Drug labeler code	Firm Name and address
* * *	* * * *
099207	Medicis Dermatologics, Inc., 4343 East Camelback Rd., suite 250, Phoenix, AZ 85018–2700.
* * *	* * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.981a [Amended]

4. Section 524.981a *Fluocinolone acetonide cream* is amended in paragraph (b) by removing ''000033'' and adding in its place ''099207''.

§ 524.981b [Amended]

5. Section 524.981b *Fluocinolone acetonide solution* is amended in paragraph (b) by removing ''000033'' and adding in its place ''099207''.

§ 524.981c [Amended]

6. Section 524.981c *Fluocinolone acetonide, neomycin sulfate cream* is amended in paragraph (b) by removing ''000033'' and adding in its place ''099207''.

Dated: July 23, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–20248 Filed 7-30-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Animal Drugs, Feeds, and Related Products; Change of Sponsor; Corrections

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of June 30, 1997 (62 FR 35075 at 35076). The document amended the animal drug regulations to reflect the change of sponsor for 52 approved new animal drug applications (NADA's) from Fermenta Animal Health Co. to Boehringer Ingelheim Animal Health, Inc. The document was published with two inadvertent errors. This document corrects those errors.

EFFECTIVE DATE: July 31, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

In FR Doc. 97–16967, appearing on page 35075, in the **Federal Register** of Monday, June 30, 1997, the following corrections are made: On page 35076, in the first column, in amendment 11, in the third line, ''(a)(6)'' is corrected to read ''(b)(6)''; and on the same page, in the second column, in amendment 19, beginning in the fourth line, ''000069, 054273, and 057561'' is corrected to read ''000069, 054273, 057561, and 059130''.

Dated: July 21, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–20250 Filed 7-30-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Apramycin

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 two supplemental new animal drug applications (NADA's) filed by Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA's provide for revised tolerances for total residues of apramycin (i.e., the safe concentration) in edible swine tissues.

EFFECTIVE DATE: July 31, 1997.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, is sponsor of supplemental NADA 106–964 that provides for the use of Apralan® (apramycin sulfate) soluble powder in swine drinking water and supplemental NADA 126–050 that provides for the use of Apralan® (apramycin sulfate) Type A medicated article in swine feed, both for control of porcine colibacillosis (weanling pig scours) caused by strains of *Escherichia coli* sensitive to apramycin. These supplemental NADA's provide for a change in the tolerance for total residues of apramycin (i.e., the safe concentration) in edible swine tissues as provided in § 556.52 (21 CFR 556.52). Review of these supplements involved a review of new toxicology studies and information in the original approvals.

In evaluating these supplements, FDA's Center for Veterinary Medicine also considered that the proof of human food safety for antimicrobial animal drug residues includes a determination of their antimicrobial activity for all antimicrobial new animal drug products. In the absence of studies to determine the microbiological safety of antimicrobial drug residues, the acceptable daily intake (ADI) for apramycin is limited to 25 micrograms per kilogram (μg/kg) of body weight per day (for appropriate studies see ''Guidance: Microbial Testing of Antimicrobial Drug Residues in Food,'' January, 1996). As indicated in the freedom of information summaries, the safe concentration for total apramycin residues is established at 5 parts per million (ppm) for muscle, 15 ppm for liver, and 30 ppm for fat and kidney. These revised safe concentrations warrant removal of the existing tolerances for total residues in § 556.52, because those tolerances are now incorrect. Because this approval does not result in a different tolerance than that currently codified for marker residue in swine kidney, and because the sponsor did not petition FDA to change the tolerance, the tolerance of 0.1 ppm in swine kidney remains codified. FDA is also codifying the ADI for apramycin of 25 μg/kg of body weight per day. The supplement is