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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier J. Cooke

Food and Drug Administration

Notice of Approval of New Animal Drug Application; Ivermectin Pour-On

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that in 2001 it approved a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provided for topical use of an ivermectin solution on cattle for control of certain internal parasites for 14 days after treatment. The applicable section of the regulation did not require amendment.

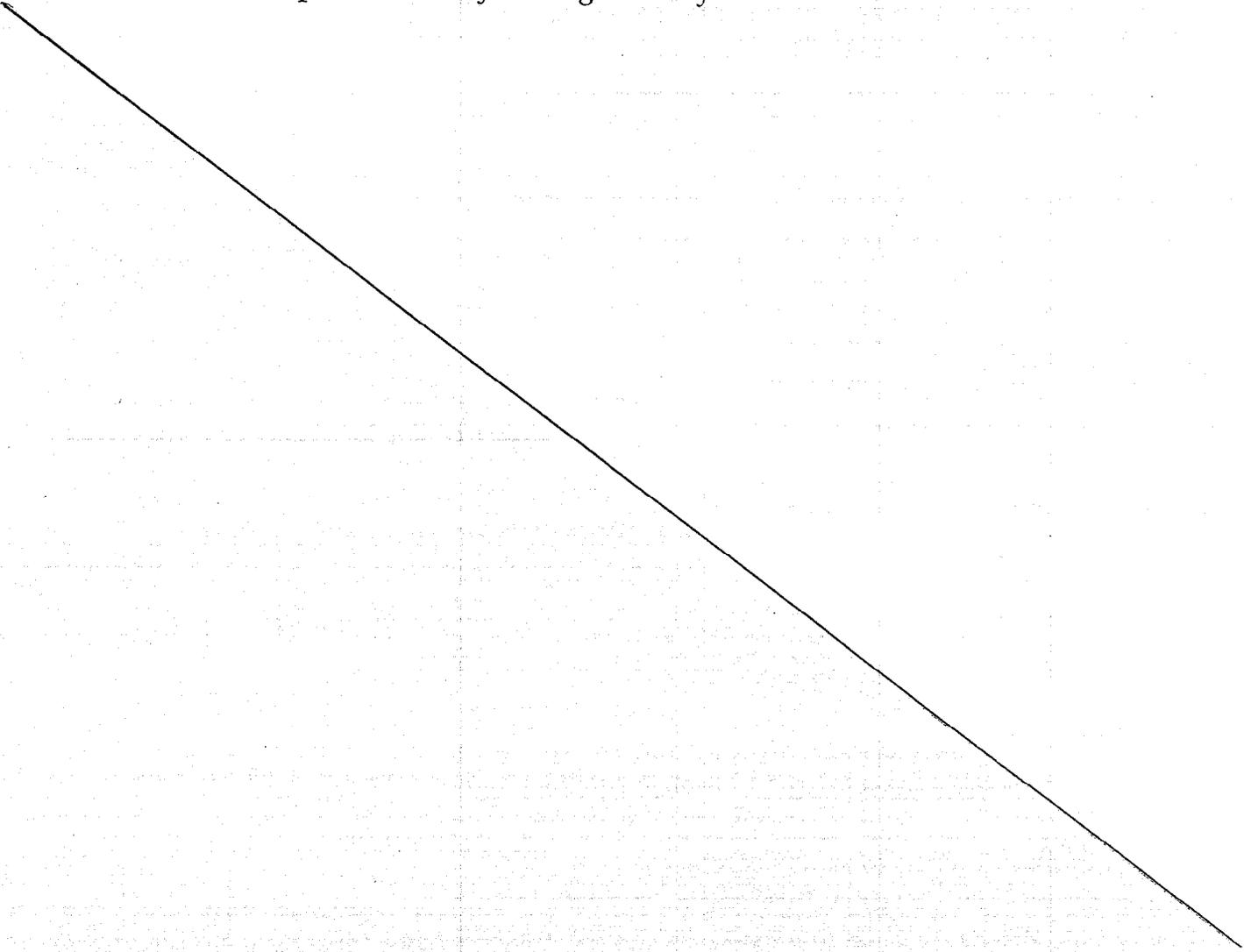
FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), FDA is providing notice that in 2001 it approved a supplemental ANADA that was not the subject of a final rule. A final rule was not published because § 524.1193 (21 CFR 524.1193) did not require amendment.

On May 16, 2001, FDA approved a supplement filed by Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, to ANADA 200-219 for PHOENECTIN (ivermectin) Pour-On. The supplemental ANADA provided for topical use of a 0.5 percent ivermectin solution on cattle for control of infections of *Ostertagia ostertagi*, *Haemonchus placei*, *Trichostrongylus axei*,

Oesophagostomum radiatum, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment. This supplemental approval was based on the expiration of marketing exclusivity granted the pioneer product, Merial, Ltd.'s IVOMEC Pour-On for Cattle, in 1997 (62 FR 38907, July 21, 1997). No new data were submitted. The necessary amendment to § 524.1193 was made in a final rule (66 FR 13236, March 5, 2001) for the approval of another generic copy of the pioneer product.

A freedom of information summary containing approved product labeling may be seen in the Division of Dockets Management (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.



Dated: 6/25/03

cv0351

June 25, 2003.

SF SFS/K

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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J. Cooke