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## FEDERAL RESERVE SYSTEM

### 12 CFR Part 225

[Regulation Y; Docket No. R-1057]

#### Bank Holding Companies and Change in Bank Control

**AGENCY:** Board of Governors of the Federal Reserve System.

**ACTION:** Interim rule with request for public comments.

**SUMMARY:** The Board of Governors is adopting on an interim basis, effective immediately, amendments to the interim rule published in the **Federal Register** on January 25, 2000, that established procedures for bank holding companies and foreign banks that operate a branch, agency, or commercial lending company in the United States to elect to become financial holding companies. The rule was promulgated on an interim basis, effective March 11, 2000, to implement provisions of the recently enacted Gramm-Leach-Bliley Act that enable bank holding companies and foreign banks that meet applicable statutory requirements to become financial holding companies and thereby engage in a broader range of financial and other activities than are permissible for bank holding companies.

As a result of its experience in processing elections under the interim rule, the Board is amending the interim rule to make three changes concerning the elections by foreign banks. First, in order to make the processing of elections by foreign banks parallel to the processing of elections filed by domestic bank holding companies, the interim rule is being amended to permit elections filed by foreign banks that meet the rule's well managed and well capitalized standards to become effective on the 31st day after filing, unless the Board finds the election ineffective or the foreign bank agrees to

extend the review period. Second, in order to make the requirements for foreign banks consistent with the requirements imposed on bank holding companies, the Board is amending the interim rule to require that all U.S. depository institution subsidiaries (such as thrifts and nonbank trust companies) of electing foreign banks be well capitalized and well managed and have satisfactory or better composite and Community Reinvestment Act ratings. Third, the Board is amending the interim rule to encourage foreign banks that are chartered in countries where no other bank from that country has received a comprehensive consolidated supervision determination from the Board to use the pre-clearance process provided by the interim rule if such bank is considering making a financial holding company election. The Board also is seeking comment on whether comprehensive consolidated supervision should be required in connection with comparability determinations on capital and management. Finally, the Board is amending provisions of the interim rule applicable to bank holding companies by removing the compliance rating component from the definition of well managed for depository institutions for purposes of determining qualification as a financial holding company.

The Board solicits comments on all aspects of the interim rule, including these amendments, and will amend the rule as appropriate in response to comments received.

**DATES:** These amendments to the interim rule are effective on March 15, 2000. Comments on these amendments to the interim rule must be received by April 17, 2000.

**ADDRESSES:** Comments should refer to docket number R-1057 and should be sent to Ms. Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW, Washington, DC, 20551 or mailed electronically to [regs.comments@federalreserve.gov](mailto:regs.comments@federalreserve.gov). Comments addressed to Ms. Johnson also may be delivered to the Board's mail room between the hours of 8:45 a.m. and 5:15 p.m. and, outside of those hours, to the Board's security control room. Both the mail room and the security control room are accessible from the Eccles Building courtyard entrance, located on 20th Street between

Constitution Avenue and C Street, NW. Members of the public may inspect comments in Room MP-500 of the Martin Building between 9:00 a.m. and 5:00 p.m. on weekdays.

**FOR FURTHER INFORMATION CONTACT:** Ann E. Misback, Assistant General Counsel (202/452-3788), Thomas M. Corsi, Managing Senior Counsel (202/452-3275), or Christopher W. Clubb, Senior Counsel (202/452-3904), Legal Division; for the hearing impaired only, Telecommunications Device for the Deaf (TDD), Janice Simms (202) 872-4984.

#### SUPPLEMENTARY INFORMATION:

##### Background

Title I of the Gramm-Leach-Bliley Act (Pub. L. No. 106-102, 113 Stat. 1338 (1999)) amends section 4 of the Bank Holding Company Act (12 U.S.C. 1843) ("BHC Act") to authorize bank holding companies and foreign banks that qualify as "financial holding companies" to engage in securities, insurance, and other activities that are financial in nature or incidental to a financial activity. The Gramm-Leach-Bliley Act defines a financial holding company as a bank holding company that meets certain eligibility requirements. In order for a bank holding company to become a financial holding company and be eligible to engage in the new activities authorized under the Gramm-Leach-Bliley Act, the Act requires that all depository institutions controlled by the bank holding company be well capitalized and well managed. With regard to a foreign bank that operates a branch or agency or owns or controls a commercial lending company in the United States, the Act requires the Board to apply comparable capital and management standards that give due regard to the principle of national treatment and equality of competitive opportunity.

In order to implement the provisions of the Gramm-Leach-Bliley Act governing the creation and conduct of financial holding companies, on January 19, 2000, the Board amended its Regulation Y by adding subpart I to establish procedures for bank holding companies as well as foreign banks that operate a branch, agency, or commercial lending company in the United States to elect to become financial holding companies. The Board promulgated the

rule on an interim basis, effective March 11, 2000 (65 FR 3785, January 25, 2000).

#### Amendments to Interim Rule

Based on its experience to date, the Board is amending the interim rule as it was issued on January 19, 2000, in order to address three issues that arose in connection with processing elections filed by foreign banks. In addition, the Board is amending the regulatory definition of well managed in the interim rule that is applicable to depository institutions for purposes of determining qualification for financial holding company status.

With respect to the foreign bank provisions, the first amendment is intended to make the processing of elections filed by foreign banks parallel to the processing of elections filed by domestic bank holding companies. Under the provisions of the interim rule as issued on January 19, 2000, an election to become a financial holding company by a foreign bank or company is not effective until the Board makes an affirmative finding that the foreign bank's capital and management meet standards comparable to those applicable to U.S. banks owned by financial holding companies. In contrast, a domestic bank holding company's election to become a financial holding company is effective within 31 days of its filing unless the Board determines that it is ineffective.

In adopting the interim rule, the Board was concerned that it would be unable to carry out its statutory responsibility to apply comparable standards to foreign banks within the constraint of a short notice process and thus adopted the review procedure described above. The Board's experience, however, in reviewing and acting on the elections filed by foreign banks that meet the standards set out in the interim rule indicates that such elections may be reviewed and comparable standards may be applied within a 31 day notice period. Accordingly, based on this experience and to accommodate concerns expressed regarding the difference in process applicable to foreign banks, the Board has decided to amend the interim rule to adopt a 31 day review process for foreign bank elections, as is currently applicable for bank holding company elections.

Under the amendment, if a foreign bank meets the rule's quantitative capital requirements, as well as the well managed standards, an election filed by that foreign bank would become effective on the 31st day after filing, unless the Board were to find the election ineffective or the foreign bank

agreed to extend the review period. The Board would retain the ability to find the election ineffective because the capital is not comparable to the capital required for a U.S. bank owned by a financial holding company. In addition, the rule is being amended to allow the Board to find an election ineffective if the Board does not have sufficient information to assess whether the foreign bank meets the standards. The Board is of the view that these changes would ensure that foreign banks that meet the rule's requirements will receive treatment on the same basis as U.S. bank holding companies. If a foreign bank does not meet the rule's specified requirements, it may nevertheless file a pre-clearance request for a specific determination on the comparability of its capital and management.

The second change is intended to clarify the interim rule with respect to foreign banks that do not have a U.S. subsidiary bank, but may have other U.S. depository institution subsidiaries, such as thrifts and nonbank trust companies. As mentioned above, the Gramm-Leach-Bliley Act requires that all depository institutions controlled by a bank holding company be well capitalized and well managed in order for that bank holding company to be eligible to become a financial holding company. The interim rule as issued on January 19, 2000, required only that a foreign bank and each of its U.S. branches, agencies, and commercial lending subsidiaries be well capitalized and well managed in order for the foreign bank to be eligible to be treated as a financial holding company. In order to make the requirements for foreign banks consistent with the requirement imposed on bank holding companies, the interim rule is being amended to require that all U.S. depository institution subsidiaries of the foreign bank must be well capitalized and well managed in order for the foreign bank to be eligible to be treated as a financial holding company. As a result, the rule also is being amended to require that the foreign bank certify in any declaration filed that its U.S. depository institution subsidiaries are well capitalized and well managed.

The third change relates to the review of comprehensive consolidated supervision ("CCS") in connection with financial holding company elections by foreign banks. Home country supervision is an important element in the determination that a bank is well managed and the Board expects that most foreign banks that elect to be treated as financial holding companies will be subject to comprehensive

consolidated supervision. The interim rule permits a foreign bank or company to request a review of its qualifications to be treated as a financial holding company prior to formally filing its election. In order to facilitate the Board's review of whether the management of a foreign bank meets standards comparable to those required of a U.S. bank owned by a financial holding company, the interim rule is being amended to encourage foreign banks that have not been reviewed by the Board with respect to home country supervision and that are chartered in countries where no other bank from that country has received a CCS determination from the Board (including a determination that the home country supervisor is actively working toward a system of CCS) to use the pre-clearance process if such bank is considering making an election to be treated as a financial holding company. In addition, the Board is requesting comment on whether a foreign bank should be required to meet a CCS standard in order to be treated as a financial holding company.

The amendment to the interim rule regarding bank holding companies is a revision of the definition of well managed applicable to a depository institution for purposes of determining qualification as a financial holding company under the Gramm-Leach-Bliley Act. For this purpose, the Board initially adopted the existing Regulation Y definition of well managed. The Board's definition requires that a depository institution have at least a satisfactory composite examination rating and at least a satisfactory rating for both management and compliance. This three-part definition was initially adopted by the Board as part of its effort to determine whether a bank holding company qualifies for expedited treatment in applications processing. In that context, a bank holding company qualified for expedited processing if 80 percent of the depository institution assets of the company were well managed. In order to become and remain a financial holding company under the Gramm-Leach-Bliley Act, all of the depository institution assets of a bank holding company must be well managed.

The Gramm-Leach-Bliley Act does not address compliance ratings in determining whether an institution is well managed. Accordingly, the Board is amending its regulatory definition of "well managed" for purposes of determining qualification as a financial holding company to reflect the two-part test in the statute. Thus, a depository institution will be considered well

managed for this purpose if it has a satisfactory composite rating and a satisfactory rating for management.

The Board continues to believe that compliance ratings are important, and will address issues relating to compliance in other contexts. In particular, the Board and other federal banking agencies have supervisory authority to take full action against an institution if compliance issues are raised. In addition, each agency may consider compliance ratings when determining whether to approve any merger or expansion proposal involving the depository institution or the parent bank holding company of the institution.

For these reasons, the Board is amending its interim rule to remove the compliance rating component from the definition of well managed in Regulation Y for purposes of determining qualification as a financial holding company.

#### Regulatory Flexibility Act Analysis

In accordance with section 3(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a)), the Board published an initial regulatory flexibility analysis with the interim rule on January 25, 2000. The amendments contained herein do not change that analysis.

#### Administrative Procedure Act

The interim rule became effective on March 11, 2000 without review of public comments. These amendments are effective March 15, 2000. Pursuant to 5 U.S.C. 553, the Board finds that it is impracticable to review public comments prior to the effective date of the interim rule, and that there is good cause to make the interim rule effective immediately, due to the fact that the rule sets forth procedures to implement statutory changes that became effective on March 11, 2000. The Board is seeking public comment on the interim rule until March 27, 2000, and will accept comments on the amendments until April 17, 2000. The Board will amend the rule as appropriate after reviewing the comments.

#### Paperwork Reduction Act

The amendments to the interim rule do not affect the collections of information outlined in the interim rule issued by the Board on January 19, 2000.

#### List of Subjects in 12 CFR Part 225

Administrative practice and procedure, Banks, banking, Federal Reserve System, Holding companies, Reporting and record keeping requirements, Securities.

For the reasons set out in the preamble, the Board amends 12 CFR part 225 as follows:

### PART 225—BANK HOLDING COMPANY AND CHANGE IN BANK CONTROL (REGULATION Y)

1. The authority citation for part 225 continues to read as follows:

**Authority:** 12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831(i), 1831p-1, 1843(c)(8), 1844(b), 1972(l), 3106, 3108, 3310, 3331-3351, 3907, and 3909.

2. Section 225.2(s)(1) introductory text is revised to read as follows:

#### § 225.2 Definitions.

\* \* \* \* \*

(s) *Well managed*—(1) *In general.* Except as otherwise provided in this part, a company or depository institution is well managed if:

\* \* \* \* \*

3. In § 225.81, paragraph (c) is redesignated as paragraph (d), and a new paragraph (c) is added to read as follows:

#### § 225.81 What is a financial holding company?

\* \* \* \* \*

(c) *Well managed*—(1) *In general.* For purposes of this subpart, a depository institution is well managed if:

(i) At its most recent inspection or examination or subsequent review by the appropriate Federal banking agency for the depository institution, the institution received:

(A) At least a satisfactory composite rating; and

(B) At least a satisfactory rating for management; or

(ii) In the case of a depository institution that has not received an examination rating, the Board has determined, after a review of managerial and other resources of the depository institution and after consulting the appropriate Federal banking agency for the institution, that the institution is well managed.

(2) *Merged institutions.* A depository institution that results from the merger of two or more depository institutions that are well managed shall be considered to be well managed unless the Board determines otherwise after consulting with the appropriate Federal banking agency for each depository institution involved in the merger.

\* \* \* \* \*

4. Sections 225.90 through 225.94 are revised to read as follows:

#### § 225.90 What are the requirements for a foreign bank to be treated as a financial holding company?

(a) *Foreign banks as financial holding companies.* A foreign bank that operates a branch or agency or owns or controls a commercial lending company in the United States, and any company that owns or controls such a foreign bank, will be treated as a financial holding company if:

(1) The foreign bank, and any U.S. depository institution that is owned or controlled by the foreign bank or company, is and remains well capitalized and well managed; and

(2) The foreign bank, or the company that owns the foreign bank, has made an effective election to be treated as a financial holding company under this subpart.

(b) *Standards for “well capitalized.”* A foreign bank will be considered “well capitalized” if either:

(1)(i) Its home country supervisor, as defined in § 211.21 of the Board’s Regulation K (12 CFR 211.21), has adopted risk-based capital standards consistent with the Capital Accord of the Basel Committee on Banking Supervision (Basel Accord);

(ii) The foreign bank maintains a Tier 1 capital to total risk-based assets ratio of 6 percent and a total capital to total risk-based assets ratio of 10 percent, as calculated under its home country standard;

(iii) The foreign bank maintains a Tier 1 capital to total assets leverage ratio of at least 3 percent; and

(iv) The foreign bank’s capital is comparable to the capital required for a U.S. bank owned by a financial holding company; or

(2) The foreign bank has obtained a determination from the Board under § 225.91(c) that the foreign bank’s capital is otherwise comparable to the capital that would be required of a U.S. bank owned by a financial holding company.

(c) *Standards for “well managed.”* A foreign bank will be considered “well managed” if:

(1) Each of the U.S. branches, agencies, and commercial lending subsidiaries of the foreign bank has received at least a satisfactory composite rating at its most recent assessment;

(2) The home country supervisor of the foreign bank considers the overall operations of the foreign bank to be satisfactory or better; and

(3) The management of the foreign bank meets standards comparable to those required of a U.S. bank owned by a financial holding company.

**§ 225.91 How may a foreign bank elect to be treated as a financial holding company?**

(a) *Filing requirement.* A foreign bank that operates a branch or agency or owns or controls a commercial lending company in the United States, or a company that owns or controls such a foreign bank, may elect to be treated as a financial holding company by filing a written declaration with the appropriate Reserve Bank.

(b) *Contents of declaration.* The declaration must:

(1) State that the foreign bank or the company elects to be treated as a financial holding company;

(2) Provide the risk-based and leverage capital ratios of the foreign bank as of the close of the most recent quarter and as of the close of the most recent audited reporting period;

(3) Certify that the foreign bank meets the standards of well capitalized set out in § 225.90(b)(1)(i), (ii) and (iii) or § 225.90(b)(2) as of the date the foreign bank or company files its election;

(4) Certify that the foreign bank is well managed as defined in § 225.90(c)(1) as of the date the foreign bank or company files its election;

(5) Certify that all U.S. depository institutions controlled by the foreign bank or company are well capitalized and well managed as of the date the foreign bank or company files its election; and

(6) Provide the capital ratios for all relevant capital measures (as defined in section 38 of the Federal Deposit Insurance Act) as of the close of the previous quarter for each U.S. depository institution controlled by the foreign bank or company.

(c) *Pre-clearance process.* Before filing an election to be treated as a financial holding company, a foreign bank or company may file a request for review of its qualifications to be treated as a financial holding company. The Board will endeavor to make a determination on such requests within 30 days of receipt. A foreign bank chartered in a country where no other bank from that country has been reviewed by the Board for comprehensive consolidated supervision under the Bank Holding Company Act or the International Banking Act is encouraged to use this process.

**§ 225.92 How does an election by a foreign bank become effective?**

(a) *In general.* An election described in § 225.91 is effective on the 31st day after the date that an election was received by the appropriate Federal Reserve Bank, unless the Board notifies the foreign bank or company prior to that time that:

(1) The election is ineffective; or

(2) The period is extended with the consent of the foreign bank or company making the election.

(b) *Earlier notification that an election is effective.* The Board or the appropriate Federal Reserve Bank may notify a foreign bank or company that its election to be treated as a financial holding company is effective prior to the 31st day after the election was filed with the appropriate Federal Reserve Bank. Such notification must be in writing.

(c) *Under what circumstances will the Board find an election to be ineffective?* An election to be treated as financial holding company shall not be effective if, during the period provided in paragraph (a) of this section, the Board finds that:

(1) The foreign bank certificant, or any foreign bank that operates a branch or agency or owns or controls a commercial lending company in the United States and is controlled by a foreign company certificant, is not both well capitalized and well managed;

(2) Any insured depository institution controlled by the foreign bank or company (except an institution excluded under paragraph (d) of this section) or any U.S. branch of a foreign bank that is insured by the Federal Deposit Insurance Corporation has not achieved at least a rating of "satisfactory record of meeting community needs" under Community Reinvestment Act at the institution's most recent examination;

(3) Any U.S. depository institution subsidiary of the foreign bank or company is not both well capitalized and well managed; or

(4) The Board does not have sufficient information to assess whether the foreign bank or company making the election meets the requirements of this subpart.

(d) *How is CRA performance of recently acquired insured depository institutions considered?* An insured depository institution will be excluded for purposes of the review of CRA ratings described in paragraph (c)(2) of this section consistent with the provisions of § 225.82(e).

(e) *Factors used in the Board's determination regarding comparability of capital and management.* In determining whether a foreign bank is well capitalized and well managed in accordance with comparable capital and management standards, the Board will give due regard to national treatment and equality of competitive opportunity. In this regard, the Board may take into account the foreign bank's composition of capital, accounting standards, long-

term debt ratings, reliance on government support to meet capital requirements, the extent to which the foreign bank is subject to comprehensive consolidated supervision, and other factors that may affect analysis of capital and management. The Board will consult with the home country supervisor for the foreign bank as appropriate.

**§ 225.93 What are the consequences of a foreign bank failing to continue to meet applicable capital and management requirements?**

(a) *Notice by the Board.* If a foreign bank or company has made an effective election to be treated as a financial holding company under this subpart and the Board finds that the foreign bank, or any U.S. depository institution owned or controlled by the foreign bank or company, ceases to be well capitalized or well managed, the Board will notify the foreign bank or company in writing that it is not in compliance with the applicable requirement(s) for a financial holding company and identify the areas of noncompliance.

(b) *Notification by a financial holding company required.* Promptly upon becoming aware that the foreign bank, or any U.S. depository institution owned or controlled by the foreign bank or company, has ceased to be well capitalized or well managed, the foreign bank, or any company that controls such foreign bank, must notify the Board and identify the area of noncompliance.

(c) *Execution of agreement acceptable to the Board—(1) Agreement required; time period.* Within 45 days after receiving a notice under paragraph (a) of this section, the foreign bank or company must execute an agreement acceptable to the Board to comply with all applicable capital and management requirements.

(2) *Extension of time for executing agreement.* Upon request by a company, the Board may extend the 45-day period under paragraph (c)(1) of this section if the Board determines that granting additional time is appropriate under the circumstances. A request by a company for additional time must include an explanation of why an extension is necessary.

(3) *Agreement requirements.* An agreement required by paragraph (c)(1) of this section to correct a capital or management deficiency must:

(i) Explain the specific actions that the foreign bank or company will take to correct all areas of noncompliance;

(ii) Provide a schedule within which each action will be taken;

(iii) Provide any other information that the Board may require; and

(iv) Be acceptable to the Board.

(d) *Limitations during period of noncompliance.* Until the Board determines that a company has corrected the conditions described in a notice under paragraph (a) of this section:

(1) The Board may impose any limitations or conditions on the conduct or the U.S. activities of the foreign bank or company or any of its affiliates as the Board finds to be appropriate and consistent with the purposes of the Bank Holding Company Act; and

(2) The company and its affiliates may not engage in any new activity in the United States or acquire control or shares of any company under section 4(k) of the Bank Holding Company Act (12 U.S.C. 1843(k)) without prior approval from the Board.

(e) *Consequences of failure to correct conditions within 180 days—(1) Termination of offices and divestiture.* If a foreign bank or company does not correct the conditions described in a notice under paragraph (a) of this section within 180 days of receipt of the notice or such additional time as the Board may permit, the Board may order the foreign bank or company to terminate the foreign bank's U.S. branches and agencies and divest any commercial lending companies owned or controlled by the foreign bank or company. Such divestiture must be done in accordance with the terms and conditions established by the Board.

(2) *Alternative method of complying with a divestiture order.* A foreign bank or company may comply with an order issued under paragraph (e)(1) of this section by ceasing to engage (both directly and through any subsidiary) in all activities that are not permissible for a foreign bank to conduct under sections 2(h) and 4(c) of the Bank Holding Company Act (12 U.S.C. 1841(h) and 1843(c)). The termination of activities must be done within the time period referred to in paragraph (e)(1) of this section and subject to terms and conditions acceptable to the Board.

(f) *Consultation with other Agencies.* In taking any action under this section, the Board will consult with the relevant Federal and state regulatory authorities.

**§ 225.94 What are the consequences of an insured branch or depository institution failing to maintain a satisfactory or better rating under the Community Reinvestment Act?**

(a) *Insured branch as an "insured depository institution."* A U.S. branch of a foreign bank that is insured by the Federal Deposit Insurance Corporation shall be treated as an "insured

depository institution" for purposes of § 225.84.

(b) *Applicability.* The provisions of § 225.84, with the modifications contained in this section, shall apply to a foreign bank that operates an insured branch referred to in paragraph (a) of this section or an insured depository institution in the United States, and any company that owns or controls such a foreign bank, that has made an effective election under § 225.92 in the same manner and to the same extent as they apply to a financial holding company.

By order of the Board of Governors of the Federal Reserve System, March 15, 2000.

**Jennifer J. Johnson,**

*Secretary of the Board.*

[FR Doc. 00-6849 Filed 3-20-00; 8:45 am]

**BILLING CODE 6210-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 177

[Docket No. 99F-0461]

#### Indirect Food Additives: Polymers

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of polyphenylene sulfone resins as articles or components of articles intended for repeated use in contact with food. This action is in response to a petition filed by Ticona.

**DATES:** This rule is effective March 21, 2000; submit written objections and requests for a hearing by April 20, 2000.

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

**SUPPLEMENTARY INFORMATION:** In a notice published in the *Federal Register* of March 19, 1999 (64 FR 13586), FDA announced that a food additive petition (FAP 9B4644) had been filed by Ticona, c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in part 177 *Indirect Food Additives: Polymers* (21

CFR part 177) to provide for the safe use of polyphenylene sulfone resins as articles or components of articles intended for repeated use in contact with food.

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) that the regulations in part 177 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 9B4644 (64 FR 13586, March 19, 1999). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by April 20, 2000. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the