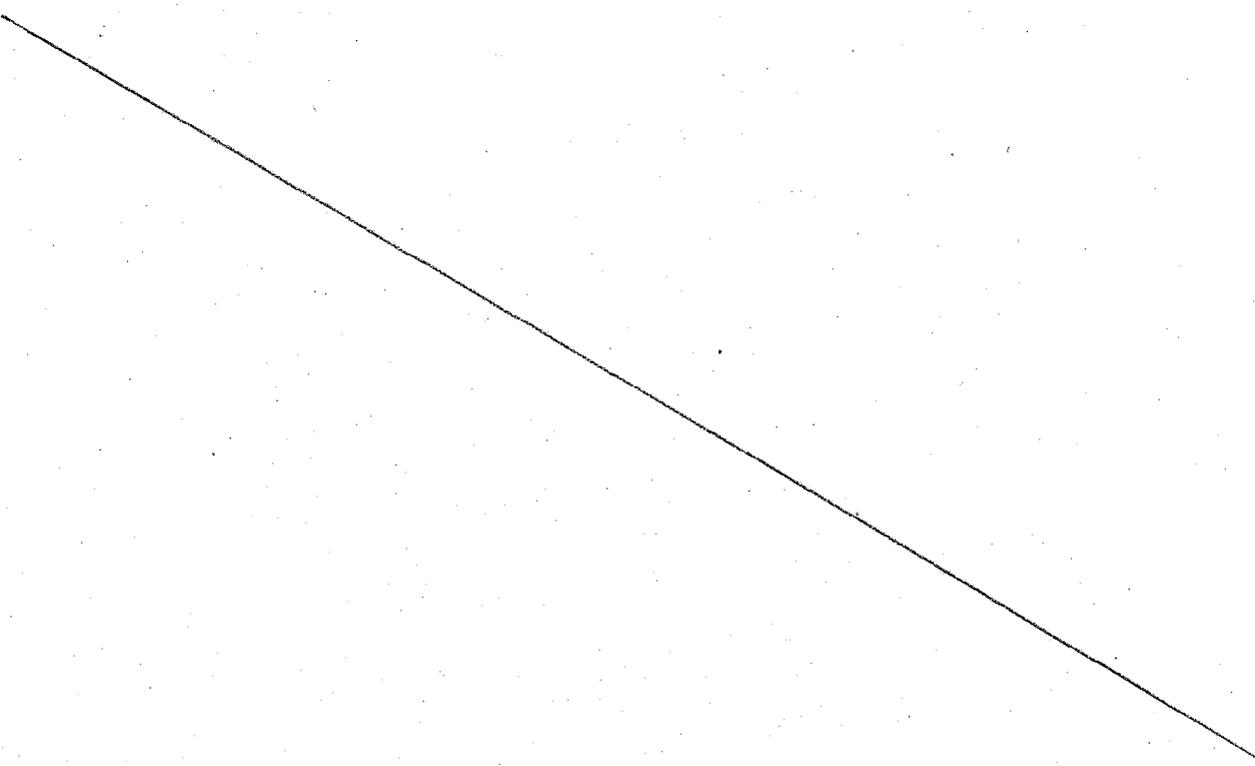
The comments received in response to the plant sterol/stanol esters interim final rule raised numerous complex issues. For example, we received many comments urging the agency to broaden the categories of foods eligible to bear the plant sterol/stanol esters health claim. Many comments also argued that the daily intake level for plant stanol esters should be the same as for plant sterol esters. Another group of comments requested that FDA allow foods containing the nonesterified form of plant sterols/stanols to bear the health claim.

The complex issues raised by these comments warrant significant attention and the expenditure of significant staff resources. Unfortunately, the Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS) within FDA's Center for Food Safety and Applied Nutrition has had to focus a large part of its health claim review resources on litigation-related work since the issuance of the plant sterol/stanol esters interim final rule. (ONPLDS is also the office responsible for reviewing all health claim petitions.) FDA's review of these comments, therefore, has been hampered by a lack of staff available to examine the scientific evidence pertaining to these complex

issues. Accordingly, an extension of time to complete the plant sterol/stanol esters final rule is needed.

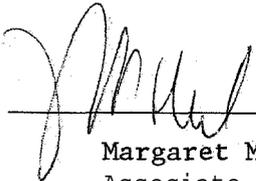
To publish a final rule regarding a health claim for plant sterol/stanol esters and CHD within 270 days of the date of publication of the interim final rule, which was on September 8, 2000, the agency would have to publish the final rule on or before June 5, 2001. However, because of the need to provide for additional time for agency staff to evaluate the issues raised by the comments on the plant sterol/stanol esters interim final rule, FDA hereby gives notice that there is cause to extend the deadline for publication of the final rule by 5.0 days. FDA will, therefore, publish a final rule in response to the interim final rule on or before July 25, 2001.

The new deadline of July 25, 2001, falls within the 540-day limit set by the statute. As noted above, section 403(r)(4)(A)(i) of the act requires FDA to complete health claim rulemakings within 540 days of the receipt of the petition. Since the current rulemaking involves two separate health claim petitions, submitted by Lipton and McNeil Consumer Healthcare, that have been combined into one rulemaking, the agency will consider the date of receipt of the earlier petition for purposes



of calculating the deadline. Lipton submitted its health claim petition on February 1, 2000; McNeil submitted its petition on February 15, 2000. Publication of a final rule on or before July 25, 2001, will allow the agency to complete this rulemaking within 540 days of the receipt of the earlier (Lipton's) petition.

Dated: 5/31/01
May 31, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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