

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

§ 176.180 [Amended]

1. In § 176.180 *Components of paper and paperboard in contact with dry food*, paragraph (b)(2), by deleting the entry for "Sorbos" from the list of substances.

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§ 182.70 [Amended]

2. In § 182.70 *Substances migrating from cotton and cotton fabrics used in dry food packaging*, by deleting the entry for "Sorbos" from the list of substances.

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

3. By adding new § 186.1839 to read as follows:

§ 186.1839 Sorbose.

(a) Sorbose (L-sorbose, sorbinose) ($C_6H_{12}O_6$, CAS Reg. No. 87-79-6) is an orthorhombic, bisphenoidal crystalline ketohexose. It was originally identified in the juice of mature berries from the mountain ash (*Sorbus aucuparia*) where it occurs as the result of microbial oxidation of sorbitol. It also occurs naturally in other plants. Sorbose can be synthesized by the catalytic hydrogenation of glucose to D-sorbitol. The resulting sorbitol can be oxidized by *Acetobacter xylinum* or by *Acetobacter suboxydans*.

(b) The following specifications are recognized by the Food and Drug Administration as suitable for sorbose when permitted for indirect food use:

Assay—not less than 95 percent.

Melting point— $165^{\circ}C \pm 2^{\circ}C$.

Optical rotation—between -42.9° and -43.2° at $20^{\circ}C$.

Density—between 1.650 and 1.654 at $15^{\circ}C$.

Total heavy metals (as lead, Pb)—not more than 40 ppm.

Arsenic (as As)—not more than 3 ppm.

(c) The ingredient is used or intended for indirect food use as a constituent of cotton, cotton fabrics, paper, and paperboard in contact with dry food.

(d) The ingredient migrates to food at levels not to exceed good manufacturing practice.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Effective date: This regulation is effective April 20, 1978.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a)).)

Dated: March 13, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 78-7374 Filed 3-20-78; 8:45 am]

[4110-03]

[Docket No. 77N-0036]

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

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

Potassium Iodide and Potassium and Calcium Iodates

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that potassium iodide and potassium and calcium iodates are generally recognized as safe for use as direct human food ingredients with specific limitations. The safety of these ingredients has been evaluated under the comprehensive safety review being conducted by this agency.

EFFECTIVE DATE: This regulation shall be effective April 20, 1978.

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 June 10, 1977 (42 FR 29925), a proposal was published to affirm that potassium iodide and potassium and calcium iodates are generally recognized as safe (GRAS) for use as direct human food ingredients with specific limitations. The proposal was made on the initiative of the Commissioner of Food and Drugs. This action is in accord with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 relating to the affirmation of GRAS food ingredients, copies of the Scientific Literature Review of iodine and iodine salts, a report of mutagenic tests on potassium iodide, and the report of the Select Committee on GRAS Substances have been made available for public review in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

In addition to proposing to affirm the GRAS status of potassium iodide

and potassium and calcium iodates with specific limitations, the Commissioner gave public notice that he was unaware of any prior-sanctioned food ingredient use for these ingredients other than for the proposed conditions of use. Persons asserting additional or extended uses, in accordance with approvals granted by the U.S. Department of Agriculture or the Food and Drug Administration prior to September 6, 1958, were given notice to submit proof of such sanction so that the safety of the prior-sanctioned use could be determined at this time. That notice was also an opportunity to have prior-sanctioned uses of potassium iodide and potassium and calcium iodates approved by issuance of an appropriate regulation under part 181—Prior-Sanctioned Food Ingredients (21 CFR part 181). *Provided*, The prior-sanctioned use could be affirmed as safe on the basis of information and data no available to the Commissioner. Notice was also given that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert such sanction at any future time.

No reports of prior-sanctioned uses for potassium iodide, and potassium and calcium iodates were submitted in response to the proposal. Therefore, in accordance with that proposal, any right to assert a prior sanction for a use of potassium iodide, and potassium and calcium iodates under conditions different from those set forth in this regulation has been waived.

No comments were received in response to the Commissioner's proposal and supporting data and information on potassium iodide, and potassium and calcium iodates. However, an oral inquiry was concerned with whether this regulation could be construed to imply that increased levels of iodine pose no potential human health hazards. The Commissioner wishes to stress that this regulation deals only with very limited uses of iodine at current levels of use. This regulation does not address any potential problems associated with increasing the total dietary intake of iodine. If new information concerning the adverse health effects of excess dietary iodine necessitates, a separate regulation restricting the use of iodine compounds in food or food-producing animals will be published. The Commissioner concludes that no change in the proposal to affirm the GRAS status of potassium iodide, and potassium and calcium iodates for the specific uses cited in these regulations (21 CFR 184.1206, 184.1614, and 184.1635) is warranted. Accordingly, it is being promulgated without change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(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), parts 182 and 184 are amended as follows:

§ 182.5634 [Deleted]

1. In part 182 by deleting § 182.5634 Potassium iodide.

2. In part 184 by adding new §§ 184.1206, 184.1634, and 184.1635 to read as follows:

§ 184.1206 Calcium iodate.

(a) Calcium iodate $[Ca(IO_3)_2 \cdot H_2O]$, CAS Reg. No. 7789-80-21, also referred to as lautarite, does not occur naturally but can be prepared by passing chlorine into a hot solution of lime ($CaCO_3$) in which iodine has been dissolved.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).¹

(c) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter.

(d) The ingredient is used in the manufacture of bread in accordance with § 184.1(b)(2) of this chapter in an amount not to exceed 0.0075 percent based on the weight of the flour.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 184.1634 Potassium iodide.

(a) Potassium iodide (KI, CAS Reg. No. 7681-11-0) is the potassium salt of hydriodic acid. It occurs naturally in sea water and in salt deposits, but can be prepared by reacting hydriodic acid (HI) with potassium bicarbonate ($KHCO_3$).

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).¹

(c) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(d) The ingredient is used in table salt in accordance with § 184.1(b)(2) of this chapter as a source of dietary iodine at a maximum level of 0.01 percent.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

§ 184.1635 Potassium iodate.

(a) Potassium iodate (KIO_3 , CAS Reg. No. 7758-05-6) does not occur naturally but can be prepared by reacting iodine with potassium hydroxide.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 2d Ed. (1972).¹

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

(c) The ingredient is used as a dough strengthener as defined in § 170.3(o)(6) of this chapter.

(d) The ingredient is used in the manufacture of bread in accordance with § 184.1(b)(2) of this chapter in an amount not to exceed 0.0075 percent based on the weight of the flour.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Effective date: This regulation is effective April 20, 1978.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a)).)

Dated: March 15, 1978.

NOTE.—Incorporation by reference approved by the Director of the Federal Register on July 10, 1973, and is on file in the Federal Register Library.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 78-7370 Filed 3-20-78; 8:45 am]

[4110-03]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 510—NEW ANIMAL DRUGS

Subpart G—Sponsors of Approved Applications

EVSCO PHARMACEUTICAL CORP.;
CHANGE OF SPONSOR ADDRESS

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: This document amends the animal drug regulations to reflect change of corporate address as requested by the sponsor, Evsco Pharmaceutical Corp.

EFFECTIVE DATE: March 21, 1978.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Under section 512(i) of the Federal Food, Drug, and Cosmetic Act, § 510.600 Names, addresses, and code numbers of sponsors of approved applications (21 CFR 510.600) of the animal drug regulations is amended to reflect a change of corporate address. This amendment to the regulations reflects approval of the following supplemental NADA's:

NADA No., and drug name and form

- 32-322 Prednisolone-neomycin sulfate-tetracaine-hexamethyltetracosane ointment.
- 32-984 Squalane-pyrethrins-piperonyl butoxide otic solution.
- 44-655 Neomycin sulfate ophthalmic ointment.
- 45-288 Neomycin sulfate-prednisolone ophthalmic ointment.
- 45-626 Kaolin-pectin-neomycin sulfate-methscopolamine bromide liquid (oral).
- 55-005 Chloramphenicol-prednisolone-tetracaine-squalane otic suspension.
- 55-034 Chloramphenicol ophthalmic solution.
- 55-052 Chloramphenicol tablets (oral).
- 65-157 Chloramphenicol-prednisolone ophthalmic ointment.
- 65-158 Chloramphenicol ophthalmic ointment.
- 65-259 Chloramphenicol-prednisolone ophthalmic ointment.
- 100-689 Diethylcarbamazine citrate syrup.
- 100-690 Diethylcarbamazine citrate tablets (oral).

Amendment of the regulations to reflect this change does not require a reevaluation of the NADA's nor does it constitute a reaffirmation of the drugs' safety and effectiveness.

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), § 510.600(c)(1) and (2) are amended by revising the address of Evsco Pharmaceutical Corp. as follows:

§ 510.600 Names, addresses, and code numbers of sponsors of approved applications.

(c) * * *

(1) * * *

Firm name and address and drug listing No.

Evsco Pharmaceutical Corp., P.O. Box 209, Harding Highway, Buena, N.J. 08310; 017030

(2) * * *

Drug listing No. firm name and address:

017030—Evsco Pharmaceutical Corp., P.O. Box 209, Harding Highway, Buena, N.J. 08310.

Effective date: March 21, 1978.

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

Dated: March 14, 1978.

C. D. VAN HOUWELING,
Director, Bureau of Veterinary
Medicine.

[FR Doc. 78-7372 Filed 3-20-78; 8:45 am]

[4110-03]

[Docket No. 75N-0020]

**PART 540—PENICILLIN ANTIBIOTIC
DRUGS FOR ANIMAL USE****Reinstatement of Certain Provisions**

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document reinstates provisions for the certification of a new animal drug containing penicillin G procaine with procaine hydrochloride. The provisions were inadvertently deleted by a previous document.

EFFECTIVE DATE: March 21, 1978.

FOR FURTHER INFORMATION CONTACT:

Frank G. Pugliese, Bureau of Veterinary Medicine (HFV-234), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3460.

SUPPLEMENTARY INFORMATION:

In the FEDERAL REGISTER of November 22, 1977 (42 FR 59852), Part 440 (21 CFR Part 440) was amended and revised to update the provisions for certification of antibiotic drugs for human use. A comment on the regulation properly pointed out that the amendment to § 440.255c *Sterile penicillin G benzathine G procaine suspension* (21 CFR 440.255c) not only deleted provisions for certification for human use of the drug containing procaine hydrochloride, but also inadvertently deleted provisions for its certification as an animal drug. The deletion occurred because § 540.255c, which continues to provide for use of the drug in animals, cross-references and incorporates the certification provisions of § 540.255c. Section § 440.255c is therefore being amended to reinstate and include certain provisions for certification of the animal drug.

Therefore, under the Federal Food, Drug, and Cosmetic Act, (secs. 507, 512, 59 Stat. 463 as amended, 82 Stat. 343-351 (21 U.S.C. 357, 360b)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 540 is amended by revising § 540.255c(b) to read as follows:

§ 540.255c *Sterile benzathine penicillin G and procaine penicillin G suspension.*

(b) *Tests and methods of assay.* The tests and methods of assay for benzathine penicillin G and procaine penicillin for aqueous injection are described in § 440.255c of this chapter, except that if the drug contains procaine hydrochloride, total potency, benzathine penicillin G content, and

procaine penicillin G content are determined as follows:

(1) *Total potency.* Place one dose of the suspension in each of two centrifuge tubes. Label one tube "sample" and the other "blank." Add 9.0 milliliters of 20-percent sodium sulfate solution to each tube and mix well. Centrifuge them at 10,000 r/min for 15 minutes or until a clear supernatant solution is obtained. Pour the supernatant solution from the sample tube into a 50-milliliter volumetric flask and dilute to mark with 1 percent pH 6.0 buffer. Determine the amount of penicillin in this flask by the iodometric assay procedure as directed in § 436.204 of this chapter. Wash the penicillin residue from the tube labeled "sample" into a 200-milliliter volumetric flask quantitatively with about 150 milliliters of water. Add 10 milliliters of 1.0N sodium hydroxide and allow to stand for 15 minutes. Acidify the solution with 10 milliliters of 1.2N hydrochloric acid and dilute to mark with water. Determine the amount of penicillin in this solution by the iodometric assay procedure. Use as a blank a suspension prepared by discarding the supernatant from the tube labeled "blank," washing the penicillin residue into a 200-milliliter volumetric flask, and making to mark with water. The total potency of the dose is the sum of the penicillin in the sample supernatant solution and in the insoluble residue of the sample.

(2) *Procaine penicillin content.* Transfer 5.0 milliliters of the solution from the 200-milliliter volumetric flask containing the residue from the "sample" tube to a 50-milliliter volumetric flask and make to mark with water. Assay 2.0 milliliters of the solution by the Bratton-Marshall method. The amount of procaine penicillin is the sum of the amount of penicillin in the sodium sulfate supernatant solution and the amount of penicillin determined by the Bratton-Marshall method.

(3) *Benzathine penicillin content.* The amount of benzathine penicillin is the difference between the total potency and the amount of procaine penicillin.

Effective date: March 21, 1978.

(Secs. 507, 512, 59 Stat. 463 as amended, 82 Stat. 343-351 (21 U.S.C. 357, 360b).)

Dated: March 13, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 78-7368 Filed 3-20-78; 8:45 am]

[1505-01]

**PART 540—PENICILLIN ANTIBIOTIC
DRUGS FOR ANIMAL USE****Amoxicillin Trihydrate Oral
Suspension****Correction**

In FR Doc. 78-2722 appearing on page 4601 in the issue of Friday, February 3, 1978 in the "SUMMARY" paragraph, the 5th line should read, "[Laboratories providing for oral use of an amoxicillin-lin]."

[4110-03]

[Docket No. 77F-0184]

**PART 573—FOOD ADDITIVES PER-
MITTED IN FEED AND DRINKING
WATER OF ANIMALS****Selenium**

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration is amending the food additive regulations to provide for the safe use of selenium in sheep feed. A petition was filed by the American Feed Manufacturers Association requesting such use.

DATES: Effective March 21, 1978; objections by April 20, 1978.

FOR FURTHER INFORMATION CONTACT:

William D. Price, Bureau of Veterinary Medicine (HFV-123), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3442.

SUPPLEMENTARY INFORMATION: Notice was given in the FEDERAL REGISTER of October 21, 1977 (42 FR 56154), that a food additive petition (MF 3433) had been filed by American Feed Manufacturers Association, 1701 North Fort Myer Drive, Arlington, Va. 22209, proposing that § 573.920 *Selenium* (21 CFR 573.920) be amended to provide for the safe use of selenium in the feed of sheep.

The Commissioner of Food and Drugs, having evaluated data in the petition and other relevant material, concludes that the food additive regulation § 573.920 should be amended to provide for the use of the petitioned additive.

The environmental impact analysis report and other relevant material