services; § 13.85 *Government approval, action, connection or standards:* Inspection;[1] § 13.260 *Terms and conditions.* Subpart—*Offering unfair, improper and deceptive inducements to purchase or deal:* § 13.1955 *Free goods;* § 13.1975 *Government penalty;* § 13.1980 *Guarantee, in general.*

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45) [Cease and desist order, Coral Stone Construction Company et al., Chicago, Ill., Docket 7309, January 8, 1959]

In the Matter of Coral Stone Construction Company, a Corporation, and Norman Stone, Theodore T. Stone, Betty Stone, and Morton I. Kovin, Individually and as Officers of Said Corporation

This proceeding was heard by a hearing examiner on the complaint of the Commission charging a seller of building materials in Chicago with representing falsely in advertising to obtain home improvement and repairs contracts, that monthly payments on remodeling jobs were smaller than was the fact; that governmental authorities regularly inspect homes for violations of building codes and levy fines therefor; that valuable gifts would be given to prospects who allowed it to bid on a job; and that its "Coral Stone" was backed by a lifetime guarantee not to chip or crack.

After acceptance of an agreement containing a consent order, the hearing examiner made his initial decision and order to cease and desist which became on January 8 the decision of the Commission.

The order to cease and desist is as follows:

It is ordered, That respondents Coral Stone Construction Company, a corporation, and its officers, and Norman Stone, Theodore T. Stone, Betty Stone, and Morton I. Kovin, individually and as officers of said corporation, and respondents' agents, representatives, and employees directly or through any corporate or other device, in connection with the offering for sale, sale and distribution of building materials required in the execution of contracts for repairs or other improvements on homes or other structures, in commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

(a) Representing, directly or by implication, that certain periodic payments may be made to liquidate the amount due on contracts with respondents unless it is expressly stated that such payments may be made only by those who can qualify.

(b) Representing, directly or by implication, that governmental authorities make inspections of homes or other structures, to find violations of building codes or other laws and levy fines for violations, unless restricted to the particular areas in which such inspections are actually made.

(c) Representing, directly or by implication, that respondents give articles of merchandise as a gift to persons who merely permit them to submit a bid for repairs or other work on homes or other buildings and improvements or for any other reason that is not in accordance with the facts.

(d) Representing, directly or by implication, that a product is guaranteed unless the terms and nature of the guarantee and the manner in which the guarantor will perform are clearly set forth.

By "Decision of the Commission", etc., report of compliance was required as follows:

It is ordered, That the respondents herein shall within sixty (60) days after service upon them of this order, file with the Commission a report in writing setting forth in detail the manner and form in which they have complied with the order to cease and desist.

Issued: January 8, 1959.

By the Commission.

[SEAL] ROBERT M. PARRISH, *Secretary.*

[F.R. Doc. 59-1050; Filed, Feb. 5, 1959; 8:48 a.m.]

[Docket 7187]

PART 13—DIGEST OF CEASE AND DESIST ORDERS

Furs by Weiss, Inc., and Joseph Weiss

Subpart—*Advertising falsely or misleadingly:* § 13.30 *Composition of goods:* Fur Products Labeling Act. Subpart—*Invoicing products falsely:* § 13.1108 *Invoicing products falsely:* Fur Products Labeling Act. Subpart—*Misbranding or mislabeling:* § 13.1190 *Composition:* Fur Products Labeling Act; § 13.1212 *Formal regulatory and statutory requirements:* Fur Products Labeling Act. Subpart—*Neglecting, unfairly or deceptively, to make material disclosure:* § 13.1845 *Composition:* Fur Products Labeling Act; § 13.1852 *Formal regulatory and statutory requirements:* Fur Products Labeling Act; § 13.1865 *Manufacture or preparation:* Fur Products Labeling Act; § 13.1886 *Quality, grade or type of product;* § 13.1900 *Source or origin:* Fur Products Labeling Act: *Place.*

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; sec. 8, 65 Stat. 179; 15 U.S.C. 45, 69f) [Cease and desist order, Furs By Weiss, Inc., et al., Cleveland, Ohio, Docket 7187, January 8, 1959]

In the Matter of Furs by Weiss, Inc., a Corporation, and Joseph Weiss, Individually and as an Officer of Said Corporation

This proceeding was heard by a hearing examiner on the complaint of the Commission charging a furrier in Cleveland, Ohio, with violating the Fur Products Labeling Act by naming on labels attached to fur products and in newspaper advertising, animals other than those producing certain furs; by failing in other respects to comply with the labeling requirements and with the invoicing provisions of the Act; and by advertising in newspapers which failed to disclose the names of animals producing certain furs, the country of origin of imported furs, or the facts that certain products contained artificially colored or cheap or waste fur.

After acceptance of an agreement for a consent order, the hearing examiner made his initial decision and order to cease and desist which became on January 8 the decision of the Commission.

The order to cease and desist is as follows:

It is ordered, That the respondents, Furs By Weiss, Inc., a corporation, and its officers, and Joseph Weiss, individually and as an officer of said corporation, and respondents' representatives, agents or employees, directly or through any corporate or other device, in connection with the introduction into commerce, or the sale, advertising or offering for sale in commerce, or the transportation or distribution in commerce, of fur products, or in connection with the sale, advertising, offering for sale, transportation or distribution of fur products which are made in whole or in part of fur which has been shipped and received in commerce, as "commerce", "fur" and "fur product" are defined in the Fur Products Labeling Act, do forthwith cease and desist from:

1. Misbranding fur products by:

(a) Failing to affix labels to fur products showing:

(1) The name or names of the animal or animals producing the fur or furs contained in the fur product as set forth in the Fur Products Name Guide and as prescribed under the Rules and Regulations;

(2) That the fur product contains or is composed of used fur, when such is the fact;

(3) That the fur product contains or is composed of bleached, dyed, or artificially colored fur, when such is the fact;

(4) That the fur product is composed in whole or in substantial part of paws, tails, bellies, or waste fur, when such is the fact;

(5) The name, or other identification issued and registered by the Commission, of one or more persons who manufactured such fur product for introduction into commerce, introduced it into commerce, sold it in commerce, advertised or offered it for sale in commerce, or transported or distributed it in commerce;

(6) The name of the country of origin of any imported furs used in the fur product.

(b) Setting forth on labels the name of an animal in addition to the name of the animal that produced the fur.

(c) Setting forth on labels attached to fur products:

(1) Information required under section 4(2) of the Fur Products Labeling Act and the rules and regulations promulgated thereunder in abbreviated form;

(2) Information required under section 4(2) of the Fur Products Labeling Act and the rules and regulations promulgated thereunder which is mingled with non-required information;

(3) Information required under section 4(2) of the Fur Products Labeling Act and the rules and regulations promulgated thereunder in handwriting.

[1] New.

(d) Failing to set forth on labels all the information required under section 4(2) of the Fur Products Labeling Act and the rules and regulations promulgated thereunder on one side of the labels.

(e) Failing to set forth separately on labels attached to fur products composed of two or more sections containing different animal furs the information required under section 4(2) of the Fur Products Labeling Act and the rules and regulations promulgated thereunder with respect to the fur comprising each section.

2. Falsely or deceptively invoicing fur products by:

(a) Failing to furnish invoices to purchasers of fur products showing:

(1) The name or names of the animal or animals producing the fur or furs contained in the fur product as set forth in the Fur Products Name Guide and as prescribed under the rules and regulations;

(2) That the fur product contains or is composed of used fur, when such is the fact;

(3) That the fur product contains or is composed of bleached, dyed, or otherwise artificially colored fur, when such is the fact;

(4) That the fur product is composed in whole or in substantial part of paws, tails, bellies, or waste fur, when such is the fact;

(5) The name and address of the person issuing such invoices;

(6) The name of the country of origin of any imported furs contained in the fur product.

(7) The item number or mark assigned to the fur product.

3. Falsely or deceptively advertising fur products through the use of any advertisement, representation, public announcement, or notice which is intended to aid, promote, or assist, directly or indirectly, in the sale or offering for sale of fur products, and which:

(a) Fails to disclose the name or names of the animal or animals producing the fur or furs contained in the fur product as set forth in the Fur Products Name Guide and as prescribed under the said rules and regulations.

(b) Fails to disclose that the fur products contain or are composed of bleached, dyed, or otherwise artificially colored fur, when such is the fact.

(c) Fails to disclose that the fur products are composed in whole or in substantial part of paws, tails, bellies, or waste fur, when such is the fact.

(d) Contains the name of an animal other than the name of the animal that produced the fur.

(e) Fails to disclose the name of the country of origin of the imported furs contained in fur products.

By "Decision of the Commission", etc., report of compliance was required as follows:

It is ordered, That the respondents herein shall, within sixty (60) days after service upon them of this order, file with the Commission a report in writing setting forth in detail the manner and form in which they have complied with the order to cease and desist.

Issued: January 8, 1959.

By the Commission.

[SEAL] ROBERT M. PARRISH, *Secretary*.

[F.R. Doc. 59-1051; Filed, Feb. 5, 1959; 8:49 a.m.]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER A—GENERAL

PART 9—COLOR CERTIFICATION

FD&C Yellow Nos. 1, 2, 3, and 4

In the matter of amending the color-certification regulations with respect to FD&C Yellow No. 1, FD&C Yellow No. 2, FD&C Yellow No. 3, and FD&C Yellow No. 4:

An order was published in the FEDERAL REGISTER on May 4, 1957 (22 F.R. 3173), deleting the above-identified colors from § 9.3 *List of straight colors and specifications for their certification for use in food, drugs, and cosmetics* and amending § 9.5 *List of straight colors and specifications for their certification for use in externally applied drugs and cosmetics* by adding thereto the four colors External D&C Yellow No. 7, External D&C Yellow No. 8, External D&C Yellow No. 9, and External D&C Yellow No. 10.

The only objection to this order was filed by the Certified Color Industry Committee. The grounds for the objection were that these four colors would produce no adverse effect on man at the levels of actual use in the human diet. The objection recognized that the pharmacological tests known to the Industry Committee have established that FD&C Yellow Nos. 1, 3, and 4 produce adverse physiological effects as a concentration of 1,000 parts per million (0.1 percent) of the diet of test animals. The objection suggested that the Department of Health, Education, and Welfare establish tolerances to prohibit the use of excessive concentrations of these four colors in foods. A public hearing was requested.

The decision of the Court of Appeals for the Fifth Circuit in Florida Citrus Exchange v. Folsom drew the Department's construction of the coal-tar color provisions of the Federal Food, Drug, and Cosmetic Act into question, and for that reason the Deputy Commissioner of Food and Drugs on August 15, 1957 (22 F.R. 6613), stayed the delisting provisions in their entirety and stated that an announcement with respect to the requested hearing would be made at a later date.

On December 15, 1958, in Flemming v. Florida Citrus Exchange, the Supreme Court of the United States reversed the Fifth Circuit decision and held that a coal-tar color that is not itself a harmless substance is not to be certified and, if it is not certified, it is not to be used at all. The Court agreed with the Department's construction that there is no authority in existing law to establish a tolerance for a toxic coal-tar color.

The Supreme Court's decision having established the proper construction of the law, the objection of the Certified Color Industry Committee to the delisting of FD&C Yellow Nos. 1, 2, 3, and 4 is without substance, and no purpose could be served by holding a public hearing. The Department has no authority to certify colors that are themselves toxic, as is the case with FD&C Yellow Nos. 1, 2, 3, and 4, and the Department has no authority to establish a tolerance for such a color, as requested by the Industry Committee.

Accordingly, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 701(e), 52 Stat. 1055, as amended 70 Stat. 919, 72 Stat. 948; 21 U.S.C. 371(e)), and the authority delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (22 F.R. 1045; 23 F.R. 9500): *It is ordered*, That the regulations for the certification of coal-tar colors (21 CFR 9.3, 9.5) be amended as indicated below:

1. Section 9.3 *List of straight colors and specifications for their certification for use in food, drugs, and cosmetics* is amended by deleting from paragraph (a) the names of the following straight colors and the respective specifications therefor:

FD&C Yellow No. 1.
FD&C Yellow No. 2.
FD&C Yellow No. 3.
FD&C Yellow No. 4.

2. Paragraph (a) of § 9.5 *List of straight colors and specifications for their certification for use in externally applied drugs and cosmetics* is amended by adding thereto, immediately following the specifications for Ext D&C Yellow No. 6, the following:

EXT D&C YELLOW No. 7

SPECIFICATIONS

Disodium salt of 2,4-dinitro-1-napthol-7-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water-insoluble matter, not more than 0.2 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Martius yellow, not more than 0.03 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

EXT D&C YELLOW No. 8

SPECIFICATIONS

Dipotassium salt of 2,4-dinitro-1-naphthof-7-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Martius yellow, not more than 0.03 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

EXT D&C YELLOW No. 9

SPECIFICATIONS

1-Phenylazo-2-naphthylamine.
Volatile matter (at 80° C.), not more than 0.2 percent.
Sulfated ash, not more than 0.3 percent.
Water-soluble matter, not more than 0.3 percent.
Matter, insoluble in carbon tetrachloride, not more than 0.5 percent.
Intermediates, not more than 0.05 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 99.0 percent.
Melting point, not less than 99° C.

EXT D&C YELLOW No. 10

SPECIFICATIONS

1-o-Tolylazo-2-naphthylamine.
Volatile matter (at 80° C.), not more than 0.2 percent.
Sulfated ash, not more than 0.3 percent.
Water-soluble matter, not more than 0.3 percent.
Matter, insoluble in carbon tetrachloride, not more than 0.5 percent.
Intermediates, not more than 0.05 percent.
Pure dye (as determined by titration with titanium trichloride), not less than 99.0 percent.
Melting point, not less than 120° C.

Effective date. The amendment of the color-certification regulations (§§ 9.3 and 9.5) promulgated by this order shall become effective 90 days after publication of this order in the FEDERAL REGISTER.

(Sec. 701, 52 Stat. 1055, as amended 70 Stat. 919, 72 Stat. 948; 21 U.S.C. 371. Interprets or applies secs. 406(b), 504, 604, 52 Stat. 1046, 1049, 1052; 21 U.S.C. 346(b), 354, 364)

Dated: January 27, 1959.

[SEAL] JOHN L. HARVEY,
Deputy Commissioner of Food and Drugs.

[F.R. Doc. 59-1054; Filed, Feb. 5, 1959; 8:49 a.m.]

SUBCHAPTER C—DRUGS

PART 141a—PENICILLIN AND PENICILLIN-CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

PART 146a—CERTIFICATION OF PENICILLIN AND PENICILLIN-CONTAINING DRUGS

Penicillin-Streptomycin- (or Dihydrostreptomycin-) Bacitracin Methylene Disalicylate-Neomycin Ointment

Under the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended; sec. 701, 52 Stat. 1055, as amended; 21 U.S.C. 357, 371) and delegated to the Commissioner of Food and Drugs by the Secretary (23 F.R. 9500), the regulations for tests and methods of assay and certification of penicillin and penicillin-containing drugs (21 CFR Parts 141a, 146a) are amended as follows:

1. Part 141a is amended by adding thereto the following new section:

§ 141a.98 Penicillin-streptomycin-bacitracin methylene disalicylate-neomycin ointment; penicillin-dihydrostreptomycin-bacitracin methylene disalicylate-neomycin ointment.

(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141a.8(a). Its penicillin content is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Streptomycin content.* Proceed as directed in § 141a.65(a)(2). Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(3) *Dihydrostreptomycin content.* Proceed as directed in § 141a.65(a)(3). Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(4) *Bacitracin methylene disalicylate content.* Proceed as directed in § 141a.49(a)(3). Its potency is satisfactory if it contains not less than 85 percent of the equivalent number of units of bacitracin that it is represented to contain.

(5) *Neomycin content.* Proceed as directed in § 141a.65(a)(4)(iii). Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.8(b).

2. Part 146a is amended by adding thereto the following new section:

§ 146a.20 Penicillin-streptomycin-bacitracin methylene disalicylate-neomycin ointment; penicillin-dihydrostreptomycin-bacitracin methylene disalicylate-neomycin ointment.

Penicillin-streptomycin-bacitracin methylene disalicylate-neomycin ointment and penicillin-dihydrostreptomycin-bacitracin methylene disalicylate-neomycin ointment conform to all requirements prescribed by § 146a.70 for penicillin-streptomycin-bacitracin methylene disalicylate ointment and penicillin-dihydrostreptomycin-bacitracin methylene disalicylate ointment, except that:

(a) Each dose, as recommended in its labeling, shall contain the equivalent of not less than 2,000 units of bacitracin and not less than 100 milligrams of neomycin. The neomycin used conforms to the standards prescribed by § 146e.410(a) of this chapter, except the standard for toxicity.

(b) In addition to the labeling prescribed by § 146a.70(a)(2), each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of neomycin in each prescribed dose.

(c) In addition to complying with the requirements of § 146a.70(a)(3), a person who requests certification of a batch shall submit with his request a statement showing the batch marks and (unless it was previously submitted) the results and date of the latest tests and assays of the neomycin used in making the batch for potency, moisture, and pH. He shall also submit in connection with his request (unless it was previously submitted) a sample consisting of 5 packages of the neomycin used in making the ointment, containing approximately equal portions of 0.5 gram each.

(d) The fees for the services rendered with respect to the sample submitted in accordance with paragraph (c) of this section shall be $4.00 for each immediate container of the neomycin used in making the ointment.

Notice and public procedure are not necessary prerequisites to the promulgation of this order, and I so find, since it was drawn in collaboration with interested members of the affected industry and since it would be against public interest to delay providing for tests and methods of assay and certification of the new antibiotic-containing drugs covered by this order.

Effective date. This order shall become effective upon publication in the FEDERAL REGISTER, since both the public and the affected industry will benefit by the earliest effective date, and I so find.

(Sec. 701, 52 Stat. 1055, as amended; 21 U.S.C. 371. Interprets or applies sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357)

Dated: January 30, 1959.

[SEAL] JOHN L. HARVEY,
Deputy Commisioner of Food and Drugs.

[F.R. Doc. 59-1052; Filed, Feb. 5, 1959; 8:49 a.m.]

PART 141d — CHLORAMPHENICOL AND CHLORAMPHENICOL-CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

PART 146d — CERTIFICATION OF CHLORAMPHENICOL AND CHLORAMPHENICOL-CONTAINING DRUGS

Chloramphenicol Sodium Succinate; Chloramphenicol Sodium Succinate for Aqueous Injection

Under the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended; sec. 701, 52 Stat. 1055, as amended; 21 U.S.C. 357, 371) and delegated to the Commissioner of Food and Drugs by the Secretary (22 F.R. 1045; 23 F.R. 9500), the regulations for tests and methods of assay and certification of chloramphenicol and chloramphenicol-containing drugs are amended by adding to 21 CFR, Parts 141d and 146d the following new sections:

§ 141d.314 Chloramphenicol sodium succinate.

(a) *Potency (by spectrophotometric assay)*—(1) *Working standard.* Prepare the standard stock solution by dissolving an appropriate amount (accurately weighed) of the chloramphenicol working standard in sterile distilled water to give a solution containing 20

μg. per milliliter. Using a suitable spectrophotometer, determine the absorbance of the solution in a 1-centimeter cell at 278 mμ compared with distilled water as a blank. Calculate the absorptivity as follows:

$$E^{1\%}_{1\text{ cm.}} = \frac{\text{absorbance at 278 m}\mu}{\text{grams of standard per 100 milliliters}}$$

(2) *Procedure.* Dissolve the sample to be tested in sufficient sterile distilled water to give a solution containing 30 μg. per milliliter. Using a suitable spectrophotometer, determine the absorbance of the solution in a 1-centimeter cell at 276 mμ compared with distilled water as a blank. Calculate the absorptivity as follows:

$$E^{1\%}_{1\text{ cm.}} = \frac{\text{absorbance at 276 m}\mu}{\text{grams of sample per 100 milliliters}}$$

Calculate the potency of the sample as follows:

$$\frac{E^{1\%}_{1\text{ cm.}} \text{ of sample}}{E^{1\%}_{1\text{ cm.}} \text{ of standard}} \times 1{,}000$$

=micrograms of chloramphenicol per milligram of chloramphenicol sodium succinate.

(b) *Sterility.* Using 40 milligrams from each container tested, proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(c) *Toxicity.* Use sterile physiological salt solution as the diluent, and proceed as directed in § 141a.4 of this chapter, using as a test dose 0.5 milliliter of a solution containing 2 milligrams of chloramphenicol activity per milliliter.

(d) *Pyrogens.* Use sterile physiological salt solution as the diluent and proceed as directed in § 141a.3 of this chapter, using as a test dose 1.0 milliliter per kilogram, of a solution containing 5 milligrams of chloramphenicol activity per milliliter.

(e) *Histamine.* Proceed as directed in § 141b.105 of this chapter, using as a test dose 0.6 milliliter of a solution containing 5 milligrams of chloramphenicol activity per milliliter.

(f) *Moisture.* Proceed as directed in § 141a.26(e) of this chapter.

(g) *pH.* Proceed as directed in § 141a.5(b) of this chapter, using an aqueous solution containing 200 milligrams per milliliter.

(h) *Specific rotation.* Accurately weigh the sample to be tested in a volumetric flask and dilute with sufficient distilled water to give a solution containing approximately 50 milligrams per milliliter. Transfer the solution to a tube of 1-decimeter length and determine the angular rotation in a suitable polarimeter, using sodium light or a 589.3-mμ filter, and calculate the specific rotation.

§ 141d.315 Chloramphenicol sodium succinate for aqueous injection.

(a) *Potency.* Dissolve the entire contents of each vial to be tested in the minimum volume of distilled water recommended in the labeling, withdraw the entire removable contents and further dilute with sufficient distilled water to give a concentration of 20 μg. per milliliter of chloramphenicol (estimated). With a suitable spectrophotometer, determine the absorbance of this solution in a 1-cm. cell at 276 mμ compared with distilled water as a blank. Also determine the absorbance of an aqueous solution of the chloramphenicol standard containing exactly 20 μg. per milliliter.

$$\text{Potency per vial} = \frac{\text{absorbancy of sample}}{\text{absorbancy of standard}} \times \text{labeled potency of vial (immediate container.)}$$

Its potency is satisfactory if it contains not less than 90 percent of the chloramphenicol activity that it is represented to contain.

(b) *Sterility.* Proceed as directed in § 141d.314(b).

(c) *Toxicity.* Proceed as directed in § 141d.314(c).

(d) *Pyrogens.* Proceed as directed in § 141d.314(d).

(e) *Histamine.* Proceed as directed in § 141d.314(e).

(f) *Moisture.* Proceed as directed in § 141d.314(f).

(g) *pH.* Proceed as directed in § 141d.314(g).

§ 146d.314 Chloramphenicol sodium succinate.

(a) *Standards of identity, strength, quality, and purity.* Chloramphenicol sodium succinate is the light-yellow, water-soluble, ethanol-insoluble crystalline sodium salt of the 3-monosuccinate ester of chloramphenicol. It is so purified and dried that:

(1) Its potency is not less than 650 μg. per milligram.

(2) It is sterile.

(3) It is nontoxic.

(4) It is nonpyrogenic.

(5) It contains no histamine nor histamine-like substances.

(6) Its moisture content is not more than 5.0 percent.

(7) The pH of an aqueous solution containing 200 milligrams per milliliter is not less than 6.4 and not more than 7.0.

(8) Its specific rotation in an aqueous solution containing 50 milligrams per milliliter at 25° C. is +6.5° ±1.5°.

(b) *Packaging; labeling; request for certification, samples; fees.* Chloramphenicol sodium succinate conforms to all requirements and procedures prescribed for chloramphenicol by § 146d.301 (b), (c), (d), and (e), except that:

(1) The expiration date shall be the date that is 36 months after the month during which the batch was certified.

(2) The request for certification shall be accompanied or followed by the results of tests and assays of the batch for potency, sterility, toxicity, pyrogens, histamine, moisture, pH, and specific rotation.

(3) When a batch is packaged for repacking or for use as an ingredient in the manufacture of another drug, each package submitted for sterility testing shall contain approximately 500 milligrams of the drug in lieu of 40 milligrams.

§ 146d.315 Chloramphenicol sodium succinate for aqueous injection.

(a) *Standards of identity, strength, quality, and purity.* Chloramphenicol sodium succinate for aqueous injection is a dry mixture of chloramphenicol sodium succinate and one or more suitable and harmless buffer substances and preservatives. It is so purified that:

(1) It is sterile.

(2) It is nontoxic.

(3) It is nonpyrogenic.

(4) It contains no histamine nor histamine-like substances.

(5) Its moisture content is not more than 5 percent.

(6) The pH of a solution prepared as directed in its labeling is not less than 6.4 and not more than 7.0.

The chloramphenicol sodium succinate used conforms to the requirements prescribed by § 146d.314(a), except that it is exempt from the requirements of § 146d.314(a) (2) and (4) when the chloramphenicol sodium succinate for aqueous injection, in which it is used, has been rendered sterile and pyrogen-free. Each other ingredient used, if its name is recognized in the U.S.P. or N.F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging; labeling; request for certification, samples; fees.* Chloramphenicol sodium succinate for aqueous injection conforms to the requirements and procedures prescribed by § 146d.307 (b), (c), (d), and (e) for chloramphenicol for aqueous injection, except that:

(1) The expiration date of the drug shall be 36 months.

(2) In lieu of the requirements specified by § 146d.307(d)(2), a person who requests certification of a batch shall submit in connection with his request results of tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: Potency, sterility, toxicity, pyrogens, histamine content, moisture, and pH.

(ii) The chloramphenicol sodium succinate used in making the batch: Potency and specific rotation.

Notice and public procedure are not necessary prerequisites to the promulgation of this order, and I so find, since it was drawn in collaboration with interested members of the affected industry and since it would be against public interest to delay providing for tests and methods of assay and certification of these new antibiotic drugs.

Effective date. This order shall become effective upon publication in the FEDERAL REGISTER, since both the public and the affected industry will benefit by the earliest effective date, and I so find.

(Sec. 701, 52 Stat. 1055, as amended; 21 U.S.C. 371. Interprets or applies sec. 507, 59 Stat. 463, as amended; 21 U.S.C. 357)

Dated: January 30, 1959.

[SEAL] JOHN L. HARVEY,
Deputy Commissioner of Food and Drugs.

[F.R. Doc. 59-1053; Filed, Feb. 5, 1959; 8:49 a.m.]