ANNEX

Subpart A, part 2 of the Appendix to the TSUS remains modified by insertion in numerical sequence the following provision:

Item	Articles	Rates of Duty 1	Rates of Duty 2	Effective Period
923.18	Ferrochromium, containing over 3 percent by weight of carbon, valued less than 38 cents per pound of chromium content provided for in item 606.24	4.625 per lb. on chromium content	4.625 per lb. on chromium content	On or before November 15, 1982

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Rules and Regulations

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FEDERAL RESERVE SYSTEM

12 CFR Part 201

Extensions of Credit by Federal Reserve Banks; Changes In Discount Rates

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors has amended its Regulation A, "Extensions of Credit by Federal Reserve Banks," for the purpose of adjusting discount rates with a view to accommodating commerce and business in accordance with other related rates and the general credit situation of the country. In addition, the Board adopted a surcharge of 2 percentage points on frequent use of the discount window by large borrowers.

EFFECTIVE DATE: The changes were effective on the dates specified below.

FOR FURTHER INFORMATION CONTACT: James McAfee, Assistant Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 (202/452-3259).

SUPPLEMENTARY INFORMATION: Pursuant to the authority of 5 U.S.C. 553(b)(3)(B) and (d)(3), these amendments are being published without prior general notice of proposed rulemaking, public participation, or deferred effective date. The Board has for good cause found that current economic and financial considerations required that these amendments must be adopted immediately.

PART 201—EXTENSIONS OF CREDIT BY FEDERAL RESERVE BANKS

Pursuant to section 14(d) of the Federal Reserve Act 12 U.S.C. 357, Part 201 is amended as set forth below:

1. Section 201.51 is revised to read as follows:

§ 201.51 Short term adjustment credit for depository institutions.

The rates for short term adjustment credit provided to depository institutions under § 201.3(a) of Regulation A are:

Federal Reserve Bank	Rate	Effective
Boston	13	Nov. 2, 1981.
New York	13	Do.
Philadelphia	13	Do.
Cleveland	13	Do.
Richmond	13	Do.
Atlanta	13	Nov. 3, 1981.
Chicago	13	Nov. 2, 1981.
St. Louis	13	Do.
Minneapolis	13	Do.
Kansas City	13	Nov. 3, 1981.
Dallas	13	Nov. 6, 1981.
San Francisco	13	Nov. 2, 1981.

A 2 percent surcharge is imposed additionally on borrowings for short-term adjustment purposes of institutions with deposits of $500 million or more.

2. Section 201.52 is revised to read as follows:

§ 201.52 Extended credit to depository institutions.

(a) The rates for seasonal credit extended to depository institutions under § 201.3(b)(1) of Regulation A are:

Federal Reserve Bank	Rate	Effective
Boston	13	Nov. 2, 1981.
New York	13	Do.
Philadelphia	13	Do.
Cleveland	13	Do.
Richmond	13	Do.
Atlanta	13	Nov. 3, 1981.
Chicago	13	Nov. 2, 1981.
St. Louis	13	Do.
Minneapolis	13	Do.
Kansas City	13	Nov. 3, 1981.
Dallas	13	Nov. 6, 1981.
San Francisco	13	Nov. 2, 1981.

(b) The rates for other extended credit provided to depository institutions under sustained liquidity pressures or where there are exceptional circumstances or practices involving a particular institution under § 201.3(b)(2) of Regulation A are:

Federal Reserve Bank	Rate	Effective
Boston	13	Nov. 2, 1981.
New York	13	Do.
Philadelphia	13	Do.
Cleveland	13	Do.
Richmond	13	Do.
Atlanta	13	Nov. 3, 1981.
Chicago	13	Nov. 2, 1981.
St. Louis	13	Do.
Minneapolis	13	Do.
Kansas City	13	Nov. 3, 1981.
Dallas	13	Nov. 6, 1981.
San Francisco	13	Nov. 2, 1981.

Note.—These rates apply for the first 60 days of borrowing. A 1 percent surcharge applies for borrowing during the next 90 days, and a 2 percent surcharge applied for borrowing thereafter.

(12 U.S.C. 248(i), Interprets or applies 12 U.S.C. 357)

By order of the Board of Governors, November 9, 1981.

James McAfee,

Assistant Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 155

[Docket No. 78N-0103]

Canned Vegetables; Amendment of Standard of Identity for Asparagus

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standard of identity for "Certain other canned vegetables", to provide for the use of ascorbic acid, erythorbic acid, and the sodium salts of ascorbic acid and erythorbic acid as antioxidants to preserve color in "white" and "green-tipped and white" asparagus.

DATES: Effective July 1, 1983, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this

date. Voluntary compliance may begin January 18, 1982. Objections by December 17, 1981.

ADDRESS: Written objections are to be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: F. Leo Kauffman, Bureau of Foods (HFF–214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–245–1164.

SUPPLEMENTARY INFORMATION: A proposal to amend the standard of identity for § 155.200 *Certain other canned vegetables* (21 CFR 155.200) by deleting those provisions applicable to canned asparagus and to establish separate standards of identity and quality for this food was published in the **Federal Register** of December 15, 1978 (43 FR 58580). The purpose of the proposal was to adopt, insofar as practicable, a "Recommended International Standard for Canned Asparagus" (CAC/RS 56–1972) developed by the Codex Alimentarius Commission of the Food and Agriculture Organization/World Health Organization. The comment period which ended February 13, 1979, was reopened by a notice published in the **Federal Register** of May 15, 1979 (44 FR 28331), and extended to September 14, 1979, at the request of two trade associations.

Seven letters, each containing one or more comments, were received from manufacturers and processors, trade associations, and a supplier. Five comments opposed adoption of the proposal as published and stated that the present requirements for canned asparagus in § 155.200 are adequate and reflect current industry practices. Several comments stated that the proposed changes would cause major difficulties and added cost burdens to an industry which is already rapidly declining because of escalating costs of raw materials and hand labor. One comment added that the proposed changes coupled with consumer resistance to totally unfamiliar sizes and styles would, in all likelihood, mean the death of the industry. Another comment stated that the proposed changes could force companies to discontinue packing canned asparagus, and another comment contended that the impact of the proposed standards would put the Michigan asparagus growers out of business. Other comments addressed specific provisions of the proposed standards and concluded that the proposed requirements were overly restrictive and did not reflect current industry manufacturing practices. No comment favored the proposal.

On the basis of these comments and its policy of limiting the number of new regulations, FDA concludes that the proposed separate standards are unnecessary and that canned asparagus will continue to be regulated under § 155.200 *Certain other canned vegetables.*

The Codex Alimentarius Commission will be informed that an imported food which complies with the requirements of the Codex standard for canned asparagus may move freely in interstate commerce in this country, providing it complies with applicable U.S. laws and regulations.

One comment supported that provision in the proposed regulation permitting the use of ascorbic acid to preserve color in "white" and "green-tipped and white" asparagus and suggested permitting the optional use of erythorbic acid, which is a stereoisomer of ascorbic acid. The comment stated that erythorbic acid, a safe and suitable (generally recognized as safe (GRAS)) substance, would provide food manufacturers with a more economical alternative to ascorbic acid with equivalent antioxidant efficiency. The comment also suggested that the sodium salts of either ascorbic acid or erythorbic acid, also GRAS substances, be permitted in the standard.

FDA agrees and § 155.200 is amended by adding new paragraph (c)(9) to provide for the optional use of ascorbic acid, erythorbic acid, and their sodium salts as antioxidants to preserve color in "white" and "green-tipped and white" asparagus. Accordingly, currently designated paragraph (c) (9), (10), (11), and (12) has been redesignated (c) (10), (11), (12), and (13) as set forth below.

PART 155—CANNED VEGETABLES

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 155 is amended in § 155.200 by redesignating existing paragraphs (c) (9) through (12) as (c) (10) through (13) and adding new paragraph (c)(9), to read as follows:

§ 155.200 Certain other canned vegetables.

* * * * *

(c) * * *

(9) In the case of canned asparagus, ascorbic acid, erythorbic acid, or the sodium salts of ascorbic acid or erythorbic acid may be added in an amount necessary to preserve color in the "white" and "green-tipped and white" color types.

(10) In the case of canned asparagus packed in glass containers, stannous chloride may be added in a quantity not to exceed 15 parts per million calculated as tin (Sn), except that in the case of asparagus packed in glass containers with lids lined with an inert material the quantity of stannous chloride added may exceed 15 parts per million but not 20 parts per million calculated as tin (Sn).

(11) In the case of canned black-eyed peas, disodium EDTA may be added in a quantity not to exceed 145 parts per million.

(12) In the case of potatoes, calcium disodium EDTA may be added in a quantity not to exceed 110 parts per million.

(13) A vinegar or any safe and suitable organic acid for all vegetables (except artichokes, in which the quantity of such optional ingredient is prescribed by the introductory text of paragraph (c) of this section, and except canned mushrooms, in which no vinegar is permitted), in a quantity which, together with the amount of any lemon juice or concentrated lemon juice that may be added, is not more than sufficient to permit effective processing by heat without discoloration or other impairment of the article. Organic acid, other than ascorbic acid as provided for in paragraph (c)(7) of this section, shall be used in canning mushrooms only where the inside metal of the container is fully enamel-lined and in glass containers with fully enamel-lined caps.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before December 17, 1981 submit to the Dockets Management Branch (HFA–305), address above, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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 objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. Except as to any provisions that may be stayed by the filing of proper objections, compliance with this final regulation, including any required labeling changes, may begin January 18, 1982, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1983, shall fully comply. Notice of the filing of objections or lack thereof will be published in the **Federal Register.**

(Sec. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)))

Dated: November 6, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-32907 Filed 11-13-81; 8:45 am]

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21 CFR Parts 211 and 610

[Docket No. 80N-0080]

Human and Veterinary Drug Products; Exemption From Expiration Dating and Stability Testing Requirements for Allergenic Extracts

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is exempting certain allergenic extract products from the requirements for expiration dating and stability testing that are contained in the current good manufacturing practice regulations for drug products. This action responds to petitions that have been received from seven manufacturers of allergenic extract products. Allergenic extract products will remain subject to the expiration dating requirements of 21 CFR Part 610 which govern biologic product labeling and any testing requirements that may be included in an approved license amendment.

EFFECTIVE DATE: January 18, 1982.

FOR FURTHER INFORMATION CONTACT: Steven H. Unger, Bureau of Drugs (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD. 20857, 301-443-5220.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 22, 1980 (45 FR 48918), FDA proposed to amend the regulations describing current good manufacturing practice (CGMP) for human and veterinary drug products to exempt certain allergenic extracts from the expiration dating and stability testing provisions of the CGMP regulations. The action was taken in response to the requests of seven manufacturers of allergenic extracts who argued that compliance with those provisions was not feasible under current knowledge and technology.

The proposal gave 60 days for submission of written comments. Only one comment was submitted on the proposal. The comment supported the proposal and urged that it be finalized.

The effect of the amendment is to exempt allergenic extracts labeled "No U.S. Standard of Potency" from the CGMP provisions governing expiration dating and stability testing of products. The stability testing provisions of the CGMP regulations require that a drug's expiration date be established on the basis of stability studies conducted on the drug product (21 CFR 211.166).

As stated in the July 22, 1980 proposal, stability testing of a biological product entails the assessment of the product's biological activity (potency) measured ordinarily against the potency of a standard preparation. For allergenic extracts without established standards of potency, the stability tests contemplated by § 211.166 (21 CFR 211.166) cannot be conducted. Standards for most allergenic extracts have not yet been developed, due in large part to the complex nature of these preparations that are extracted from naturally occurring materials such as pollens, molds, foods, insects, dusts, and animal danders. As potency standards are developed, for example, antigen E potency of short ragweed extracts, manufacturers will be required to perform stability studies and to submit appropriate license amendments to support the dating period for their products. Allergenic extracts labeled "No U.S. Standard of Potency" remain subject to the expiration dating requirements set forth in § 610.53 (21 CFR 610.53) and any testing requirements that are included in an approved license application.

FDA advises that in the **Federal Register** of July 31, 1981 (46 FR 39129), a final rule was published that codified antigen E as an official standard of potency for short ragweed pollen extracts. In response to a comment concerning stability studies (item number 7 (46 FR 39130)), FDA advised manufacturers that stability studies consistent with the GCMP requirements were to be underway when the rule becomes effective on January 27, 1982 and, pending completion of the studies, manufacturers could label their products with the dating period prescribed under § 610.53(a). However, FDA notes that § 610.53(a), as amended by this final rule, will no longer apply to allergenic extracts with U.S. standards of potency. Several manufacturers have for some time been submitting antigen E stability data to the Bureau of Biologics, FDA. The Bureau also has been developing its own data. FDA has evaluated these available data and finds that they are satisfactory to establish interim dating periods, pending completion of stability studies, for the different forms (glycerinated, nonglycerinated, freeze-dried) and antigen E concentrations of short ragweed pollen extracts. Therefore, in lieu of interim expiration dating based on § 610.53(a), FDA will furnish to each licensed manufacturer of allergenic extracts a summary of the available antigen E stability data and the dating periods supported by these data. On or after January 27, 1982, manufacturers must label their short ragweed pollen extracts or mixed extracts that include short ragweed pollen extract as a component with the expiration date supported by the stability data that will be furnished by the Bureau.

FDA will consider any manufacturer who labels its products with the expiration dates based on the stability data as being in compliance with §§ 211.137 and 211.166 if the manufacturer has an approved stability study underway to verify that the stability of its specific product is consistent with the furnished data. This policy in no way precludes a manufacturer from submitting its own stability data, in the form of an amendment to the license application, for a different dating period for a specific extract. FDA advises that this policy has no effect on the minimum quantity of antigen E required in each lot of extract or the lot release requirements for short ragweed pollen extract that become effective on January 27, 1982.

The economic impact of this rule has been assessed in accordance with Executive Order 12291. It has been determined that the rule is not a major rule as defined by that Order. Specifically, this rule exempts allergenic extracts that are labeled "No U.S. Standard of Potency" from the expiration dating and stability testing requirements of the CGMP regulations.