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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 101**

**[Docket No. 98P-0683]**

**Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease**

**AGENCY:** Food and Drug Administration, HHS.

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

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**SUMMARY:** The Food and Drug Administration (FDA) is extending, for 80 days, the period for issuance of a final rule in response to its proposal of November 10, 1998, entitled 'Food Labeling: Health Claims; Soy Protein 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 November 10, 1998, date of publication of the proposal. Comments to that proposal have persuaded the agency of the need to propose an alternative procedure to assess compliance with qualifying amounts of soy protein in foods that may bear the proposed health claim. FDA will publish a reproposal of the procedure for compliance assessment in the **Federal Register** shortly. The agency then intends to issue one final rule in response to both proposals on or before October 25, 1999.

**FOR FURTHER INFORMATION CONTACT:** Susan M. Pilch, Center for Food Safety and Applied Nutrition (HFS-465), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4500.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 22, 1997 (62 FR 28229), FDA published a final rule to amend § 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

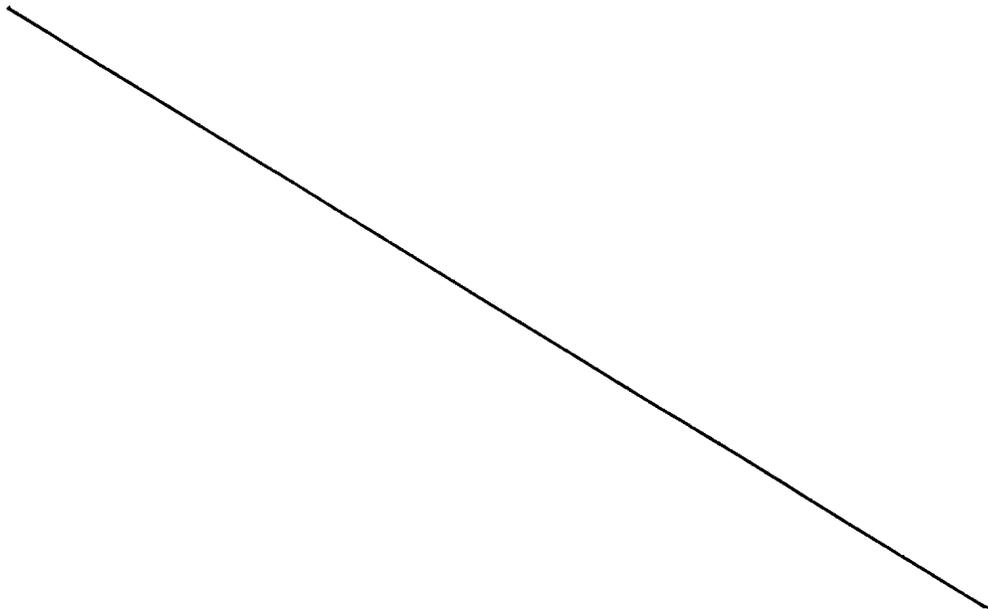
authorize the use of the claim at issue and to provide for extensions of that timeframe for cause. In that final rule, FDA adopted § 101.70(j)(4)(i), which provides that within 270 days of the date of publication of a proposal to authorize a health claim, the agency will publish a final rule that either 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 in part to amend § 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 FDA must publish a final rule on a health claim petition within 540 days of receipt of the petition or FDA is required to provide the relevant House and Senate legislative committees with the reason for failing to do so. Accordingly, FDA amended § 101.70(j)(4)(ii) to state that rulemakings on health claim petitions shall be completed within 540 days of receipt of those petitions. 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 26717 at 26718).

In the **Federal Register** of November 10, 1998 (63 FR 62977), FDA proposed adding § 101.82 to authorize the use, on food labels and in food labeling, of health claims on the association between soy protein and reduced risk of coronary heart disease (CHD) (the soy protein proposed rule). In the soy protein proposed rule, the agency presented the rationale for a health claim on this food-disease relationship as provided for 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 tentatively concluded that, based on the totality of publicly available scientific evidence, soy protein included in a diet low in saturated fat and cholesterol may reduce the risk of CHD. The soy protein proposed rule included qualifying criteria for the purpose of identifying soy protein-containing foods eligible to bear the proposed health claim and a proposed analytical method for assessing compliance with the qualifying criteria. Comments received in response to the soy protein proposed rule have persuaded FDA that the proposed method for assessment of compliance is inadequate for many products. Accordingly, FDA intends to publish, in a separate document, a reproposal for an alternative procedure. This procedure would rely on measurement of total protein and require manufacturers, in certain circumstances, to maintain records that document the amount of soy protein in products and to make these records available to appropriate regulatory officials for inspection and copying upon request.

To publish a final rule regarding a health claim for soy protein and CHD within 270 days of the date of publication of the proposed rule, which was November 10, 1998, the agency should publish the final rule on or before August 6, 1999. However, because of the need to provide for public notice and comment on the reproposal, FDA hereby gives notice that there is cause to



extend the period for publication of the final rule for a period of 80 days. FDA will, thus, publish a single final rule in response to both proposals on or before October 25, 1999, which is within 540 days of the date of receipt of the petition.

Dated: July 28, 1999

July 28, 1999



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

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*Michael W. Bell*