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

approved as of June 24, 1997, and the regulations in § 556.52 are revised to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 556

Animal drugs, Foods.

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 556 is amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: Secs. 402, 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 360b, 371).

2. Section 556.52 is revised to read as follows:

§ 556.52 Apramycin.

A tolerance of 0.1 part per million is established for parent apramycin (marker residue) in kidney (target tissue) of swine. The acceptable daily intake (ADI) for total residues of apramycin is 25 micrograms per kilogram of body weight per day.

Dated: July 21, 1997.

Robert C. Livingston,

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

[FR Doc. 97–20081 Filed 7-30-97; 8:45 am]

BILLING CODE 4160–01–F

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

29 CFR Part 2200

Rules of Procedure for E–Z Trials

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Final Rule.

SUMMARY: This document eliminates the sunset provision from the procedures governing the E–Z Trial program and continues the E–Z Trial program as part of the Commission Rules of Procedure, as codified in Title 29 of the Code of Federal Regulations as Part 2200. In addition, this document implements revisions to the procedural rules governing the E–Z Trial program which are intended to assist the E–Z Trial process in meeting its objective of allowing parties in less complex cases to argue their cases before the Commission with as few legal formalities as possible.

DATES: Effective July 31, 1997.

FOR FURTHER INFORMATION CONTACT: Earl R. Ohman, Jr., General Counsel, (202) 606–5410, Occupational Safety and Health Review Commission, 1120 20th Street NW, 9th Floor, Washington DC 20036–3419.

SUPPLEMENTARY INFORMATION: On June 24, 1997, the Occupational Safety and Health Review Commission published in the **Federal Register** (62 FR 34031) proposed changes to the procedural rules governing the E–Z Trial program. The Commission would like to thank those who took the time and interest to submit comments.

The Secretary of Labor responded by stating that it appears that many of the concerns she initially had with the E–Z Trial program can be avoided if the Commission continues to exercise sound judgment in the designation of cases for E–Z Trial, to be receptive to motions by either party to modify or discontinue the procedure, and to conduct pre-hearing conferences in such a manner as to prevent surprises at trial. The Secretary also expressed her wish that the Commission remain open to future modifications of the rule as it gains experience with the E–Z Trial program.

The Commission has evaluated the E–Z Trial program during its pilot stage and has decided to eliminate the sunset provision of the E–Z Trial procedures and to maintain E–Z Trial as part of the Commission's Rules of Procedure. The Commission notes that E–Z Trial has reduced the time necessary to try and reach a decision in cases of the type eligible for E–Z Trial from 423 days to 141 days—a two-thirds reduction. In addition, feedback received from the focus groups held concerning E–Z Trial reflects that the program has realized many of its other goals. The comments received in response to the proposed amendments raise issues which the Commission hopes its modified procedures adequately address and the Commission remains open to future modifications as the need may arise.

1. Eligibility for E–Z Trial

The Commission proposed amending Rule 202 to make cases involving a fatality or an allegation of willfulness ineligible for E–Z Trial. The Commission also proposed that cases having an aggregate proposed penalty of more than $10,000, but not more than $20,000, may be considered for E–Z Trial designation at the discretion of the Chief Administrative Law Judge. The Commission received no comments specifically opposing these changes. Accordingly, the Commission adopts the proposed amendments.

2. Disclosure of Information

Currently, Rule 206 requires the Secretary of Labor to disclose to the employer copies of the narrative (Form OSHA 1–A) and the worksheet (Form OSHA 1–B), or their equivalents, within 12 working days after a case has been designated for E–Z Trial. The Commission proposed amending the rule to require the Secretary to provide the employer with reproductions of any photographs or videotapes that the Secretary intends to use at the hearing within 30 calendar days of designation for E–Z Trial.

One commentator suggested that the Secretary should be required to disclose all photographs or videotapes, not just the ones the Secretary anticipates using at the hearing. The commentator stated that there may be photographs or videotapes which would be helpful to an employer's defense, but which the Secretary does not intend to use, and noted that under the proposed rule, the Secretary is not required to disclose such evidence. While the Commission expects that the Secretary would turn over such material without being required to do so, in order to make it clear that no loophole exists in the E–Z Trial procedures and because the E–Z Trial process favors disclosure over the traditional avenues of discovery, the Commission has decided that the Secretary should provide to the employer as part of the disclosure requirement any exculpatory evidence, including photographs and videotapes. Accordingly, the Commission has revised Rule 206 to include the