Ethylene 1,4-cyclohexylene dimethylene terephthalate copolymers	Inherent viscosity	Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/ square centimeter of food-contact surface)	Test for orientability	Conditions of use
* *	*	*	*	* *
3. Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 95 mole percent of ethylene glycol and 1 to 5 mole percent of 1,4-cyclohexanedimethanol (70 percent *trans* isomer, 30 percent *cis* isomer).	No test required .	For each corresponding condition of use, must meet specifications described in § 177.1630(f), (g), (h), or (j).	No test required	For each corresponding specification, may be used as a base sheet and base polymer in accordance with conditions of use described in § 177.1630(f), (g), (h), or (j).

* * * * *

3. Section 177.1630 is amended by revising paragraphs (a), (b), and the introductory text of paragraph (j) and by amending paragraph (e)(4)(ii) by alphabetically adding a new substance to the ''List of Substances and Limitations'' to read as follows:

§ 177.1630 Polyethylene phthalate polymers.

* * * * *

(a) Polyethylene phthalate films consist of a base sheet of ethylene terephthalate polymer, ethylene terephthalate-isophthalate copolymer, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in § 177.1315(b)(3), to which have been added optional substances, either as constituents of the base sheet or as constituents of coatings applied to the base sheet.

(b) Polyethylene phthalate articles consist of a base polymer of ethylene terephthalate polymer, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in § 177.1315(b)(3), to which have been added optional substances, either as constituents of the base polymer or as constituents of coatings applied to the base polymer.

* * * * *

(e) * * *

(4) * * *

(ii) * * *

Ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in § 177.1315(b)(3).

* * * * *

(j) Polyethylene phthalate plastics, composed of ethylene terephthalate-isophthalate containing a minimum of 98 weight percent of polymer units derived from ethylene terephthalate, or ethylene-1,4-cyclohexylene dimethylene terephthalate copolyesters described in § 177.1315(b)(3), conforming with the specifications prescribed in paragraph (j)(1) of this section, are used as provided in paragraph (j)(2) of this section.

Dated: November 10, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–28545 Filed 11–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 310, 355, and 369

[Docket No. 80N–0042]

RIN 0910–AA01

Anticaries Drug Products for Over-The-Counter Human Use; Final Monograph; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the Federal Register of October 6, 1995 (60 FR 52474). The document established conditions under which over-the-counter (OTC) anticaries drug products (products that aid in the prevention of dental cavities) are generally recognized as safe and effective and not misbranded. The document was published with some errors. This document corrects those errors.

EFFECTIVE DATE: October 7, 1996.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2304.

SUPPLEMENTARY INFORMATION: In FR Doc. 95–24693, appearing on page 52474 in the Federal Register of Friday, October 6, 1995, the following corrections are made:

1. On page 52484, in the first column, in the first full paragraph, beginning in the 12th line from the bottom, the phrase ''as the following: 'anticavity fluoride' (select one of the following'' is corrected to read ''as: (select one or both of the following: 'anticavity' or 'fluoride' ''.

2. On page 52504, in the table, in the entry for ''Sodium monofluorophosphate (1,500 ppm):'', the designation ''NM'' is removed. § 355.50 [Corrected]

3. One page 52508, in the third column, in § 355.50 Labeling of anticaries drug products, in paragraph (a), beginning in line 4, the phrase ''as the following: 'anticavity fluoride' (select one of the following'' is corrected to read ''as: (select one or both of the following: 'anticavity' or 'fluoride')''.

Dated: November 16, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–28600 Filed 11–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Semduramicin; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations that reflect approval of a new animal drug application (NADA) filed by Pfizer, Inc. The previous amendment, which appeared in the Federal Register of April 13, 1994 (59 FR 17476), provided for making a semduramicin Type A medicated article used to make a Type C medicated broiler chicken feed for the prevention of coccidiosis. The agency has since realized it needs to more accurately reflect both the assay limits for semduramicin Type A articles and the limitation for its use. This action is being taken to ensure the accuracy and consistency of the regulations.

EFFECTIVE DATE: November 24, 1995.

FOR FURTHER INFORMATION CONTACT: Thomas Letonja, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1656.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 13, 1994 (59 FR 17476), FDA published a final rule to announce the approval of Pfizer's new animal drug application (NADA) 140–940. The NADA provides for use of Aviax™ (semduramicin sodium) Type A medicated article to make a semduramicin Type C medicated broiler chicken feed used for the prevention of coccidiosis. That document inadvertently failed to reflect the correct assay limits for Type A medicated articles in 21 CFR 558.4 and the correct limitation for use in 21 CFR 558.555(b)(1)(iii). This document corrects those errors. Due to these amendments, FDA is also providing an amended freedom of information (FOI) summary for public display. The FOI summary has been amended to reflect the correct assay limits and efficacy evaluation. The amended copy of the FOI summary is available at the Dockets Management Branch (HFA–305), 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.4 [Amended]

2. Section 558.4 *Medicated feed applications* is amended in paragraph (d) in the ''Category I'' table in the entry for ''Semduramicin'' under the second column by removing ''94–102'' and adding in its place ''90–110''.

§ 558.555 [Amended]

3. Section 558.555 *Semduramicin* is amended in paragraph (b)(1)(iii) by removing the last sentence.

Dated: November 13, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–28598 Filed 11–22–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Hoffmann-La Roche, Inc. The supplemental NADA provides for use of a 20-percent lasalocid Type A medicated article in making a Type C medicated feed for rabbits used as a coccidiostat.

EFFECTIVE DATE: November 24, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.