and banks involved, the effects of the proposal on competition, and the convenience and needs of the communities to be served by the companies and banks involved. If a public meeting is requested, the protest should indicate that there are members of the public who wish to speak on the issues in a public forum.

(iii) The protest will be transmitted by the Reserve Bank to the applicant, and the applicant will generally be allowed eight business days to respond in writing to the protest.

(2) *Arranging the Public Meeting.* Public meetings will be arranged and presided over by a representative of the Federal Reserve System ("Presiding Officer"). In determining the time and place for the public meeting, such factors as convenience to the parties, the number of people expected to attend the meeting, access to public transportation and possible after-hour security problems will be taken into account.

(3) *Conducting the Public Meeting.* Prior to the meeting, all necessary steps will be taken to ensure that the meeting is conducted appropriately, including scheduling of witnesses, submission of written materials and other arrangements. In conducting the public meeting the Presiding Officer will have the authority and discretion to ensure that the meeting proceeds in a fair and orderly manner. Generally, the public meeting will consist of opening and closing remarks by the Presiding Officer, a presentation by the protestant and a presentation by the applicant. An official transcript will be made of the proceedings and entered into the record. The conclusion of the public meeting normally marks the close of the public portion of the record on the application.

(4) *Notification of Board decision on the application.* After a decision is made on the application, and the applicant is notified of the decision, staff will notify the protestant by telephone. This notification will be confirmed promptly in writing. As set forth in § 262.3(k) of the Board's Rules of Procedure (12 CFR 262.3(k)) or § 265.3 of the Board's Rules Regarding Delegation of Authority (12 CFR 265.3), a party to the application may request reconsideration of the Board's order, or review of the Reserve Bank's decision.

PART 265—[AMENDED]

2. Pursuant to its authority under section 11(k) of the Federal Reserve Act (12 U.S.C. 248(k)) and section 5(b) of the Bank Holding Company Act (12 U.S.C. 1844(b)) the Board of Governors is amending 12 CFR Part 265 (Rules Regarding Delegation of Authority) effective January 31, 1984 by revising (b)(10) of § 265.2 to read as follows:

§ 265.2 Specific functions delegated to Board employees and to Federal Reserve Banks.

* * * * *

(b) * * *

(10) Pursuant to the provisions of section 265.25 of this chapter (Rules of Procedure) after consultation with the directors of other interested Divisions of the Board and the appropriate Reserve Bank, to order, under such terms and conditions as the General Counsel deems appropriate, that a public meeting or other proceeding be held in connection with any application or notice filed with the Board and to designate the presiding officer in any such proceeding.

* * * * *

3. Pursuant to its authority under sections 3(a), 4(c)(8) and 5(b) of the Bank Holding Company Act, 12 U.S.C. 1842(a), 1843(c)(8) and 1844(b); and section 18(c) of the Federal Deposit Insurance Act (12 U.S.C. 1828(c)) and sections 9 and 11(i) of the Federal Reserve Act (12 U.S.C. 321 and 248(i)), the Board is amending 12 CFR Part 262 (Rules of Procedure) effective January 31, 1984.

PART 262—RULES OF PROCEDURE

In Part 262, § 262.3 is amended by revising the first five sentences in paragraph (e) as follows:

§ 262.3 Applications.

* * * * *

(e) * * * The Board is only required to consider a comment or a request for a hearing with respect to an application or notice if it is in writing and received by the Secretary of the Board or the appropriate Federal Reserve Bank on or before the latest date prescribed in any notice with respect to the application or notice, or where no such date is prescribed, on or before the 30th day after the date notice is first published. Similarly, the Board will consider comments on an application from the Attorney General or a banking supervisory authority to which notification of receipt of an application has been given, only if such comment is received by the Secretary of the Board within 30 days of the date of the letter giving such notification. Any comment on an application or notice that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing. In every case where a timely comment or request for hearing is received as provided herein, a copy of such comment or request shall be forwarded promptly to the applicant for its response. The Board will consider the applicant's response only if it is in writing and sent to the Secretary of the Board on or before eight business days after the date of the letter by which it is forwarded to the applicant. * * *

By order of the Board of Governors, effective January 31, 1984.

William W. Wiles,

Secretary of the Board.

[FR Doc. 84-3065 Filed 2-13-84; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 24

[T.D. 84-42]

Customs Regulations Amendment Relating to Acceptance of Uncertified Checks From Customhouse Brokers

AGENCY: U.S. Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: The Customs Regulations provide that an uncertified check drawn by an interested party shall be accepted by Customs for the payment of duty provided certain conditions are met. An uncertified check, drawn by a customhouse broker (broker) licensed in a district where an entry for merchandise is filed on behalf of an importer, shall be accepted by Customs for the deposit of estimated duties. This document amends the regulations to provide that a broker, not licensed in the district where an entry is filed, also is an interested party for the purpose of acceptance of such broker's own uncertified check for the deposit of estimated duties for the entry transactions on behalf of an importer, provided the broker has on file a power of attorney which is unconditioned geographically for the performance of ministerial acts. Customs may look to the principal (importer) or to the surety should the check be dishonored. The purpose of this amendment is to relieve brokers of the unnecessary burden of requiring them to submit certified checks.

EFFECTIVE DATE: March 15, 1984.

FOR FURTHER INFORMATION CONTACT: Jerry Laderberg, Entry, Licensing and Restricted Merchandise Branch, U.S. Customs Service, 1301 Constitution

Avenue, NW., Washington, D.C. 20229, (202–566–5765).

SUPPLEMENTARY INFORMATION:

Background

Section 141.1(b), Customs Regulations (19 CFR 141.1(b)), provides, in part, that the liability for duties, both regular and additional, attaching on importation constitutes a personal debt due from the importer to the United States. An "importer," as defined in § 101.1(k), Customs Regulations (19 CFR 101.1(k)), means the person primarily liable for the payment of any duties or an authorized agent acting on his behalf.

Section 111.1(b), Customs Regulations (19 CFR 111.1(b)), defines customhouse broker to mean a person who is licensed under Part 111 to transact Customs business on behalf of others.

Pursuant to § 111.2, Customs Regulations (19 CFR 111.2), a broker must obtain a separate license to transact the business of a broker, for each Customs district in which he desires to conduct business.

Section 24.1(a)(3), Customs Regulations (19 CFR 24.1(a)(3)), which relates to the collection of Customs duties, taxes, and other charges provides that an uncertified check drawn by an interested party on a national or state bank or trust company of the United States, shall be accepted by Customs if the check is acceptable for deposit by a Federal Reserve bank, branch Federal Reserve bank, or other designated depository. Further, an uncertified check can be accepted only if there is on file with the district director an entry bond or other bond to secure the payment of the duties, taxes, or other charges, or if a bond has not been filed, the organization or individual drawing and tendering the uncertified check has been approved by the district director to make payment in this manner. Section 24.1(a)(3) also provides that in determining whether an uncertified check shall be accepted in the absence of a bond, the district director shall use available credit data obtainable without cost to the Government, such as that furnished by banks, local business firms, better business bureaus, or local credit exchanges, sufficient to satisfy him of the credit standing or reliability of the drawer of the check.

Under this regulation, an uncertified check, drawn by a broker licensed in a district where an entry for merchandise is filed on behalf of an importer, shall be accepted by Customs for deposit of estimated duties. However, a question has been raised as to whether a broker, tendering an uncertified check to Customs for deposit of estimated duties for entries filed by another broker on behalf of an importer in a district in which the tendering broker is not licensed, is an authorized agent of the importer and therefore, an interested party for the purpose of the acceptance of the payment by Customs.

In a ruling dated March 11, 1982, Customs held that a broker not licensed in a district where an entry is filed is an authorized agent of the importer for the purpose of acceptance of the broker's uncertified check for the deposit of estimated duties for entry transactions made by another broker on behalf of the importer if the unlicensed broker holds a power of attorney from the importer which is unconditioned geographically for the performance of ministerial acts.

Traditionally, most powers of attorney are limited geographically to particular districts, districts in which the importer is importing merchandise. In order to allow a broker to tender an uncertified check in districts in which he is not qualified, an unlimited power of attorney from the client-importer is necessary.

This ruling relieves a broker of an unnecessary burden in that the broker, not licensed in a district in which his client may file an entry, would no longer always be required to obtain a certified check for the payment of duties.

Customs believes it is necessary to incorporate the holding of this ruling into section 24.1 to assure uniformity of application by district directors and better inform brokers and broker associations of this practice.

In this regard, on May 16, 1983, Customs published a document in the **Federal Register** (48 FR 21965) proposing to amend § 24.1(a)(3) to provide that a broker, not licensed in the district where an entry is filed, is an interested party for the purpose of acceptance of such broker's own uncertified check for the deposit of estimated duties for entry transactions provided the broker has on file the necessary power of attorney which is unconditioned geographically for the performance of ministerial acts. Customs may look to the principal (importer) or to the surety should the check be dishonored.

Commenters had until July 15, 1983, to submit comments. After considering the comments received in response to the proposal and further review of the matter, Customs has determined to adopt the final rule, as proposed.

Discussion of Comments

One commenter supports the proposal because it will ease the handling of shipments for all parties involved in the importation of merchandise.

Another commenter suggests that there is no need to implement the proposal now in light of Customs proposal relating to the revised bond structure. Customs does not believe we should wait for the bond proposal to be implemented, but should proceed with the uncertified check proposal now.

A third commenter notes that Customs would have difficulty in verifying if a broker were licensed in another district or had a power of attorney for the importer. Customs recognizes this but believes the party tendering the uncertified check should be required to verify to a Customs field office that he is qualified.

One commenter believes that adoption of the proposal would authorize a broker to transact Customs business in a district without a license. Customs considered this point but rejected this argument in its ruling of March 11, 1982.

This commenter also suggests that the district director should have the authority to require certified checks (rather than uncertified checks) to be filed when deemed necessary, such as when uncertified checks deposited by a broker have been returned unpaid.

Customs believes this comment has merit. The regulations provide that an uncertified check shall be accepted if there is on file with the district director a bond to secure payment of the duty or if a bond has not been filed, the organization or individual drawing and tendering the uncertified check has been approved by the district director to make payment in such matter. However, the mandatory nature of Customs acceptance of uncertified checks is beyond the scope of this document. Customs will consider this aspect in a separate document.

One commenter supports the proposal but is opposed to the idea that the broker must have an unlimited power of attorney from a client to have uncertified checks accepted in a district in which he is not licensed.

Customs disagrees. As noted above, most powers of attorney are limited geographically to particular districts. To allow a broker to tender an uncertified check in districts in which he is not qualified, an unlimited power of attorney from the client-importer is necessary.

Executive Order 12291

This document does not meet the criteria for a "major rule" as specified in section 1(b) of E.O. 12291. Accordingly, no regulatory impact analysis has been prepared.

Regulatory Flexibility Act

Pursuant to the provisions of section 605(b) of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601 *et seq.*), it is hereby certified that the regulations set forth in this document will not have a significant economic impact on a substantial number of small entities. Accordingly, it is not subject to the regulatory analysis or other requirements of 5 U.S.C. 604.

Drafting Information

The principal author of this document was Charles D. Ressin, Regulations Control Branch, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Part 24

Customs duties and inspection, Imports, Accounting.

Amendments to the Regulations

Section 24.1(a)(3), Customs Regulations (19 CFR 24.1(a)(3)), is amended as set forth below.

Approved: January 24, 1984.

Alfred R. De Angelus,

Acting Commissioner of Customs.

John M. Walker, Jr.,

Assistant Secretary of the Treasury.

PART 24—CUSTOMS FINANCIAL AND ACCOUNTING PROCEDURE

Section 24.1(a)(3), Customs Regulations (19 CFR 24.1(a)(3)), is amended by adding a new sentence at the end of the paragraph to read as follows:

§ 24.1 Collection of Customs duties, taxes, and other charges.

(a) * * *

(3) * * * For purposes of this paragraph, a customhouse broker, not licensed in the district where an entry is filed, is an interested party for the purpose of Customs acceptance of such broker's own check, provided the broker has on file the necessary power of attorney which is unconditioned geographically for the performance of ministerial acts. Customs may look to the principal (importer) or to the surety should the check be dishonored.

* * * * *

(R.S. 251, as amended (19 U.S.C. 66), sec. 1, 19 Stat. 247 249 (19 U.S.C. 197); sec. 1, 36 Stat. 965 (19 U.S.C. 198), sec. 624, 46 Stat. 759 (19 U.S.C. 1624), sec. 641, 46 Stat. 759, as amended (19 U.S.C. 1641), sec. 648, 46 Stat. 762 (19 U.S.C. 1648))

[FR Doc. 84–3967 Filed 2–13–84; 8:45 am]

BILLING CODE 4820–02–M

19 CFR Part 24

[T.D. 84–41]

Interim Customs Regulations Amendment Regarding Collection of Medicare Compensation Costs

AGENCY: U.S. Customs Service, Treasury.

ACTION: Interim regulations.

SUMMARY: This document amends the Customs Regulations on an interim basis to allow Customs to include in charges assessed to parties-in-interest for reimbursable services provided by Customs officers, Medicare compensation costs equal to 1.3 percent of the assessed amount. The inclusion of these costs in assessed charges will result in at least partial recovery of Customs' cost of matching employees' statutorily mandated contribution for Medicare coverage. The estimated recovery of Medicare costs by Customs is approximately $500,000 annually.

EFFECTIVE DATE: April 16, 1984.

Comments: This regulation is being published on an interim basis, April 16, 1984. However, written comments received before April 16, 1984 will be considered in determining whether any changes to the regulation are required before a permanent rule is published.

FOR FURTHER INFORMATION CONTACT: James Kenny, Headquarters Accounting Division, (202–566–2021), U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229.

SUPPLEMENTARY INFORMATION:

Background

Various statutes provide Customs with the administrative authority to charge fees to recover the costs of a particular service rendered. For example, 19 U.S.C. 58a provides that the Secretary of the Treasury may charge such fees as may be necessary to recover the costs of providing certain vessel services. The fees are to be consistent with the User Charge Statute (31 U.S.C. 9701). Section 4.98(a), Customs Regulations (19 CFR 4.98(a)), sets forth the specific services and bases for calculating each flat fee. Similarly, Customs charges and bills parties-in-interest for reimbursement in connection with services rendered by Customs officers or employees during regular hours (see section 24.17, Customs Regulations (19 CFR 24.17)), or on Customs overtime assignments under 19 U.S.C. 267 or 1451 (see § 24.16, Customs Regulations (19 CFR 24.16)). The bills cover full compensation and/or travel and subsistence of the Customs officer performing the service.

The User Charge Statute provides that each service or thing of value provided by an agency to a person is to be self-sustaining to the extent possible. The head of an agency may prescribe regulations establishing the charge for a service or thing of value provided by the agency. Regulations so prescribed are subject to policies prescribed by the President and shall be as uniform as practicable. Each charge shall be fair and based on the costs to the Government, the value of the service or thing to the recipient, public policy or interest served, and other relevant facts. The statute does not affect a law prohibiting the determination and collection of charges and the disposition of those charges, and prescribing bases for determining charges, but a charge may be redetermined under the statute consistent with the prescribed bases.

Congress, by passage of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97–248, Sept. 3, 1982, 96 Stat. 324), extended Medicare coverage to federal employees not otherwise subject to Social Security withholding taxes. As a result of the legislation, 1.3 percent of a federal employee's wages are withheld for Social Security and that amount is matched by the Government. Both regular and overtime wages are subject to the withholding tax. Customs is currently making the matching payments for the 1.3 percent Medicare compensation program for salaries paid Customs employees for reimbursable services they provide for parties-in-interest. It is estimated that the Customs share of these payments amounts to approximately $500,000 annually.

Although the Tax Equity and Fiscal Responsibility Act does not provide specific language providing for reimbursement of the 1.3 percent amount by parties-in-interest, Customs is of the opinion that authority to collect such monies is provided by title 31, United States Code, section 9701 (User Charge Statute), and title 19, United States Code, sections 267 and 1451 (Customs overtime provisions). Further, passing such charges on to those who actually benefit from the services provided would be in keeping with the Administration's policy in this regard.

Comments

Before adopting the regulation as a permanent rule, consideration will be given to any written comments timely submitted to the Commissioner of Customs. Comments submitted will be available for public inspection in accordance with section 103.11(b), Customs Regulations (19 CFR 103.11(b)), on normal business days between the

hours of 9:00 a.m. to 4:30 p.m. at the Regulations Control Branch, Customs Service Headquarters, Room 2426, 1301 Constitution Avenue, NW., Washington, D.C. 20229.

Inapplicability of Notice Provision

Because of the on-going loss of revenue caused by the current inability to collect these monies from parties-in-interest, it has been determined that, pursuant to 5 U.S.C. 553(b)(3)(B), notice and public procedure are inapplicable and unnecessary.

E.O. 12291 and Regulatory Flexibility Act

Inasmuch as Customs does not believe that the amendment meets the criteria for a "major rule" within the meaning of section 1(b) of E.O. 12291, a regulatory impact analysis has not been prepared.

Pursuant to the provisions of section 5 of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601 *et seq.*), it is hereby certified that the regulation will not have a significant economic impact on a substantial number of small entities within the meaning of the Act. Accordingly, the amendment is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Drafting Information

The principal author of this document was Larry L. Burton, Regulations Control Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Part 24

Accounting, Claims, Customs duties and inspection, Imports, Taxes, Wages.

Amendment to the Regulations

PART 24—[AMENDED]

Section 24.17, Customs Regulations (19 CFR 24.17), is amended by adding a new paragraph (f), as set forth below:

§ 24.17 Other services of officers; reimbursable.

* * * * *

(f) *Medicare Compensation Costs.* In addition to other expenses and compensation chargeable to parties-in-interest as set forth in this section, such persons shall also be required to reimburse Customs in the amount of 1.3 percent of the reimbursable compensation expenses incurred. Such payment will reimburse Customs for its share of Medicare costs.

(Pub. L. 97–248, Sept. 3, 1982, 96 Stat. 324; 31 U.S.C.) 9701 (19 U.S.C. 267 and 1451))

Robert P. Schaffer,

Acting Commissioner of Customs.

Approved: January 24, 1984.

John M. Walker, Jr.,

Assistant Secretary of the Treasury.

[FR Doc. 84–3966 Filed 2–13–84; 8:45 am]

BILLING CODE 4820–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 102, 114, 122, 170, 180, 184, and 186

[Docket No. 83N–0334]

Incorporation by Reference; Updating of Text

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulatory text pertaining to materials incorporated by reference in those parts of Title 21 of the Code of Federal Regulations concerned with food and its labeling. This action is being taken to meet the requirements for incorporation by reference set forth in Title 1 of the Code of Federal Regulations (1 CFR Part 51).

DATES: Effective February 14, 1984. Comments by March 15, 1984.

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

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: Title 1 of the Code of Federal Regulations (1 CFR Part 51) requires the filing and updating of material that has been incorporated by reference in the Code of Federal Regulations. The purpose of this requirement is to ensure the public availability and accuracy of material that has been incorporated from other sources.

Accordingly, FDA has reviewed the regulations concerned with food and its labeling (21 CFR Parts 100–199) that include materials incorporated by reference. The agency has concluded that it is necessary to amend a number of these regulations to bring them into compliance with the requirements prescribed in 1 CFR Part 51.

Many of the incorporated materials consist of methods or specifications that were published in compendia such as the Food Chemicals Codex or the Official Methods of Analysis of the Association of Official Analytical Chemists. In many cases, although this material has not been modified in the compendium, the volume of the compendium cited when a regulation was established has been superseded by a subsequent volume. In addition, many of the individual methods have been superseded by updated versions of the methods, which, though updated, do not represent a substantial change in the method. Because the agency believes that in such cases the most recently published method or compendia should be cited in the incorporating regulatory text, it is thus providing this information and making some minor editorial changes in the affected regulations.

In accordance with 5 U.S.C. 553 (b) and (d) and 21 CFR 10.40, FDA has determined that there is good cause not to follow the usual requirements of prior notice and comment and delayed effective date. The reason for this determination is that the changes in the materials that are being incorporated by reference are not substantive. The agency, nevertheless, is providing a 30-day period during which it will accept comments on the changes it is adopting in this final rule. If FDA decides on the basis of comments received that the changes should be modified or revoked, it will provide further notice in the **Federal Register.**

The agency has determined pursuant to 21 CFR 25.24(b)(22) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

FDA has considered the effect that this final rule would have on small entities, including small businesses, consistent with the objectives of the Regulatory Flexibility Act. The agency has determined that the effect of this proposal will be to improve the availability of the materials incorporated, while not significantly affecting their content or other factors affecting their use. Therefore, FDA certifies that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has determined that this final rule will not be a major rule as defined by the Order.

List of subjects

21 CFR Part 101

Food labeling, Misbranding, Nutrition labeling, Warning statements.

21 CFR Part 102

Common or usual name, Food labeling.

21 CFR Part 114

Acidified foods, Good manufacturing practices.

21 CFR Part 122

Fish, Good manufacturing practices, Smoked fish.

21 CFR Part 170

Food additives.

21 CFR Part 180

Food additives, Interim listed food additives.

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients.

21 CFR Part 186

Food ingredients, Generally recognized as safe (GRAS) food ingredients, Indirect food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Title 21 of the Code of Federal Regulations is amended as follows:.

PART 101—FOOD LABELING

1. Part 101 is amended:

a. In § 101.9 by revising the second and third sentences in paragraph (c)(4), to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(4) * * * Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference, except when the official procedure for a specific food requires another factor. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

* * * * *

b. In § 101.25 by revising the fifth and sixth sentences in paragraph (e)(3), to read as follows:

§ 101.25 Labeling of foods in relation to fat and fatty acid and cholesterol content.

* * * * *

(e) * * *

(3) * * * The determination of *cis, cis*-methylene-interrupted polyunsaturated fatty acids will be by the method prescribed in the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), §§ 28.071–28.074, which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

* * * * *

PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

2. Part 102 is amended in § 102.23 by revising paragraph (c) (1), (2), (3), (4), (6), (7), (8), and (9), to read as follows:

§ 102.23 Peanut spreads.

* * * * *

(c) * * *

(1) Protein quantity: "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC), 13th Ed. (1980), using the method described in section 27.007, which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(2) Biological quality of protein: AOAC, 13th Ed. (1980), using the method described in sections 43.212–43.216, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(3) Niacin: AOAC, 13th Ed. (1980), using the method described in sections 43.044–43.046, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(4) Vitamin B_6: AOAC, 13th Ed. (1980), using the method described in sections 43.188–43.193, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

* * * * *

(6) Iron: AOAC, 13th Ed. (1980), using the method described in sections 43.217–43.219, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(7) Zinc: AOAC, 13th Ed. (1980), using the method described in sections 25.150–25.153, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(8) Copper: AOAC, 13th Ed. (1980), using the method described in sections 25.038–25.043, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

(9) Magnesium: AOAC, 13th Ed. (1980), using the method described in sections 2.109–2.113, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (c)(1) of this section.

PART 114—ACIDIFIED FOODS

3. Part 114 is amended in § 114.90 by revising the first and second sentences in paragraph (a)(4)(ii), by revising the fifth sentence in paragraph (a)(4)(iv), by revising the fourth sentence in paragraph (a)(4)(v), and by revising paragraph (c), to read as follows:

§ 114.90 Methodology.

(a) * * *

(4) * * *

(ii) Standardize the instrument and electrodes with commercially prepared standard 4.0 pH buffer or with freshly prepared 0.05 molar potassium acid phthalate buffer solution prepared as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC), 13th Ed. (1980), section 50.007(c), under "Buffer Solutions for Calibration of pH Equipment—Official Final Action," which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

(iv) * * * To check the operation of the pH meter, check the pH reading using another standard buffer such as one having a pH of 7.0, or check it with freshly prepared 0.025 molar phosphate solution prepared as outlined in the AOAC, 13th Ed. (1980), section 50.007(e), which is incorporated by reference * * *.

(v) * * * Electrodes should be rinsed with water, then blotted and immersed in a pH 9.18 borax buffer prepared as

outlined in the AOAC, 13th Ed. (1980), section 50.007(f), which is incorporated by reference.

* * * * *

(c) *Titratable acidity.* Acceptable methods for determining titratable acidity are described in the AOAC, 13th Ed. (1980), section 22.060, under "Titratable Acidity—Official Final Action," for "Indicator Method," and section 22.061 for "Glass Electrode Method—Official Final Action," which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(4)(ii) of this section. The procedure for preparing and standardizing the sodium hydroxide solution is described in the AOAC, 13th Ed. (1980), sections 50.032–50.035, under "Sodium Hydroxide—Official Final Action" by the "Standard Potassium Hydroxide Phthalate Method," which is also incorporated by reference and available as set forth in paragraph (a)(4)(ii) of this section.

PART 122—SMOKED AND SMOKE-FLAVORED FISH

4. Part 122 is amended in § 122.3 by revising paragraph (d), to read as follows:

§ 122.3 Definitions

* * * * *

(d) "Water phase salt" means the percent salt (sodium chloride) in the finished product as determined by the method described in "Official Methods of Analysis of the Association of Official Analytical Chemists" (AOAC), 13th Ed. (1980), sections 18.034 and 18.035, under "Volumetric Method—Official Final Action," which is incorporated by reference, multiplied by 100 and divided by the percent salt (sodium chloride) plus the percent moisture in the finished product as determined by the method described in the AOAC, 13th Ed. (1980), section 18.023, under "Total Solids for all Marine Products, Except Raw Oysters—Official Final Action." Copies of the material incorporated by reference may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

PART 170—FOOD ADDITIVES

5. Part 170 is amended in § 170.30 by revising paragraph (h)(1), to read as follows:

§ 170.30 Eligibility for classification as generally recognized as safe (GRAS).

* * * * *

(h) * * *

(1) It complies with any applicable food grade specifications of the Food Chemicals Codex, 2d Ed. (1972), or, if specifically indicated in the GRAS affirmation regulation, the Food Chemicals Codex, 3d Ed. (1981), which are incorporated by reference, except that any substance used as a component of articles that contact food and affirmed as GRAS in § 186.1 of this chapter shall comply with the specifications therein, or in the absence of such specifications, shall be of a purity suitable for its intended use. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL STUDY

6. Part 180 is amended as follows:

a. In § 180.25 by revising paragraph (b), to read as follows:

§ 180.25 Mannitol.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 188–190, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

b. In § 180.30 by revising paragraph (a), to read as follows:

§ 180.30 Brominated vegetable oil.

* * * * *

(a) The additive complies with specifications prescribed in the "Food Chemicals Codex," 3d Ed. (1981), pp. 40–41, which is incorporated by reference, except that free fatty acids (as oleic) shall not exceed 2.5 percent and iodine value shall not exceed 16. Copies of the material incorporated by reference may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St NW., Washington, DC 20418.

* * * * *

c. In § 180.37 by revising paragraph (b), to read as follows:

§ 180.37 Saccharin, ammonium saccharin, calcium saccharin, and sodium saccharin.

* * * * *

(b) The food additives meet the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 22, 62, 266–267, 297–299, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

7. Part 184 is amended as follows:

a. In § 184.1007 by revising paragraph (b) (1), (6), and (7) to read as follows:

§ 184.1007 Aconitic acid.

* * * * *

(b) * * *

(1) *Assay.* Not less than 98.0 percent of $C_3H_3(COOH)_3$, using the "Food Chemicals Codex," 3d Ed. (1981), pp. 86–87, test for citric acid, which is incorporated by reference, and a molecular weight of 174.11. Copies of the material incorporated by reference may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

(6) *Readily carbonizable substances.* Passes "Food Chemicals Codex," 3d Ed. (1981), pp. 86–87, test for citric acid, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

(7) *Residue on ignition.* Not more than 0.1 percent as determined by "Food Chemicals Codex," 3d Ed. (1981), pp. 86–87, test for citric acid, which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

* * * * *

b. In § 184.1021 by revising paragraph (b), to read as follows:

§ 184.1021 Benzoic acid.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 35, which is incorporated by reference. Copies may

be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

* * * * *

c. In § 184.1025 by revising paragraph (b), to read as follows:

§ 184.1025 Caprylic acid.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 207, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

* * * * *

d. In § 184.1069 by revising paragraph (b), to read as follows:

§ 184.1069 Malic acid.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 183-184, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

* * * * *

e. In § 184.1091 by revising paragraph (b), to read as follows:

§ 184.1091 Succinic acid.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 314–315, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, D.C. 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, D.C. 20408.

* * * * *

f. In § 184.1095 by revising paragraph (b), to read as follows:

§ 184.1095 Sulfuric acid.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 317–318, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

g. In § 184.1115 by revising paragraph (b), to read as follows:

§ 184.1115 Agar-agar.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 11, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

h. In § 184.1143 by revising paragraph (b), to read as follows:

§ 184.1143 Ammonium sulfate.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 22–23, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

i. In § 184.1206 by revising paragraph (b), to read as follows:

§ 184.1206 Calcium iodate.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 53, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

j. In § 184.1230 by revising paragraph (b), to read as follows:

§ 184.1230 Calcium sulfate.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 66, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

k. In § 184.1257 by revising the first and second sentences in the introductory text of paragraph (b) and by revising paragraph (b)(1), to read as follows:

§ 184.1257 Clove and its derivatives.

* * * * *

(b) Clove bud oil, clove leaf oil, clove stem oil, and eugenol meet the specifications of the "Food Chemicals Codex," (FCC), 3d Ed. (1981), pp. 87–89, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

(1) The assay for phenols, as eugenol, by the FCC test, 3d Ed. (pp. 87–88), or the volatile oils content by the FCC test, 3d Ed. (pp. 87–88) should conform to the representation of the vendor;

* * * * *

l. In § 184.1259 by revising paragraph (b)(3) and by revising the first and second sentences in paragraph (b)(6), to read as follows:

§ 184.1259 Cocoa butter substitute from palm oil.

* * * * *

(b) * * *

(3) Heavy metals (as lead), 10 parts per million maximum ("Food Chemicals Codex," 3d Ed. (1981), pp. 512–513, which is incorporated by reference, copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408).

* * * * *

(6) Residual catalyst ("Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), sections 25.049–25.055, which is incorporated by reference), residual fluorine; limit of detection 0.2 part per million F; multiply fluoride result by 2.63 to convert to residual catalyst. Copies of the material incorporated by reference may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

m. In § 184.1271 by revising paragraph (b), to read as follows:

§ 184.1271 L-Cysteine.

* * * * *

(b) The ingredient meets the appropriate part of the specification set forth in the "Food Chemicals Codex," 3d Ed. (1981), pp. 92–93, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

n. In § 184.1272 by revising paragraph (b), to read as follows:

§ 184.1272 L-Cysteine monohydrochloride.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 92–93, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

o. In § 184.1282 by revising paragraph (b), to read as follows:

§ 184.1282 Dill and its derivatives.

* * * * *

(b) Dill oils meet the description and specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 100–102, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

p. In § 184.1293 by revising paragraph (b), to read as follows:

§ 184.1293 Ethyl alcohol.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 112–113, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

q. In § 184.1295 by revising paragraph (b), to read as follows:

§ 184.1295 Ethyl formate.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 376, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

r. In § 184.1317 by revising paragraph (b), to read as follows:

§ 184.1317 Garlic and its derivatives.

* * * * *

(b) Garlic oil meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 132, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

s. In § 184.1330 by revising paragraph (b), to read as follows:

§ 184.1330 Acacia (gum arabic).

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 7, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

t. In § 184.1333 by revising the first sentence in paragraph (b)(4), to read as follows:

§ 184.1333 Gum ghatti.

* * * * *

(b) * * *

(4) *Identification test.* Add 0.2 ml of diluted lead acetate as outlined in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), section 31.178(b), p. 529, under "Dilute Basic Lead Acetate Standard Solution," which is incorporated by reference (copies are available from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408), to 5 ml of a cold 1-in-100 aqueous solution of the gum.

* * * * *

u. In § 184.1339 by revising paragraph (b), to read as follows:

§ 184.1339 Guar gum.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 141, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

v. In § 184.1343 by revising paragraph (b), to read as follows:

§ 184.1343 Locust (carob) bean gum.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 174–175, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

w. In § 184.1349 by revising paragraph (b), to read as follows:

§ 184.1349 Karaya gum (sterculia gum).

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 157, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

x. In § 184.1351 by revising paragraph (b), to read as follows:

§ 184.1351 Gum tragacanth.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 337, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

y. In § 184.1490 by revising paragraph (b), to read as follows:

§ 184.1490 Methylparaben.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 199, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW.,

Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

z. In § 184.1555 by revising paragraph (b)(2), to read as follows:

§ 184.1555 Rapeseed oil.

* * * * *

(b) * * *

(2) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 201, relating to mono- and diglycerides, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408. An additional specification requires the iodine number to be 4 or less.

* * * * *

aa. In § 184.1634 by revising paragraph (b), to read as follows:

§ 184.1634 Potassium iodide.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 246–247, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

bb. In § 184.1635 by revising paragraph (b), to read as follows:

§ 184.1635 Potassium iodate.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 245–246, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

cc. In § 184.1643 by revising paragraph (b), to read as follows:

§ 184.1643 Potassium sulfate.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 252, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Fderal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

dd. In § 184.1660 by revising paragraph (b), to read as follows:

§ 184.1660 Propyl gallate.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 257–258, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

ee. In § 184.1670 by revising paragraph (b), to read as follows:

§ 184.1670 Propylparaben.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 258, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

ff. In § 184.1699 by revising paragraph (b), to read as follows:

§ 184.1699 Oil of rue.

* * * * *

(b) Oil of rue meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 266, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

gg. In § 184.1733 by revising paragraph (b), to read as follows:

§ 184.1733 Sodium benzoate.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 278, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

hh. In § 184.1807 by revising paragraph (b), to read as follows:

§ 184.1807 Sodium thiosulfate.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 304, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

ii. In § 184.1835 by revising paragraph (b), to read as follows:

§ 184.1835 Sorbitol.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 308, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

jj. In § 184.1973 by revising paragraph (b), to read as follows:

§ 184.1973 Beeswax (yellow and white).

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 34–35, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

8. Part 186 is amended as follows:

a. In § 186.1025 by revising paragraph (b), to read as follows:

§ 186.1025 Caprylic acid.

* * * * *

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), p. 207, which is incorporated by reference. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

b. In § 186.1551 by revising the first sentence in paragraph (b), to read as follows:

§ 186.1551 Hydrogenated fish oil.

* * * * *

(b) Hydrogenation of fish oils results in a final product with a melting point greater than 32° C as determined by Section Cc 1–25, Official and Tentative Methods of the American Oil Chemists' Society method (reapproved 1973) or equivalent.

* * * * *

Interested persons may, on or before March 15, 1984, submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation is effective February 14, 1984.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: January 23, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84–3916 Filed 2–13–84; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Cythioate Oral Liquid and Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two new animal drug applications (NADA's) filed by Bayvet Division of Miles Laboratories, Inc., providing for use of cythioate oral liquid and tablets for oral treatment of dogs for control of fleas, and to codify existing approvals for identical products held by American Cyanamid.

EFFECTIVE DATE: February 14, 1984.

FOR FURTHER INFORMATION CONTACT: Bob G. Griffith, Bureau of Veterinary Medicine (HFV–112), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3430.

SUPPLEMENTARY INFORMATION: Bayvet Division of Miles Laboratories, Inc., P.O. Box 390, Shawnee Mission, KS 66201, filed NADA 132–336 for Proban (cythioate) Oral Liquid and NADA 132–337 for Proban (cythioate) Tablets. The drug is for oral use in dogs for control of fleas. The products are identical to those approved in NADA's 33–606 and 33–342, sponsored by American Cyanamid Co. Although Bayvet is and has been an approved alternate manufacturer and distributor under American Cyanamid's NADA's, Bayvet is now sponsoring its own NADA's for the products. American Cyanamid Co. has authorized use of the data and information in its NADA's to support approval of Bayvet's NADA's. The NADA's are approved and the regulations are amended accordingly.

Approval of these NADA's is based on the initial approvals of Cyanamid's NADA's on June 3, 1968. It does not change the approved use of the drug and will not increase use of the drug. Although these approvals are not of supplemental NADA's, they are equivalent to Category I supplemental NADA approvals, which do not require reevaluation of the safety and effectiveness data and information in the parent application (42 FR 63467; December 23, 1977). For the purpose of action on this application, FDA did not rereview data in the Cyanamid NADA's, and these approvals do not imply reaffirmation of those data to support the safe and effective use of either the Cyanamid or Bayvet products.

Cyanamid's approved NADA's, and Bayvet's NADA's that are now being approved, provide for the use of Proban only on the prescription or other order of a licensed veterinarian. In 1976, American Cyanamid filed a supplement to NADA 33–606 to obtain FDA approval for over-the-counter (OTC) marketing of Proban, directly to consumers. FDA's Bureau of Veterinary Medicine (the Bureau) concluded that the supplemental application should be denied because, in part, American Cyanamid had failed to establish that Proban would be safe for OTC use and that adequate directions could be written for lay use (41 FR 51078, 51084; November 19, 1976). The Bureau also reviewed information supporting the original 1968 approval of Proban as a prescription drug, and concluded that the data failed to demonstrate that Proban is effective for its intended use (45 FR 40236, 40237; June 13, 1980). Under section 512(d) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(d)), Cyanamid requested and was granted a hearing on the Bureau's decision not to approve the supplemental NADA (45 FR 42036; June 13, 1980). In his initial decision of June 16, 1981, the Administrative Law Judge found that Cyanamid had failed to meet the statutory requirements for approval of the supplemental NADA on the basis of both safety and effectiveness. The Commissioner of Food and Drugs has not yet issued a final agency decision.

The standards for demonstrating that a product is effective for its intended uses are the same regardless of whether the product is for prescription or OTC use. In addition, evidence contained in the hearing record may indicate that the safety data in the original Proban NADA's do not satisfy the requirements of section 512(d)(1) (A), (B), and (D) of the act. Thus, if the ultimate decision on Cyanamid's supplemental NADA for OTC use of Proban results in a conclusion that Proban has not been demonstrated to be safe and/or effective for the control of fleas in dogs, the Bureau may consider action to withdraw approval for NADA's 33–342 and 33–606. Withdrawal of those NADA's would necessarily affect Bayvet's approvals, as Bayvet's approvals depend on data in Cyanamid's NADA's.

Approvals for American Cyanamid's NADA 33–606 for cythioate oral liquid and NADA 33–342 for cythioate tablets are not codified in the Code of Federal Regulations. This document also codifies Cyanamid's original approvals.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs, Oral use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

1. By adding new § 520.530, to read as follows:

§ 520.530 Cythioate oral liquid.

(a) *Specifications.* Each milliliter contains 15 milligrams of cythioate.

(b) *Sponsor.* See Nos. 000859 and 010042 in § 510.600 of this chapter.

(c) *Special considerations.* Cythioate is a cholinesterase inhibitor. Do not use this product in animals simultaneously