in the use of [phthalocyaninato(2-)] copper in contact lenses.

FDA gave interested persons until November 28, 1986, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA had concluded that the final rule published in the Federal Register of October 28, 1986, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the October 28, 1986, final rule. Accordingly, the amendments promulgated thereby became effective November 28, 1986.

Dated: March 6, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87–5446 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Parts 331, 332, and 357

[Docket No. 82N–0154]

Labeling of Drug Products for Over-The-Counter Human Use; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that changed its "exclusivity" policy for labeling of over-the-counter (OTC) drug products. This document indicates that specific paragraphs in 21 CFR 331.130(b), 332.30(a), and 357.250(b) where other statements describing indications for use are located. By indicating these specific paragraphs, FDA will eliminate the ambiguity associated with the use of the term "above".

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug and Biologics (HFN–210), Food and Drugs Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In FR Doc. 86–9720, appearing on page 16258 in the issue of Thursday, May 1, 1986, the following corrections are made:

§ 331.30 [Corrected]

1. On page 16266, in the third column under § 331.30 *Labeling of antacid products,* paragraph (b), 14th line, "above" is corrected to read "in this paragraph (b)".

§ 332.30 [Corrected]

2. On page 16266, in the third column under § 332.30 *Labeling of antiflatulent products,* paragraph (a), 9th line, "above" is corrected to read "in this paragraph (a)".

§ 357.250 [Corrected]

3. On page 16267, in the second column under § 357.250 *Labeling of cholecystokinetic drug products,* paragraph (b), 9th line "above" is corrected to read "in this paragaph (b)".

Dated: March 5, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–5382 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 341

[Docket No. 75N–052B]

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Monograph for OTC Bronchodilator Drug Products; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that established conditions under which over-the-counter (OTC) bronchodilator drug products (drug products used in the symptomatic treatment of wheezing and shortness of breath of asthma) are generally recognized as safe and effective and not misbranded. This document indicates the specific paragraph in 21 CFR 341.76(b) where other statements describing indications for use are located. By indicating this specific paragraph, FDA will eliminate the ambiguity associated with the use of the term "below."

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In FR Doc. 86–22151, appearing on page 35326 in the issue of Thursday, October 2, 1986, the following correction is made on page 35339: In the third column under § 341.76 *Labeling of bronchodilator drug products,* paragraph (b), 8th line, "below" is corrected to read "in this paragraph (b)".

Dated: March 5, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–5380 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 344

[Docket No. 77N–0334]

Topical Otic Drug Products for Over-the-Counter Human Use; Final Monograph; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that established conditions under which over-the-counter (OTC) topical otic drug products (drug products for the ear) are generally recognized as safe and effective and not misbranded. This document indicates the specific paragraph in 21 CFR 344.50(b) where other statements describing indications for use are located. By indicating this specific paragraph, FDA will eliminate the ambiguity associated with the use of the term "above."

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In FR Doc. 86–17854, appearing on page 28656 in the issue of Friday, August 8, 1986, the following correction is made on page 28661: In the second column under § 344.50 *Labeling of topical otic drug products,* paragraph (b), 10th line, "above" is corrected to read "in this paragraph (b)".

Dated: March 5, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–5381 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 357

[Docket No. 79N–0378]

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

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that established conditions under which over-the-counter (OTC) anthelmintic drug products (products that destroy pinworms) are generally recognized as safe and effective and not misbranded. This document indicates the specific paragraph in 21 CFR 357.150(b) where other statements describing indications for use are located. By indicating this specific paragraph, FDA will eliminate the ambiguity associated with the use of the term "above."

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In FR Doc. 86–17180, appearing on page 27756 in the issue of Friday, August 1, 1986, the following correction is made on page 27759: In the second column under § 357.150 *Labeling of anthelmintic drug products,* paragraph (b), 8th line, "above" is corrected to read "in this paragraph (b)".

Dated: March 5, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–5379 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Parts 510, 520, 522, 524, and 529

Animal Drugs, Feeds, and Related Products; Change of Sponsor; Labeler Code; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect (1) a change of sponsor of several new animal drug applications (NADA's) from Burns-Biotec Laboratories, Inc., to Schering Corp. and (2) a change of sponsor of an NADA to Summit Hill Laboratories from Burns-Biotec Laboratories, Inc. The regulations are also amended to designate the correct drug labeler code assigned to Shering Corp. for its veterinary drug products.

EFFECTIVE DATE: March 13, 1987.

FOR FURTHER INFORMATION CONTACT: John W. Borders, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6243.

SUPPLEMENTARY INFORMATION: Burns-Biotec Laboratories, Inc., 8530–8536 K St., P.O. Box 3113, Omaha, NE 68103, has informed FDA of a change of sponsor for NADA 48–854, glyceryl guaiacolate injection for horses, to Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752. The NADA provides for the intravenous use of glyceryl quaiacolate as a muscle relaxant in horses. Summit Hill Laboratories (drug labeler code 037990) has confirmed the change of sponsor. Summit Hill has also filed a supplemental NADA containing updated manufacturing facilities, methods, and controls information

Schering Corp., Galloping Hill, Rd., Kenilworth, NJ 07933, filed several supplemental NADA's providing for a change of sponsor from its subsidiary, Burns-Biotec Laboratories, Inc. The NADA's affected are:

NADA	Product	Ingredient
9–167	P.L.H. (cattle, horses, swine, sheep, dogs).	Pituitary luteninizing hormone for injection.
9–505	F.S.H.-P. (cattle, horses, swine, sheep, dogs).	Follicle stimulating hormone-pituitary for injection.
10–793	Nonemic (swine)	Iron dextran injection.
12–635	BO-SE and L-SE (calves, lambs, ewes, sows).	Sodium selenite, vitamin E injection.
30–313	Seletoc Caps and Minicaps (dogs).	Sodium selenite, vitamin E.
30–314	MU-SE (cattle, calves, swine)	Sodium selenite, vitamin E injection.
30–315	E-SE (equine)	Sodium selenite, vitamin E injection.
30–316	Selectoc injection (horses, dogs).	Sodium selenite vitamin E injection.
31–971	Cuprate (cattle)	Cupric glycinate injection.
40–322	Kymar (intment Improved (horses, dogs, cats).	Neomycin pamitate, hydrocortisone acetate.
46–288	Histavet-P (horses)	Pyrilamine maleate injection.
119–807	Beuthanasia-D Special (dogs)	Euthanasia solution.

The change of sponsor to Schering Corp. does not involve any changes in current manufacturing facilities, equipment, procedures, or production personnel. FDA is amending the regulations to reflect the change of sponsor.

FDA is amending 21 CFR 510.600(c) (1) and (2) and the sponsor paragraphs of 21 CFR 520.540a, 520.540b, 520.970a. 520.970b, 520.1044a, 520.1044b, 520.1044c, 520.1100, 520.1341, 520.2100, 520.2473a, 522.161, 522.163, 522.518, 522.540. 522.900, 522.970, 522.1044, 522.1060b, 522.1182, 522.1820, 522.1822, 522.1890, 522.2063, 522.2100, 524.1044a, 524.1044b, 524.1044c, 524.1044d, 524.1044e, 524.1044f, 524.2350, 529.1044a, and 529.1044b providing for use of the veterinary drug products currently sponsored by Schering; this action is required to change the drug labeler code currently used in those regulations from 000085 to 000061. Schering has been assigned drug labeler code 000085 for human drug products and 000061 for veterinary drug products. Therefore, the regulations are amended to insert the correct labeler code.

FDA is also amending 21 CFR 510.600(c)(1) and (2) to remove Burns-Biotec Laboratories, Inc. because it is no longer the sponsor of any approved NADA's.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 529

Animal drugs.

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, Parts 510, 520, 524, and 529 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR Part 510 continues to read as follows:

Authority: Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a)); 21 CFR 5.10 and 5.83.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in paragraph (c)(1) in the entry for Schering Corp. by revising the drug labeler code to read "000061" and by removing the entry for Burns-Biotec Laboratories, Inc., and in paragraph (c)(2) by revising the entry for "000085" to read "000061" and numerically inserting it in proper sequence, and by removing the entry for "000845".

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

3. The authority citation for 21 CFR Part 520 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.