DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Liquid

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 an abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for oral use of ivermectin solution in horses for the treatment and control of various species of internal and cutaneous parasites.

DATES: This rule is effective January 24, 2001.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861, filed ANADA 200–292 for IVERSOL (ivermectin) Liquid for Horses. The application provides for oral use of 1.0 percent ivermectin solution in horses for the treatment and control of various species of gastrointestinal nematodes, lungworms, stomach bots, and cutaneous larvae and microfilariae. MedPharmex's IVERSOL Liquid for Horses is approved as a generic copy of Merial Ltd.'s EQVALAN® (ivermectin) Oral Liquid for Horses, approved under NADA 140–439. ANADA 200–292 is approved as of December 7, 2000, and 21 CFR 520.1195 is amended 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 this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

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, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.1195 [Amended]

2. Section 520.1195 *Ivermectin liquid* is amended in paragraph (b) by adding '', 051259,'' after ''050604''.

Dated: January 8, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–1865 Filed 1–23–01; 8:45 am]

BILLING CODE 4160–01–S

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2, 15 and 68

[CC Docket No. 99–216; FCC 00–400]

2000 Biennial Regulatory Review of Adopting Technical Criteria and Approving Terminal Equipment

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document privatizes the process by which technical criteria are established for customer premises equipment (CPE or terminal equipment) that may be sold for connection to the public switched telephone network, and for the approval of such equipment to demonstrate compliance with the relevant technical criteria. Streamlining these procedures will reduce unnecessary costs and delays associated with bringing terminal equipment to the consumer without measurably increasing the possibility of harm to the public switched telephone network. Privatizing the terminal equipment approval process will significantly reduce the Commission's regulatory burden and allow it to focus on enforcement of the industry-established technical criteria for terminal equipment. The Commission will maintain its role as the forum of last resort for disputes regarding terminal equipment standards and approval procedures.

DATES: Effective February 23, 2001, except that § 68.105 and the definition of ''demarcation point'' in § 68.3 will not be effective until approval of the Office of Management and Budget has been obtained. The FCC will publish a document announcing the effective date of this rule and definition.

FOR FURTHER INFORMATION CONTACT: Susan Magnotti, 202/418–0871, Fax 202/418–2345, TTY 202/4184, smagnott@fcc.gov, Network Services Division, Common Carrier Bureau, or Dennis Johnson, 202/418–0809, Fax 202/418–2345, TTY 202/418–0484, dcjohnso@fcc.gov, Network Services Division, Common Carrier Bureau.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order (Order) in the 2000 Biennial Review of Part 68 of the Commission's Rules and Regulations, CC Docket No. 99–216, FCC 00–400, adopted November 9, 2000 and released December 21, 2000. The full text of the Report and Order is available for inspection and copying during the weekday hours of 9 a.m. to 4:30 p.m. in the FCC Reference Center, Room CY–A257, 445 12th Street, SW., Washington, DC 20554, or copies may be purchased from the Commission's copy contractor, International Transcription Services, Inc., 445 12th Street, SW., Suite CY–B400, Washington, DC 20554, phone (202) 857–3800.

Synopsis of the Report and Order

1. In May 2000, the Commission released a Notice of Proposed Rulemaking (NPRM), 65 FR 34629 (May 31, 2000) proposing to privatize most elements of the process by which technical criteria are established for customer premises equipment (CPE or terminal equipment) as well as the compliance assessment procedures for such equipment. In response, the majority of comments recommended adoption of the Commission's proposals. This Order will streamline the Commission's rules by allowing the Commission to replace approximately 130 pages of technical criteria currently in the rules with only a few pages of simple principles that terminal equipment shall not cause any of the prescribed harms to the public switched telephone network, that providers of