exemptive applications under Section 36 when appropriate.

EFFECTIVE DATE: February 18, 1998.

FOR FURTHER INFORMATION CONTACT: Catherine McGuire, Chief Counsel, or Paul P. Andrews, Special Counsel at (202) 942–0073, Office of Chief Counsel, Division of Market Regulation, Mail Stop 7–11, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549.

SUPPLEMENTARY INFORMATION:

I. Amendment To Rules of Practice

The Securities and Exchange Commission (''Commission'') today announces an amendment to its Rules of Practice governing Delegations of Authority to the Director of the Division of Market Regulation (''Director'').[1] The amendment adds to Rule 30–3 a new paragraph (a)(63) authorizing the Director to grant or deny exemptions from Section 11(d)(1) of the Securities Exchange Act of 1934 (''Exchange Act''), where appropriate, under Section 36 of the Exchange Act.[2]

Section 36(a) provides that:

> Except as provided in subsection (b) [not applicable here], but notwithstanding any other provision of this title, the Commission, by rule, regulation, or order, may conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision or provisions of this title or of any rule or regulations thereunder, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.

The delegation of authority to the Director is intended to conserve Commission resources by permitting the staff to review and act on exemptive applications under Section 36(a) when appropriate. Nevertheless, the staff may submit matters to the Commission for consideration as it deems appropriate. In addition, under Section 4A(b) of the Exchange Act, the Commission retains discretionary authority to review, upon its own initiative or upon application by a party adversely affected, any exemption granted or denied by the Division pursuant to delegated authority. Information concerning the filing of exemptive relief applications can be found in Release No. 34–39624; Rule 240.0–12, 17 CFR 240.0–12.

The Commission finds, in accordance with Section 553(b)(3)(A) of the Administrative Procedure Act, 5 U.S.C. § 553(b)(3)(A), that this amendment relates to agency organization, procedure, or practice. Accordingly, notice, opportunity for public comment, and publication of the amendment prior to its effective date are unnecessary.

II. List of Subjects in 17 CFR Part 200

Administrative practice and procedure, Authority delegations (Government agencies).

III. Text of Amendment

For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

1. The general authority citation for Part 200 is revised to read as follows:

Authority: 15 U.S.C. 77s, 78d–1, 78d–2, 78w, 78*ll*(d), 78mm, 79t, 77sss, 80a–37, 80b–11, unless otherwise noted.

* * * * *

2. Section 200.30–3 is amended by adding paragraph (a)(63) to read as follows:

200.30–3 Delegation of authority to Director of Division of Market Regulation.

* * * * *

(a) * * *

(63) Pursuant to section 36 of the Act (15 U.S.C. 78mm) to review and, either unconditionally or on specified terms and conditions, grant or deny exemptions from section 11(d)(1) of the Act (15 U.S.C. 78k(d)(1)).

* * * * *

By the Commission.

Dated: February 9, 1998.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–3932 Filed 2–17–98; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Rel. No. 34–39624]

Commission Procedures for Filing Applications for Orders for Exemptive Relief Pursuant to Section 36 of the Exchange Act

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission is amending its Rules of General Application to set forth procedures to be followed by the Divisions of Market Regulation and Corporation Finance in assessing and processing applications for exemptive relief pursuant to Section 36 of the Securities Exchange Act of 1934. Section 36 requires the Commission to determine the procedures under which an exemptive order under that section may be granted.

EFFECTIVE DATE: February 18, 1998.

FOR FURTHER INFORMATION CONTACT: Catherine McGuire, Chief Counsel, or Paul P. Andrews, Special Counsel at (202) 942–0073, Office of Chief Counsel, Division of Market Regulation, Mail Stop 7–11; or Anita Klein, Special Counsel at (202) 942–2900, Office of Chief Counsel, Division of Corporation Finance, Mail Stop 3–3, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549.

SUPPLEMENTARY INFORMATION:

I. Background

The National Securities Markets Improvement Act of 1996 (''NSMIA'') added Section 36 to the Securities Exchange Act of 1934 (''Exchange Act'').[1] This section gives the Securities and Exchange Commission (''Commission'') the authority to exempt any person, security, or transaction from the provisions of the Exchange Act. The Commission has similar authority under the Trust Indenture Act of 1939 (15 U.S.C. 77ddd(d)), the Investment Company Act of 1940 (15 U.S.C. 80a–6(c)), and the Investment Advisers Act of 1940 (15 U.S.C. 80b–6(a)). In particular, Section 36(a)(1) provides that ''the Commission by rule, regulation, or order, may conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision or provisions of [the Exchange Act] or any rule or regulation thereunder, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.'' 15 U.S.C. 78mm(a).[2]

Before the Commission may begin using its new order authority, it must develop procedures that applicants must follow in seeking such an exemption from provisions of the Exchange Act. Accordingly, the Commission is amending its Rules of General Application to set forth the following procedures pursuant to which

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[1] 17 CFR 200.30–3.

[2] 15 U.S.C. 78k(d)(1) and 78mm.

[1] Pub. L. No. 104–290, 110 Stat. 3442.

[2] The Commission also has authority to issue exemptive orders that grant relief from specific provisions of the Exchange Act as well as from specific Commission rules promulgated thereunder. For example, either by rule or by order, the Commission may, pursuant to Section 15(a)(2) of the Exchange Act, conditionally or unconditionally exempt any broker or dealer from the registration provisions of Section 15(a)(1).

it will consider applications for these exemptive orders. These procedures are similar to those now used by the Commission in considering exemptive order applications under the Trust Indenture Act (*see* 17 CFR 260.4d–7; 260.4d–8), the Investment Company Act (*see* 17 CFR 270.0–2; Investment Company Act Release No. 14492 (April 30, 1985)); and the Investment Advisers Act (*see* 17 CFR 275.0–5). Applicants should also be aware, however, that under Section 36(a)(2), the Commission has sole discretion to decline to consider any application.

Some provisions under the Exchange Act give the Commission specific authority to provide exemptions.[3] In those areas, the Commission intends to continue to consider exemptive requests under the specific exemptive provisions. Under general exemptive authority, the Division of Corporation Finance will evaluate on a case-by-case basis any requests for exemptive relief it receives. With respect to areas of the Exchange Act administered by the Division of Market Regulation[4] where the Exchange Act does not provide specific exemptive authority, the Commission currently views two areas as appropriate for requests for exemptive relief under Section 36: (1) Requests made under Section 11(d)(1) of the Exchange Act, which prohibits broker-dealers from extending, arranging, or maintaining credit on a new issue the broker-dealer is distributing and for thirty days thereafter; and (2) requests made under the various statutory and regulatory requirements otherwise imposed on a broker or dealer by Sections 15 and 17 of the Exchange Act, if such broker or dealer has received an exemption from the Commission from the registration provisions of Section 15.[5]

II. Amendment to Rules of General Application

The Commission today announces an amendment to its Rules of General Application governing procedures to be followed for filing application for exemptive orders pursuant to Section 36 of the Exchange Act. The amendment adds new Rule 240.0–12 which sets forth the general procedures.

The Commission finds, in accordance with Section 553(b)(3)(A) of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(A), that these rules relate to agency organization, procedure, or practice, an agency interpretation, and a general statement of policy. Accordingly, notice, opportunity for public comment, and publication of these procedures and guidelines prior to their effective date are unnecessary.

List of Subjects in 17 CFR Part 240

Brokers, Confidential business information, Fraud, Reporting and recordkeeping requirements, Securities.

For the reasons set out in the preamble, Title 17, Chapter II, Part 240 of the Code of Federal Regulations is amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The general authority citation for Part 240 is revised to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78f, 78i, 78j, 78k, 78k–1, 78*l*, 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78ll(d), 78mm, 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 and 80b–11, unless otherwise noted.

* * * * *

2. Section 240.0–12 is added to read as follows:

§ 240.0–12 Commission procedures for filing applications for orders for exemptive relief under Section 36 of the Exchange Act.

(a) The application shall be in writing in the form of a letter, must include any supporting documents necessary to make the application complete, and otherwise must comply with § 240.0–3. All applications must be submitted to the Office of the Secretary of the Commission. Requestors may seek confidential treatment of their applications to the extent provided under § 200.81 of this chapter. If an application is incomplete, the Commission, through the Division handling the application, may request that the application be withdrawn unless the applicant can justify, based on all the facts and circumstances, why supporting materials have not been submitted and undertakes to submit the omitted materials promptly.

(b) An applicant may submit a request electronically in standard electronic mail text or ASCII format. The electronic mailbox to use for these applications is described on the Commission's website at www.sec.gov in the ''Exchange Act Exemptive Applications'' subsection located under the ''Current SEC Rulemaking'' section. In the event electronic mailboxes are revised in the future, applicants can find the appropriate mailbox by accessing the Commission's website directory of electronic mailboxes at http://www.sec.gov/asec/mailboxs.htm.

(c) An applicant also may submit a request in paper format. Five copies of every paper application and every amendment to such an application must be submitted to the Office of the Secretary at 450 Fifth Street, N.W., Washington, D.C. 20549. Applications must be on white paper no larger than 8½ by 11 inches in size. The left margin of applications must be at least 1½ inches wide, and if the application is bound, it must be bound on the left side. All typewritten or printed material must be on one side of the paper only and must be set forth in black ink so as to permit photocopying.

(d) Every application (electronic or paper) must contain the name, address and telephone number of each applicant and the name, address, and telephone number of a person to whom any questions regarding the application should be directed. The Commission will not consider hypothetical or anonymous requests for exemptive relief. Each applicant shall state the basis for the relief sought, and identify the anticipated benefits for investors and any conditions or limitations the applicant believes would be appropriate for the protection of investors. Applicants should also cite to and discuss applicable precedent.

(e) Amendments to the application should be prepared and submitted as set forth in these procedures and should be marked to show what changes have been made.

(f) After the filing is complete, the applicable Division will review the application. Once all questions and issues have been answered to the satisfaction of the Division, the staff will make an appropriate recommendation to the Commission. After consideration of the recommendation by the Commission, the Commission's Office of the Secretary will issue an appropriate response and will notify the applicant. If the application pertains to a section of the Exchange Act pursuant to which the Commission has delegated its authority to the appropriate Division, the Division Director or his or her designee will issue an appropriate response and notify the applicant.

(g) The Commission, in its sole discretion, may choose to publish in the **Federal Register** a notice that the application has been submitted. The

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[3] For example, Section 12(h) of the Exchange Act permits the Commission to exempt certain persons, or classes of persons, from the provisions of Sections 12(g), 13, 14, 15(d), and 16.

[4] The Division of Corporation Finance is responsible for administering various sections of the Exchange Act, including provisions of Sections 10A, 12, 13, 14, 15(d), 16, and 21E. The Division of Market Regulation administers other provisions of the Exchange Act, including Sections 6, 11, 15, 17 and 19. The Division of Investment Management administers Section 13(f) of the Exchange Act and that Division follows certain other procedures in considering exemptive applications.

[5] *See*, e.g., Exchange Act Section 15(c)(3) and the rules thereunder.

notice would provide that any person may, within the period specified therein, submit to the Commission any information that relates to the Commission action requested in the application. The notice also would indicate the earliest date on which the Commission would take final action on the application, but in no event would such action be taken earlier than 25 days following publication of the notice in the **Federal Register**.

(h) The Commission may, in its sole discretion, schedule a hearing on the matter addressed by the application.

By the Commission.

Dated: February 5, 1998.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–3931 Filed 2–17–98; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 96P–0338]

Food Labeling: Health Claims; Soluble 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 announcing its decision to authorize the use, on food labels and in food labeling, of health claims on the association between soluble fiber from psyllium seed husk and reduced risk of coronary heart disease (CHD). Based on its review of evidence submitted with comments to the proposal, as well as evidence described in the proposal, the agency has concluded that soluble fiber from psyllium seed husk, similar to beta (β)-glucan soluble fiber from whole oats, when included as part of a diet low in saturated fat and cholesterol, may reduce the risk of CHD by lowering blood cholesterol levels. The agency has concluded, based on the totality of publicly available scientific evidence, that there is significant scientific agreement among qualified experts to support the relationship between soluble fiber in psyllium seed husk and CHD. Therefore, the agency has decided to amend the regulation that authorized a health claim on soluble fiber from whole oats and the risk of CHD to include soluble fiber from psyllium seed husk. FDA has determined that label statements alerting consumers to the need to consume adequate amounts of liquids with products containing dry or incompletely hydrated psyllium will be required on products bearing the health claim. FDA is announcing this action in response to a petition filed by the Kellogg Co. (the petitioner).

DATES: This regulation is effective February 18, 1998. The Director of the Office of the Federal Register approves of the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 101.81(c)(2)(ii)(B), effective February 18, 1998.

FOR FURTHER INFORMATION CONTACT: Virginia L. Wilkening, 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

On November 8, 1990, the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535) was signed into law. This new law amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the most notable aspects of the 1990 amendments was that they confirmed FDA's authority to regulate health claims on food labels and in food labeling. FDA published final rules implementing the 1990 amendments on January 6, 1993 (58 FR 2478). In those final rules, FDA adopted § 101.14 (21 CFR 101.14), which sets out the rules for the authorization and use of health claims. The agency also adopted § 101.70 (21 CFR 101.70), which establishes a process for petitioning the agency to authorize health claims about a substance-disease relationship and sets out the types of information that any such petition must include.

In addition, FDA conducted an extensive review of the evidence on the 10 substance disease relationships listed in the 1990 amendments. As a result of its review, FDA authorized a health claim in § 101.77 (21 CFR 101.77) on the association between diets low in saturated fat and cholesterol and high in vegetables, fruits, and grain products that contain soluble fiber and a reduced risk of heart disease (58 FR 2552, January 6, 1993). In that rulemaking, FDA reviewed the evidence relating dietary fiber to heart disease and concluded that it was difficult to determine the relationship because dietary fiber comprises a diverse group of chemical substances that may be associated with different physiological functions (58 FR 2552 at 2572). Chemically and physiologically, cellulose, lignin, hemicellulose, pectin, and alginate (all relatively purified fiber types) behave differently from one another. Likewise, wheat bran, oat bran, and rice bran are not similar in composition. The agency noted that the available evidence made it difficult to correlate the role of specific fiber components to health effects.

However, in its final rule, FDA noted that hypocholesterolemic properties may be documented for specific food fibers (58 FR 2552 at 2567). Further, the agency stated that if manufacturers could document, through appropriate studies, that dietary consumption of the soluble fiber in their particular food has the effect of lowering low density lipoprotein (LDL)-cholesterol, and has no adverse effects on other heart disease risk factors (e.g., high density lipoprotein (HDL)-cholesterol), they should petition for a health claim for their particular product.

In accordance with the petition procedure in § 101.70, FDA published a final rule on the relationship between soluble fiber from whole oats and reduced risk of heart disease (the soluble fiber from whole oats final rule), § 101.81 (21 CFR 101.81) (62 FR 3584, January 23, 1997 and modified at 62 FR 15343, March 31, 1997). In that document, the agency concluded that, based on the totality of publicly available scientific evidence, there is significant scientific agreement among qualified experts to support the relationship between soluble fiber in whole oats and reduced risk of CHD. FDA also concluded that the type of soluble fiber in whole oats, β-glucan soluble fiber, is the primary component responsible for the lowering of blood total- and LDL-cholesterol associated with consumption of whole oat products when part of a diet low in saturated fat and cholesterol. The rule specified the chemical nature of the specific fiber and methods for measuring its presence in foods.

In the soluble fiber from whole oats final rule, the agency acknowledged the likelihood that consumption of β-glucan soluble fiber from sources other than whole oats, as well as soluble fiber from other sources, will affect blood lipid levels and thus the risk of heart disease (62 FR 3584 at 3587). At that time, FDA considered structuring the final rule as an umbrella regulation authorizing the use of a claim for ''soluble fiber from certain foods'' and risk of CHD. Such action would have allowed flexibility in expanding the claim to other specific food sources of soluble fiber when