Any person who will be adversely affected by the foregoing regulation may at any time on or before October 31, 1977, file with the Hearing Clerk (HFC–20), Food and Drug Administration, room 4–65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto. Objections shall be filed in accordance with the requirements of § 71.30 (21 CFR 71.30). If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and anaysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Four copies of all documents shall be filed and identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the office of the Hearing Clerk between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective October 31, 1977 except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced in the FEDERAL REGISTER.

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

Dated: September 27, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-28798 Filed 9-29-77;8:45 am]

[4110–03]

[Docket No. 77C–0233]

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

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

Bismuth Oxychloride

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: This document "permanently" lists bismuth oxychloride for use in externally applied drugs and in cosmetics generally, including those intended for use in the area of the eye. The Cosmetic, Toiletry and Fragrance Association filed a petition for such use. The provisional listing for bismuth oxychloride is deleted.

DATES: Effective date: October 31, 1977; objections by October 31, 1977.

ADDRESSES: Written objections to the Hearing Clerk (HFC–20), Food and Drug Administration, room 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Bureau of Foods (HFF–334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW, Washington, D.C. 20204 (202–472–5740).

SUPPLEMENTARY INFORMATION: The Cosmetic, Toiletry and Fragrance Association, Inc., 1133 15th St. NW, Washington, D.C. 20005, filed a petition (CAP 6C0119) for bismuth oxychloride. The petition proposed issuance of a color additive regulation to provide for safe use and exemption from certification of bismuth oxychloride to be used in coloring externally applied drugs and in cosmetics generally, including those intended for use in the area of the eye. Notice of the petition was published in the FEDERAL REGISTER of August 19, 1977 (42 FR 41920).

The Commissioner of Food and Drugs, having evaluated the data in the petition and other relevant material, concludes that bismuth oxychloride is safe and suitable for use, under the conditions prescribed in this regulation, in coloring externally applied drugs and in coloring cosmetics generally, including drugs and cosmetics intended for use in the area of the eye, and that certification is not necessary for the protection of the public health.

Bismuth oxychloride has been provisionally listed for use in cosmetics under § 81.1(g) (21 CFR 81.1(g)). With permanent listing of bismuth oxychloride under §§ 73.1162 and 73.2162, the listing under § 81.1(g) becomes obsolete.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706(b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376 (b), (c), and (d))) and the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner (21 CFR 5.1), Parts 73 and 81 are amended as follows:

1. Part 73 is amended:

a. By adding new § 73.1162 to Subpart B, to read as follows:

§ 73.1162 Bismuth oxychloride.

(a) *Identity.* (1) The color additive bismuth oxychloride is a synthetically prepared white or nearly white amorphous or finely crystalline, odorless powder consisting principally of BiOCl.

(2) Color additive mixtures for drug use made with bismuth oxychloride may contain only those diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* The color additive bismuth oxychloride shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

Volatile matter, not more than 0.5 percent.
Lead (as Pb), not more than 20 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Bismuth oxychloride, not less than 98 percent.

(c) *Uses and restrictions.* The color additive bismuth oxychloride may be safely used in coloring externally applied drugs, including those intended for use in the area of the eye, in amounts consistent with good manufacturing practice.

(d) *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 the provisions 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 pursuant to section 706(c) of the act.

b. By adding new § 73.2162 to Subpart C, to read as follows:

§ 73.2162 Bismuth oxychloride.

(a) *Identity and specifications.* (1) The color additive bismuth oxychloride shall conform in identity and specifications to the requirements of § 73.1162(a)(1) and (b).

(2) Color additive mixtures of bismuth oxychloride may contain the following diluents:

(i) For coloring cosmetics generally, only those diluents listed under § 73.1001(a)(1);

(ii) For coloring externally applied cosmetics, only those diluents listed in § 73.1001(b) and, in addition, nitrocellulose.

(b) *Uses and restrictions.* The color additive bismuth oxychloride may be safely used in coloring cosmetics generally, including cosmetics intended for use in 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 provisions of § 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 pursuant to section 706(c) of the act.

§ 81.1 [Amended]

2. Part 81 is amended in paragraph (g) of § 81.1 *Provisional lists of color additives,* by deleting the entry "Bismuth oxychloride."

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 31, 1977, file with the Hearing Clerk (HFC–20), Food and Drug Administration, Room 4–65, 5600 Fishers Lane, Rockville, Md.

20857, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of § 71.30 (21 CFR 71.30). If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Four copies of all documents shall be filed and should 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-named office during working hours, Monday through Friday.

Effective date: This regulation shall become effective October 31, 1977, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the FEDERAL REGISTER.

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

Dated: September 27, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-28796 Filed 9-29-77;8:45 am]

[4110-03]

[Docket No. 76C-0386]

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

D&C Green No. 5

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends regulations listing D&C Green No. 5 for coloring sutures to include its safe use in coloring nylon 6 [poly-(*e*-caprolactam)] sutures and deletes the requirements that sutures dyed by D&C Green No. 5 conform in all respects to the requirements of the United States Pharmacopeia. Ethicon, Inc., filed a petition for such use.

DATES: Effective October 31, 1977; objections by October 31, 1977.

ADDRESSES: Written objections to the Hearing Clerk (HFC–20), Food and Drug Administration, room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: A notice published in the FEDERAL REGISTER of October 4, 1976 (41 FR 43754) stated that a petition (CAP 6C0126) had been filed by Ethicon, Inc., Route 22, Somerville, N.J. 08876. The petition requested listing of D&C Green No. 5 under § 74.1205 (21 CFR 74.1205) as safe and suitable for coloring nylon 6 nonabsorbable sutures for use in general surgery. The petition also requested the deletion of the present requirement in § 74.1205(c)(2) that nylon (the copolymer of adipic acid and hexamethylenediamine) nonabsorbable sutures colored with D&C Green No. 5 conform in all respects to the requirements of the United States Pharmacopeia, e.g., the color may be used in new sutures designed to permit needles to be detached from suture material with less force than the U.S.P. requires. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner, having evaluated the data in the petition and other relevant material, concludes that D&C Green No. 5 is safe under the conditions set forth below for use in coloring nylon surgical sutures for use in general surgery and that certification is necessary for the protection of the public health. The generally recognized names, nylon 66 for the copolymer of adipic acid and hexamethylenediamine and nylon 6 for poly-(*e*-caprolactam), are used to identify the types of nylon sutures that may be dyed with D&C Green No. 5.

The Commissioner also concludes that there are sufficient safeguards, other than the color additive regulations, available to ensure that the dyed sutures comply with appropriate specifications for surgical sutures, i.e., the requirements of the U.S.P. if the sutures are marketed as U.S.P. requirements of the applicable new drug applications, and the general requirements of good manufacturing practice. Accordingly, the Commissioner concludes that the U.S.P. requirement is unnecessary, and § 74.1205 is amended below to delete this provision and to include some nonsubstantive changes.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706(b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376(b), (c), and (d))) and under authority delegated to the Commissioner (21 CFR 5.1), Part 74 is amended by revising paragraph (c) in § 74.1205, to read as follows:

§ 74.1205 D&C Green No. 5.

* * * * *

(c) *Uses and restrictions.* D&C Green No. 5 may be safely used to color nylon 66 (the copolymer of adipic acid and hexamethylenediamine) and/or nylon 6 [poly-(*e*-caprolactam)] nonabsorbable surgical sutures for use in general surgery, subject to the following restrictions:

(1) The quantity of the color additive does not exceed 0.6 percent by weight of the suture.

(2) When the sutures are used for the purposes specified in their labeling, there is no migration of the color additive to the surrounding tissue.

(3) If the suture is a new drug, an approved new-drug application, pursuant to section 505 of the act, is in effect for it.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 31, 1977, file with the Hearing Clerk (HFC–20), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of § 71.30 (21 CFR 71.30). If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Four copies of all documents shall be filed and should be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the Hearing Clerk's office, between 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation shall become effective October 31, 1977, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the FEDERAL REGISTER.

(Sec. 706(b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376(b), (c), and (d)))

Dated: September 26, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-28824 Filed 9-29-77;8:45 am]

[4110-03]

SUBCHAPTER A—GENERAL

[Docket No. 77C-0276]

D&C ORANGE NO. 4

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document "permanently" lists D&C Orange No. 4 for safe use in coloring drug and cosmetic products that are applied externally. The Toilet Goods Association filed a petition for such use. Certification of the color additive is necessary. This rule will remove the color additive from provisional listing.

DATES: Effective October 31, 1977; objections by October 31, 1977.

ADDRESS: Written objections to the Hearing Clerk (HFC–20), Food and Drug Administration, Room 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

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: A notice published in the FEDERAL REGISTER of November 20, 1968 (33 FR 17205) stated that a petition (CAP 35) for the "permanent" listing of D&C Orange No. 4 as a color additive for use in drugs and cosmetics that are applied externally had been filed by the Toilet Goods Association, Inc. (now the Cosmetic, Toiletry, and Fragrance Association, 1133 15th Street NW., Washington, D.C. 20005); the Pharmaceutical Manufacturers Association (1155 15th Street NW., Washington, D.C. 20005), and the Certified Color Industry Committee (now the Certified Color Manufacturers Association, 900 17th Street NW., Washington, D.C. 20006), c/o Hazelton Laboratories, Inc., P.O. Box 30, Falls Church, Va. 22046. The petition was filed pursuant to section 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 376).

The Commissioner of Food and Drugs, having evaluated the data in the petition and other relevant material, concludes that D&C Orange No. 4 is safe and suitable for use, under the conditions prescribed in this regulation, in coloring drug and cosmetic products that are applied externally, and that certification is necessary for the protection of the public health.

With permanent listing, the provisional listing for "D&C Orange No. 4" in § 81.1(b) (21 CFR 81.1(b)), which was extended to October 31, 1977, by regulation published in the FEDERAL REGISTER of February 4, 1977 (42 FR 6992), will become obsolete, and that entry is being deleted from the regulations.

This regulation does not list D&C Orange No. 4 for use in lakes as requested in the petition. The Commissioner notes that proposed regulations related to the use of color additives in lakes were published in the FEDERAL REGISTER of May 11, 1965 (30 FR 6490). The Commissioner advises that new proposed regulations governing the use of color additives in lakes will be published in the FEDERAL REGISTER in the near future and concludes that the listing of colors for use in lakes can best be implemented by general regulations. D&C Orange No. 4 will, therefore, continue to be approved for use in lakes for coloring externally applied drugs and cosmetics under the general provisional listing for "Lakes (D&C)" under § 81.1 (b).

This regulation establishes specifications for the certification of batches of D&C Orange No. 4 that are more restrictive than those currently prescribed under § 82.1254 (21 CFR 82.1254). Additionally, the identity of the color has been revised to be consistent with current chemical nomenclature. The identity nomenclature and the specifications currently prescribed in § 82.1254 become obsolete upon the effective date of new §§ 74.1254 and 74.1254 (21 CFR 74.1254 and 74.2254). However, it is necessary to retain § 82.1254 to provide for the use of the color additive in lakes. Accordingly, §82.1254 is revised to reference the identity nomenclature and specifications prescribed by § 74.1254.

Therefore, under the Federal Food, Drug, and Cosmetic Act, (sec. 706 (b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d))) and the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86-618, sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note)), and under authority delegated to the Commissioner (21 CFR 5.1). Parts 74, 81, and 82 are amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. Part 74 is amended:

a. By adding new § 74.1254 to Subpart B, to read as follows:

§ 74.1254 D&C Orange No. 4.

(a) *Identity.* (1) The color additive D&C Orange No. 4 is principally the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid.

(2) Color additive mixtures for use in externally applied drugs made with D&C Orange No. 4 may contain only those diluetns that are suitable and that are listed in Part 73 of this chapter for use in color additive mixtures for coloring externally applied drugs.

(b) *Specifications.* D&C Orange No. 4 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice.

Sum of volatile matter (at 135° C) and chlorides and sulfates (calculated as sodium salts), not more than 10 percent.

Water-insoluble matter, not more than 0.2 percent.

2-Naphthol, not more than 0.4 percent.

Sulfanilic acid, sodium salt, not more than 0.2 percent.

Subsidiary colors, not more than 3 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Mercury (as Hg), not more than 1 part per million.

Total color, not less than 90 percent.

(c) *Uses and restrictions.* D&C Orange No. 4 may be safely used for coloring externally applied drugs in amounts consistent with good manufacturing practice.

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

(e) *Certification.* All batches of D&C Orange No. 4 shall be certified in accordance with regulations in Part 80 of this chapter.

b. By adding new § 74.2254 to Subpart C, to read as follows:

§ 74.2254 D&C Orange No. 4.

(a) *Identity and specifications.* The color additive D&C Orange No. 4 shall conform in identity and specifications to the requirements of § 74.1254 (a)(1) and (b).

(b) *Uses and restrictions.* D&C Orange No. 4 may be safely used for coloring externally applied cosmetics in amounts consistent with good manufacturing practice.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Orange No. 4 shall be certified in accordance with regulations in Part 80 of this chapter.

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

§ 81.1 [Amended]

2. In Part 81, by amending the table in paragraph (b) of § 81.1 *Provisional lists of color additives,* by deleting the entry for "D&C Orange No. 4."

PART 82—LISTING OF CERTIFIED PROVISIONALLY LISTED COLORS AND SPECIFICATIONS

3. Part 82 is amended by revising § 82.1254 to read as follows:

§ 82.1254 D&C Orange No. 4.

The color additive D&C Orange No. 4 shall conform in identity and specifications to the requirements of § 74.1254 (a)(1) and (b) of this chapter. D&C Orange No. 4 is restricted to use in externally applied drugs and cosmetics.

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 31, 1977, file with the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written objections thereto. Objections shall show wherein the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of § 71.30 (21 CFR 71.30). If a hearing is requested, the objections shall state the issues for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Four copies of all documents shall be filed and identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the office of the Hearing Clerk between 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation shall become effective October 31, 1977, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced in the FEDERAL REGISTER.

(Sec. 706 (b), (c), and (d), 74 Stat. 399–403 (21 U.S.C. 376 (b), (c), and (d)).)

Dated: September 22, 1977.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.77-28825 Filed 9-29-77;8:45 am]

[4110-03]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

[Docket No. 76F-0016]

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

Ammoniated Cottonseed Meal

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document provides for use of ammoniated cottonseed meal in the feed of ruminants. The National Cottonseed Products Association, Inc., filed a petition proposing safe use of the product.

DATES: Effective September 30, 1977; objections by October 31, 1977.

ADDRESSES: Written objections to the Hearing Clerk (HFC–20), Food and Drug Administration, Room 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Bureau of Veterinary Medicine (HFV–147), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857 (301–443–4317).

SUPPLEMENTARY INFORMATION: A notice published in the FEDERAL REGISTER of February 17, 1976 (41 FR 7148), announced that a petition (MF–3539) has been filed by the National Cottonseed Products Association, Inc., P.O. Box 12023, Memphis, Tenn. 38112, proposing that § 573.140 *Ammoniated cottonseed meal* (formerly § 121.319 prior to recodification published in the FEDERAL REGISTER of September 10, 1976 (41 FR 38619)) be amended to delete the restriction that the additive be used as the sole source of nonprotein nitrogen in the feed of ruminants.

The Commissioner of Food and Drugs, having evaluated the petition and other relevant material, concludes that § 573.140 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), § 573.140 is amended by revising paragraph (b) as follows:

§ 573.140 Ammoniated cottonseed meal.

* * * * *

(b) It is used or intended for use in the feed of ruminants as a source of protein and/or as a source of nonprotein nitrogen in an amount not to exceed 20 percent of the total ration.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 31, 1977, submit to the Hearing Clerk (HFC–20), 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 September 30, 1977.

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

Dated: September 23, 1977.

FRED J. KINGMA,
Acting Director, Bureau of Veterinary Medicine.

[FR Doc.77-28826 Filed 9-29-77;8:45 am]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 76F-0461]

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

Styrene Block Polymers

Correction

In FR Doc. 77–25093, appearing in the issue of Tuesday, August 30, 1977 on page 43621, in the 2nd column, in the 3rd paragraph, the 5th line should read, "* * * for the use of styrene block polymers * * *".

[4210-01]

Title 24—Housing and Urban Development

CHAPTER VIII—LOW-INCOME HOUSING, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. R–77–344]

PART 866—LEASE AND GRIEVANCE PROCEDURES

Tenant Maintenance

AGENCY: Department of Housing and Urban Development.

ACTION: Final rule.

SUMMARY: This final rule amends Title 24, Chapter VIII, Part 866 § 866.4(g) Tenant Maintenance, to clarify the provision of § 866.4(g) permitting Public Housing Agencies (PHAs) to incorporate into the lease a provision for the performance of seasonal and other maintenance tasks by tenants where it has been common practice for tenants of the given type of dwelling unit to perform such tasks. The Department has become aware that interested parties have interpreted this section, which permits leases to provide for tenant performance of seasonal and other maintenance tasks, as (1) being limited to tenants of projects of the specified architectural or structural types mentioned as examples in the section and (2) specifying that the option of tenant performance shall be embodied in an agreement between the Public Housing Agency (PHA) and the tenant which is separate from the lease.

This rule clarifies the intent of the original issuance which was to permit PHAs to incorporate into the lease a provision for the performance of seasonal and other maintenance tasks by tenants where it has been common practice for tenants of the given type of dwelling unit to perform such tasks.

EFFECTIVE DATE: October 31, 1977.

FOR FURTHER INFORMATION CONTACT:

Edward Whipple, Chief, Rental and Occupancy Branch, 202–755–6596, U.S. Department of Housing and Urban Development, Washington, D.C. 20410.

SUPPLEMENTARY INFORMATION: The Department gave notice on January 17, 1977, at 42 FR 3181, that it was proposing to amend Title 24 of the Code of Federal Regulations, Chapter VIII, § 866.4(g), Tenant Maintenance.

Five comments were received in response to the proposed amendment. The following is a discussion of the comments and suggestions and of the changes to the amendment made in response to those comments:

1. Two comments suggested that a universal application of the proposed amendment to require all tenants to perform maintenance tasks could cause serious injury or grave hardship to disabled or elderly tenants. In addition, it was suggested that hardship might result