Water soluble matter, not more than 3 percent.
Volatile matter, not more than 10 percent.
Total iron (as Fe corrected for volatile matter), not less than 37 percent and not more than 45 percent.

(c) *Uses and restrictions.* Ferric ferrocyanide may be safely used in amounts consistent with good manufacturing practice to color externally applied drugs including those intended for use in the area of the eye.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification requirements of section 706(c) of the act.

§ 73.2299 Ferric ferrocyanide.

(a) *Identity and specifications.* The color additive ferric ferrocyanide shall conform in identity and specifications to the requirements of § 73.1299(a)(1) and (b).

(b) *Uses and restrictions.* Ferric ferrocyanide is safe for use in coloring externally applied cosmetics, including cosmetics applied to the area of the eye, in amounts consistent with good manufacturing practice.

(c) *Labeling.* The color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall bear, in addition to any information required by law, labeling in accordance with § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from certification under section 706(c) of the act.

2. Part 81 is amended:

§ 81.1 [Amended]

a. In § 81.1 *Provisional lists of color additives* by deleting from the table in paragraph (g) the entry for "Ferric ferrocyanide (iron blue)."

b. In § 81.27 by revising the introductory text of paragraph (c), and by revising paragraph (c)(2) to read as follows:

§ 81.27 Conditions of provisional listing of additives.

* * * * *

(c) The closing date for D & C Red No. 6, D & C Red No. 7, and D & C Red No. 30 is postponed until October 31, 1978, while chemistry data and analytical methods to establish specifications are developed and evaluated and subject to compliance with the requirements of this paragraph.

* * * * *

(2) The required chemistry data and analytical methods shall be submitted to the Division of Food and Color Additives, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204, by July 31, 1978, for D & C Red No. 6, D & C Red No. 7, and D & C Red No. 30.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before December 21, 1978, file written objections with the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. Objections should show how the person filing them will be adversely affected by the order, specify with particularity the provisions of the order thought to be objectionable, and state the grounds for each objection. Objections are to be filed in accordance with the requirements of § 71.30 (21 CFR 71.30). If a hearing is requested, the objections must state the issues for the hearing, be supported by grounds factually and legally sufficient to justify the relief sought, and include a detailed description and analysis of the factual information intended to be presented in support of each objection in the event that a hearing is held. Four copies of all documents should be filed. Each document should be identified with the Hearing clerk docket number found in brackets in the heading of this document. Objections may be seen in the Hearing Clerk's office between 9 a.m. and 4 p.m., Monday through Friday.

*Effective date.* December 22, 1978, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing objections or lack thereof will be announced by publication in the FEDERAL REGISTER.

(Sec. 706(b), (c), and (d)); 74 Stat. 399-403 as amended (21 U.S.C. 376(b), (c), and (d)); sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note).)

Dated: November 13, 1978.

JOSEPH P. HILE,
*Associate Commissioner for Regulatory Affairs.*

[FR Doc. 78-32502 Filed 11-20-78; 8:45 am]

[4110-03-M]

[Docket No. 77C-0208]

## PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

### Ferric Ferrocyanide (Iron Blue)

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Commissioner of Food and Drugs on his own initiative is postponing the closing date for provisional listing of ferric ferrocyanide (iron blue) until December 31, 1978, to allow time for publication and comment on a regulation to provide for the safe use of ferric ferrocyanide in externally applied drugs and cosmetics, including those intended for use in the area of the eye.

EFFECTIVE DATE: November 21, 1978.

FOR FURTHER INFORMATION CONTRACT:

Gerad L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: An order published in the FEDERAL REGISTER of August 15, 1978 (43 FR 36061) reinstated ferric ferrocyanide (iron blue) to the provisional list of color additives until November 30, 1978, to provide an opportunity for data to be submitted and reviewed so that specifications could be established for permanent listing of ferric ferrocyanide for use in externally applied drugs and cosmetics, including those intended for use in the area of the eye.

The required data have been submitted and are adequate to establish specification for "permanent" listing of ferric ferrocyanide. Published elsewhere in this issue of the FEDERAL REGISTER is a rule permanently listing ferric ferrocyanide (iron blue) for use in externally applied drugs and cosmetics, including those used in the area of the eye. The provisional listing of ferric ferrocyanide (iron blue) will be terminated when that separate rule becomes effective on December 22, 1978.

Postponement of the closing date until December 31, 1978, is necessary to provide a brief period within which to publish the final order to list ferric ferrocyanide permanently, and to allow a suitable comment period

before the regulation becomes effective. Because of the shortness of time until the November 30, 1978, closing date, the Commissioner concludes that notice and public procedure on this regulation are impractical and contrary to the public interest and that good cause exists for issuing this postponement as a final rule. This postponement will permit uninterrupted use of the color additive until the final order listing the additive permanently becomes effective.

Therefore, under the Color Additive Amendments of 1960 to the Federal Food, Drug, and Cosmetic Act (sec. 203 (a)(2) and (d)(1), Title II, Pub. L. 86-618, 74 Stat. 404-405 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner (21 CFR 5.1), part 81 of the color additive regulations is amended as follows:

§ 81.1 [Amended]

1. In § 81.1 *Provisional lists of color additives,* paragraph (g) is amended by changing the closing date for ferric ferrocyanide (iron blue) to Dec. 31, 1978.

2. In § 81.27 by revising the introductory text of paragraph (c) to read as follows:

**§ 81.27 Conditions of provisional listing of additives.**

* * * * *

(c) The closing date for D & C Red No. 6, D & C Red No. 7, and D & C Red No. 30 is postponed until October 31, 1978, and for ferric ferrocyanide (iron blue) until December 31, 1978, while chemistry data and analytical methods to establish specifications are developed and evaluated, and subject to compliance with the requirements of this paragraph.

* * * * *

Notice and public procedure and delayed effective date are not prerequisites to the promulgation of this rule because section 203(a)(2) of Pub. L. 86-618 provides for this issuance.

*Effective date.* This regulation is effective November 21, 1978.

(Sec. 203 (a)(2) and (d)(1), Title II, Pub. L. 86-618, 74 Stat. 404-405 (21 U.S.C. 376 note).)

Dated: November 13, 1978.

JOSEPH P. HILE,
*Associate Commissioner for Regulatory Affairs.*

[FR Doc. 78-32501 Filed 11-20-78; 8:45 am]

[4110-03-M]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 78N-0344]

## PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

### Trifluoromethane Sulfonic Acid

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the regulations for direct food additives to provide for the use of trifluoromethane sulfonic acid in the manufacture of "cocoa butter substitute from palm oil." This action is based on a petition filed by Procter & Gamble Co.

DATES: Effective November 21, 1978; objections by December 21, 1978.

ADDRESS: Written objections to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of March 8, 1977 (42 FR 13062), the agency announced that a generally recognized as safe (GRAS) petition (GRASP-7G0081) had been filed by the Procter & Gamble Co., 6071 Center Hill Road, Cincinnati, Ohio 45224, requesting affirmation that cocoa butter prepared from other vegetable oils is GRAS for use in human food. Trifluoromethane sulfonic acid is used as a catalyst in the manufacture of cocoa butter prepared from other vegetable oils. The final regulation, § 184.1259 (21 CFR 184.1259) affirming the GRAS status of "cocoa butter substitute from palm oil" is published elsewhere in this issue of the FEDERAL REGISTER.

The Commissioner of Food and Drugs has evaluated the data in the petition and other relevant materials and concludes that part 173 should be amended as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))) and under authority delegated to the Commissioner (21 CFR 5.1), Part 173 is amended by adding new § 173.395 to read as follows:

**§ 173.395 Trifluoromethane sulfonic acid.**

Trifluoromethane sulfonic acid has the empirical formula $CF_3SO_3H$ (CAS Reg. No. 1493-13-6). The catalyst (Trifluoromethane sulfonic acid) may safely be used in the production of cocoa butter substitute from palm oil (1-palmitoyl-2-oleoyl-3-stearin) (see § 184.1259 of this chapter) in accordance with the following conditions:

(a) The catalyst meets the following specifications:

Appearance, Clear liquid.
Color, Colorless to amber.
Neutralization equivalent, 147-151.
Water, 1 percent maximum.
Fluoride ion, 0.03 percent maximum.
Heavy metals (as Pb), 30 parts per million maximum.
Arsenic (as As), 3 parts per million maximum.

(b) It is used at levels not to exceed 0.2 percent of the reaction mixture to catalyze the directed esterification.

(c) The esterification reaction is quenched with steam and water and the catalyst is removed with the aqueous phase. Final traces of catalyst are removed by washing batches of the product three times with an aqueous solution of 0.5 percent sodium bicarbonate.

(d) No residual catalyst may remain in the product at a detection limit of 0.2 part per million fluoride as determined by 25.046 AOAC method, the "Official Methods of Analysis of the Association of Official Analytical Chemists," 12th Ed., 1976,[1] which is incorporated by reference.

Any person who will be adversely affected by the foregoing regulation may at any time on or before December 21, 1978 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, 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

[1] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

*Effective date.* This regulation shall become effective November 21, 1978.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)).)

NOTE: Incorporation by reference was approved on March 11, 1976, by the Director of the Office of the Federal Register and is on file at the Federal Register library.

Dated: November 9, 1978.

WILLIAM F. RANDOLPH,
*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 78-32503 Filed 11-20-78; 8:45 am]

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[4110-03-M]

[Docket No. 76G-0488]

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

### Cocoa Butter Substitute From Palm Oil

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that cocoa butter substitute from palm oil is generally recognized as safe (GRAS) for human use in nonstandardized confectionary products. This action, based on a petition requesting such affirmation, lists the ingredient in the regulations as a direct food substance affirmed as GRAS. This document also establishes "cocoa butter substitute from palm oil" as the common or usual name for the ingredient and provides for a 60-day comment period on the name.

DATES: Effective November 21, 1978; objections by December 21, 1978; and comments on the common or usual name provisions by January 22, 1979.

FOR FURTHER INFORMATION CONTACT:

Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In accordance with the procedures described in § 170.35 (21 CFR 170.35), Procter & Gamble Co., 6071 Center Hill Road, Cincinnati, Ohio 45224, submitted a petition (GRASP-7G0081) requesting affirmation that "cocoa butter prepared from other vegetable oils" is generally recognized as safe (GRAS) for use in human food. A notice of filing of the petition was published in the FEDERAL REGISTER of March 8, 1977 (42 FR 13062), and interested persons were given an opportunity to review the petition and submit comments to the Hearing Clerk, Food and Drug Administration. As stated in that notice, the name designated for filing ("cocoa butter prepared from other vegetable oils") was for descriptive purposes only and was not intended to establish a common or usual name for the ingredient. A common or usual name of "cocoa butter substitute from palm oil" is established by this regulation; 60 days are provided for additional comment on the name.

In response to the notice, four comments were received from firms associated with the chocolate industry. All of the comments concerned the name of the ingredient used in the notice. A summary of these comments and the conclusions of the Commissioner of Food and Drugs are discussed below.

COMMON OR USUAL NAME

1. One respondent requested that an opportunity for specific comment on the common or usual name for the ingredient be provided independent of action on the petition.

The notice of filing contained the statement that "the common or usual name for this ingredient, if any, will be established at the time that a final GRAS or food additive regulation is promulgated." This statement was intended to provide notice of the agency's intent to adopt a common or usual name and to solicit public comment and suggestions on the name. This regulation establishes the name "cocoa butter substitute from palm oil" for the GRAS substance. An additional 60 days are being provided, however, for comment on the name. At the end of the comment period, a notice will be published addressing those comments received in response to the common or usual name provision of this regulation. If appropriate, the notice will modify the common or usual name.

2. One comment described the name used in the notice of filing as inappropriate and misleading to consumers because it was the name of a naturally occurring product. The comment suggested the names "synthetic cocoa butter," "cocoa butter substitute," and "cocoa butter replacement." Another comment suggested that the petitioner's product be described as "synthetic cocoa butter," "imitation cocoa butter," or "artificial cocoa butter."

The Commissioner acknowledges that the name used in the notice of filing might be confusing to some consumers. Again, however, the notice stated that the name was for descriptive purposes only and did not establish a common or usual name for the ingredient. The name "cocoa butter substitute from palm oil" has been chosen in preference to those suggested by the comment because the common or usual name should identify the source of the oil and affirmatively describe the ingredient. The names suggested by the comments all describe what the ingredient is not. The name established by this regulation includes the source of the starting oil.

3. The petitioner suggested using a descriptive name such as "hydrogenated vegetable oil—made from palm oil" as a temporary measure. The petitioner also recommended establishing a common or usual name that will be descriptive of this specific class of food ingredients. This course of action, the petitioner contends, would provide the proper opportunity for consumer and industry participation in setting the name.

The Commissioner has considered the name "hydrogenated vegetable oil made from palm oil." This name suggests that the ingredient is simply vegetable oil that has been hydrogenated, which is clearly not the case. This name does, however, identify the source of the starting material. The ingredient 1-palmitoyl-2-oleoyl-3-stearin is a triglyceride produced by directed esterification of fully saturated 1,3 diglycerides (derived from palm oil) with the anhydride of food grade oleic acid in the presence of the catalyst (trifluoromethane sulfonic acid).

Although the ingredient is a mixture of triglycerides, the chemically accurate name is 1-palmitoyl-2-oleoyl-3-stearin, which is the predominant triglyceride in the ingredient. Precedents for the use of a specific chemical name for such mixtures are found in the food additive regulations. Sections 172.844 and 172.846 (21 CFR 172.844 and 172.846), which provide for the use of stearoyl lactylate, are examples.

The Commissioner recognizes, however, that use of the above chemical name may not be informative to the consumer. Although 1-palmitoyl-2-oleoyl-3-stearin is a chemically accurate name, it is not a name that is likely to be understood or recalled by consumers generally. In the opinion of the Commissioner, the interest of consumers is better served by an accurate and comprehensible name than by a long and technical chemical name. The name "cocoa butter substitute from palm oil" has the advantage of both identifying the basic nature of the ingredient and identifying the

source of the starting material. The chemical name is, however, used in the regulation as the most precise way to identify the ingredient insofar as food processors and ingredient manufacturers are concerned. The Commissioner invites further comments on the name stated in the regulation.

SAFETY OF THE INGREDIENT

No comments were received concerning the safety of the substance. The petitioner has presented information to show that "cocoa butter substitute from palm oil" as described in GRASP-7G0081 is similar to natural cocoa butter. Cocoa butter is a natural extractive of cacao (*Theobroma cacao* L.). Cacao is listed in § 182.20 (21 CFR 182.20) as GRAS for essential oils, oleoresins (solvent-free), and natural extractives (including distillates). Natural cocoa butter has been used for many years in chocolate confections and is considered GRAS by qualified experts knowledgeable about the safety of food ingredients. Cocoa butter is incorporated into these products as a component of chocolate liquor or as a separate ingredient. Lauric fats such as coconut and palm kernel oil, as well as palm, soybean, and cottonseed oils have been used as starting raw materials for the added fat in the making of candies and confectioner's coatings. The desirable eating quality of chocolate coatings is believed to depend primarily on the fact that cocoa butter consists predominantly of the specific triglyceride molecule, 1-palmitoyl-2-oleoyl-3-stearin. The triglycerides described in the petition are comparable to natural cocoa butter.

The predominant constituents of "cocoa butter substitute from palm oil" are glycerol and palmitic, oleic, and stearic acids. These components occur naturally as components of glycerides, lipids, lipoproteins, and membranes of both plants and animals. The synthesis and metabolism of these substances are well documented in some biochemistry textbooks such as: *Principles of Biochemistry*, 4th Ed., pp. 57-70 and 470-505 (1968) by White, Handler, and Smith and *Biochemistry*, pp. 189-198 and 513-524 (1970) by Lehninger.

"Cocoa butter substitute from palm oil" is a mixture of position-specific triglycerides whose major component is 1-palmitoyl-2-oleoyl-3-stearin. The triglycerides are produced by directed esterification of fully saturated 1,3-diglycerides (derived from palm oil) with the anhydride of food grade oleic acid. The presence of the catalyst (trifluoromethane sulfonic acid) is required. These triglycerides contain the same fatty acids and the same glycerol components as those found in the broad range of edible fats and oils considered GRAS. The ingredient has a similar chemical composition to natural cocoa butter, i.e., 26 percent palmitic acid in natural cocoa butter compared to 20 percent in the ingredient; 35 percent oleic acid compared to 32 percent in the ingredient; 3 percent linoleic acid compared to 2 percent in the ingredient; while stearic acid is 34 percent compared to 44 percent in the ingredient. In an article entitled "On the Configuration of Cocoa Butter," *Journal of the American Oil Chemist's Society*, Vol. 34, 1957, E. S. Lutton shows that the predominant triglyceride in natural cocoa butter is 1-palmitoyl-2-oleoyl-3-stearin. Other information demonstrating that the ingredient is similar to natural cocoa butter includes a discussion in "Bailey's Industrial Oil and Fat Products," 3d Ed., p. 181. The ingredient has the same or similar melting point, solids profile, and palatability as natural cocoa butter.

Unpublished safety data submitted in support of the petition include a short term (28-day) feeding study in which rats were fed 1-palmitoyl-2-oleoyl-3-stearin at a level of 15 percent in the diet and a metabolic study with rats fed $C^{14}$ labeled oleic derivatives. A published 21-month chronic feeding and a 2-year carcinogenic study with rats fed preformed oleic derivatives in used frying fats were also submitted (*Journal of Nutrition*, Vol. 93, p. 337, by G. A. Nolan et al.). Oleic derivatives are byproducts formed during the manufacture of the triglyceride and appear as contaminants in the isolated ingredient. They are also normally found in used frying fats and oils from both vegetable and animal sources. No adverse effects attributable to the test material were observed in any of the above studies. These studies support the premise that the present levels of oleic derivatives in the ingredient will not pose a significant risk to the public health.

The use of the catalyst trifluoromethane sulfonic acid in the production of cocoa butter substitute from palm oil is provided for by the food additive regulation § 173.395 (21 CFR 173.395) published elsewhere in this issue of the FEDERAL REGISTER.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 202(s), 409, 701(a), 52 Stat. 1055, 72, Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), part 184 is amended by adding new § 184.1259 to read as follows:

**§ 184.1259 Cocoa butter substitute from palm oil.**

(a) Cocoa butter substitute from palm oil (1-palmitoyl-2-oleoyl-3-stearin) is a triglyceride. It is manufactured by directed esterification of fully saturated 1,3-diglycerides (derived from palm oil) with the anhydride of food grade oleic acid in the presence of the catalyst trifluoromethane sulfonic acid (§ 173.395 of this chapter).

(b) The ingredient meets the following specifications:

(1) Over 90 percent triglycerides, not more than 7 percent diglycerides, not more than 1 percent monoglycerides, and not more than 1 percent free fatty acids.

(2) Total glycerides—98 percent minimum.

(3) Heavy metals (as lead), 10 parts per million maximum (see p. 562 "Food Chemicals Codex," 2d Ed., 1972).[1]

(4) Color—clear, bright, and free from suspended matter.

(5) Odor and taste—free from foreign and rancid odor and taste.

(6) Residual catalyst ("Official Methods of Analysis of the Association of Analytical Chemists," [2] 12 Ed., 25.046—method of determination of residual fluorine; limit of detection 0.2 part per million F; multiply fluoride result by 2.63 to convert to residual catalyst)—not detectable at a detection limit of 0.5 part per million. The ingredient shall be washed three times in batches with 0.5 percent sodium bicarbonate to remove catalyst residuals in accordance with good manufacturing practice.

(7) Residual methanol—5 parts per million maximum.

(c) The ingredient is used in the following nonstandardized food categories: Confections and frostings as defined in § 170.3(n)(9) of this chapter; in nonstandardized coatings of soft candy as defined in § 170.3(n)(38) of this chapter; and in nonstandardized sweet sauces and toppings as defined in § 170.3(n)(43) of this chapter.

(d) The ingredient is used in food in accordance with § 184.1(b)(1) at levels not to exceed good manufacturing practice.

Interested persons may, on or before January 22, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding the name established by this regulation. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Re-

[1] Copies may be obtained from: National Academy of Sciences, 2101 Constitution Avenue NW, Washington, D.C. 20037.

[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20044.

ceived comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday. A notice will be published at the end of the comment period to address the comments received in response to the common or usual name provision of this regulation. If appropriate, the notice will modify the common or usual name.

Any person who will be adversely affected by the foregoing regulation may at any time on or before December 21, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, 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. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

*Effective date.* This regulation shall become effective November 21, 1978.

(Secs. 201(s), 409, 701(a), 52 Stat. 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a)).)

Dated: November 9, 1978.

WILLIAM F. RANDOLPH,
*Acting Associate Commissioner for Regulatory Affairs.*

NOTE.—Incorporation by reference approved by the Director of the Office of the Federal Register on July 10, 1973 and August 11, 1976, and is on file in the Office of the Federal Register library.

[FR Doc. 78-32504 Filed 11-20-78; 8:45 am]

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[4110-03-M]

SUBCHAPTER 3—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

### Bambermycins

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The regulations are amended to reflect approval of a supplemental new animal drug application (NADA) filed by American Hoechst Corp. providing for a waiver of certain requirements for manufacture of certain complete chicken and swine feeds.

EFFECTIVE DATE: November 21, 1978.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Bureau of Veterinary Medicine (HFV-149), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4317.

SUPPLEMENTARY INFORMATION: American Hoechst Corp., Route 202-206 North, Somerville, N.J. 08876, filed a supplemental NADA (44-759V) providing for a waiver of the ministerial requirements of section 512(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(m)) for manufacture of a complete broiler feed containing 1 to 2 grams of bambermycins per ton and complete grower-finisher swine feed containing 2 grams of bambermycins per ton. The complete feeds are for increased rate of weight gain and improved feed efficiency.

Bambermycins, as the sole drug, meet the uniform criteria set forth in the 1971 Bureau of Veterinary Medicine memoranda for administrative waiver of the requirements of section 512(m) of the act. The pertinent provisions of the memoranda indicate that the waiver is appropriate if:

(1) The use of the product in the finished feed as recommended by labeling does not have an impact on tissue residues, i.e., an impact on an existing withdrawal period or tolerance level.

(2) The product is not a known carcinogen or is not classed with a family of known carcinogens.

(3) Appropriate documentation covering animal safety is on file. This will not require additional generation of data since this documentation is part of the NADA.

(4) The margin of safety to the animal and safety to the consumer is such that the product label does not have to contain a statement such as "use as the sole source of * * *."

(5) Data are on file to demonstrate that the product is efficacious over the approved range. These data should generally satisfy current standards for the demonstration of efficacy.

(6) Except under special circumstances, the product has been used at least 3 years in the target species without significant complaints related to or associated with it. Applications of this criterion require a review of the available drug experience reports.

The 1971 memoranda make explicit that because waiver of the requirements of section 512(m) of the act is permitted only for specific efficacy claims or at specific levels of the drugs, there should be other distinct products with corresponding labeling to cover those premixes that can be made into finished feeds with various concentrations of drugs.

The foregoing criteria established in the 1971 memoranda constitute an interim agency policy which is under review. In waiving the ministerial requirements of section 512(m) of the act, the agency has not waived the current good manufacturing practice regulations (21 CFR Part 225) for feed mills mixing such feeds.

Approval of this supplemental application does not constitute reaffirmation of the underlying safety and efficacy data for use of bambermycins in complete feeds for broiler chickens and growing-finishing swine.

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 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), § 558.95 is amended by adding paragraph (d) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(d) *Special considerations.* Complete broiler feeds and swine feeds containing bambermycins as the sole drug, processed from premixes containing 2.0 grams or 0.4 gram of bambermycins per pound and conforming to the requirements of paragraph (e)(1) and (e)(2) of this section, are not required to comply with the provisions of section 512(m) of the act.

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Effective date: November 21, 1978.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)