

FDC date	State	City	Airport	FDC No.	Subject
07/15/03 .....	TX	LAREDO .....	LAREDO INTL .....	3/5982	ILS RWY 17R, AMDT 9
07/15/03 .....	NM	ARTESIA .....	ARTESIA MUNI .....	3/5988	NDB RWY 30, AMDT 4
07/14/03 .....	PA	PERKASIE .....	PENNRIDGE .....	3/5888	RNAV (GPS) RWY 8, ORIG-A
07/14/03 .....	NY	LAKE PLACID .....	LAKE PLACID .....	3/5791	RNAV (GPS)-A, ORIG
07/11/03 .....	CO	HAYDEN .....	YAMPA VALLEY .....	3/5767	RNAV (GPS) Y RWY 10, ORIG
07/11/03 .....	CO	HAYDEN .....	YAMPA VALLEY .....	3/5769	RNAV (GPS) RWY 28, ORIG
07/11/03 .....	CO	HAYDEN .....	YAMPA VALLEY .....	3/5768	RNAV (GPS) Z RWY 10, ORIG

\*Replaces 3/5078.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 101

[Docket No. 2001Q-0313]

#### Food Labeling: Health Claims; Soluble Dietary Fiber From Certain Foods and Coronary Heart Disease

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is adopting as a final rule, without change, the provisions of the interim final rule that amended the regulation authorizing a health claim on the relationship between beta-glucan soluble fiber from whole oat sources and reduced risk of coronary heart disease (CHD). FDA is taking this action to complete the rulemaking initiated with the interim final rule.

**DATES:** This rule is effective July 28, 2003.

**FOR FURTHER INFORMATION CONTACT:** James E. Hoadley, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1450.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of October 2, 2002 (67 FR 61773), the agency published an interim final rule to amend the regulation in part 101 (21 CFR part 101) that authorizes a health claim on the relationship between soluble dietary fiber from certain foods and reduced risk of CHD, to include an additional eligible source of whole oat beta-glucan soluble fiber, oatrim, the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour. Under section 403(r)(3)(B)(i) of the

Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i)), FDA issued this interim final rule in response to a petition filed under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)). Section 403(r)(3)(B)(i) of the act states that the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) shall issue a regulation authorizing a health claim only if he or she determines, 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 (see also § 101.14(c)). Section 403(r)(4) of the act sets out the procedures that FDA is to follow upon receiving a health claim petition.

On April 21, 2001, the Quaker Oats Co. and Rhodia, Inc., (the petitioners) jointly filed a petition requesting that the agency amend the “soluble fiber from certain foods and coronary heart disease health claim” at § 101.81 to include a fourth source of beta-glucan soluble fiber eligible for the health claim. The petitioners requested that this amendment be made “with specific reference to the Quaker-Rhodia group oatrim, known as Oatrim (BETATRIM)” (Ref. 1). FDA filed the petition for comprehensive review in accordance with section 403(r)(4) of the act on July 20, 2001.

FDA considered the relevant scientific evidence presented in the petition as part of its review of the scientific literature on soluble fiber from the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour (referred to as “oatrim”) and CHD risk. The agency summarized this evidence in the interim final rule and determined that based on the available evidence: (1) CHD continues to be a disease for which the U.S. population is at risk; (2) soluble fiber from oatrim when used at levels providing 0.75 grams of beta-glucan soluble fiber per serving is a food

because it provides nutritive value; (3) oatrim when used at levels necessary to justify the health claim is safe and lawful; (4) there is a physiological equivalence of beta-glucan soluble fiber from oatrim and beta-glucan soluble fiber from whole oat sources such as oat bran and rolled oats; and (5) there is significant scientific agreement, among qualified experts, that oatrim with a beta-glucan content of up to 10 percent on a dry weight basis (dwb) and not less than that of the starting material (dwb) may reduce the risk of CHD (67 FR 61773 at 61775 to 61779). Consequently, FDA published an interim final rule amending the health claim on the relationship between soluble dietary fiber from certain foods and reduced risk of CHD (§ 101.81) to include oatrim, the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour with a beta-glucan soluble fiber content of up to 10 percent on a dwb and not less than that of the starting material (dwb) as a source of oat beta-glucan soluble fiber eligible for the health claim.

##### II. Summary of Comments and the Agency's Response

FDA solicited comments on the interim final rule. The 75-day comment period closed on December 16, 2002. The agency received no comments in response to the interim final rule. Given the absence of contrary evidence on the agency's decisions announced in the interim final rule, FDA is adopting as a final rule, without change, the interim final rule that amended § 101.81 to add oatrim, the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour with a beta-glucan soluble fiber content of up to 10 percent on a dwb and not less than that of the starting material (dwb) as a substance eligible for the health claim.

##### III. Environmental Impact

The agency has determined under 21 CFR 25.32(p) 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