

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date	4-17-00
Publication Date	4-18-00
Certifier	M. Bell

Food and Drug Administration

Albendazole Suspension for Goats; Availability of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of effectiveness, target animal safety, and human food safety, and environmental data that may be used in support of a new animal drug application (NADA) or supplemental NADA for oral use of albendazole suspension for treatment of adult liver flukes in nonlactating goats. The data, contained in Public Master File (PMF) 5582, were compiled under National Research Support Project-7 (NRSP-7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for special uses.

ADDRESSES: Submit NADA's or supplemental NADA's to the Document Control Unit (HFV-199), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

FOR FURTHER INFORMATION CONTACT: Gillian A. Comyn, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7568.

SUPPLEMENTARY INFORMATION: Albendazole suspension, used for the treatment of adult liver flukes (*Fasciola hepatica*) in nonlactating goats, is a new animal drug under section 201(v) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(v)). As a new animal drug, albendazole is subject to section 512 of the act (21 U.S.C. 360b), requiring that its uses in goats be the subject of an approved NADA or supplemental NADA. Goats are a minor species under § 514.1(d)(1)(ii) (21 CFR 514.1(d)(1)(ii)).

The NRSP-7 Project, Western Region, College of Veterinary Medicine, University of California, Davis, CA 95616, has provided target animal safety, effectiveness, human food safety, and environmental data for oral use of albendazole solution for treatment of adult liver flukes (*Fasciola hepatica*) in nonlactating goats. These data are contained in PMF 5582.

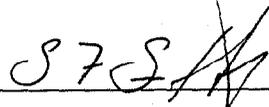
Under 21 CFR 25.15(d) and 25.33(d)(4), sponsors of NADA's and supplemental NADA's for drugs in minor species, including wildlife and endangered species, are categorically excluded from the requirement to prepare an environmental assessment or an environmental impact statement when the drug has been approved for use in another or the same species where similar animal management practices are used. The categorical exclusion applies unless, as defined in § 25.21 (21 CFR 25.21), extraordinary circumstances exist which indicate that the proposed action may significantly affect the quality of the human environment. Therefore, based upon information available, FDA agrees that when the application is submitted, the applicant may claim a categorical exclusion under § 25.33(d)(4) provided that the applicant can state that to the best of the applicant's knowledge, as in § 25.21, no extraordinary circumstances exist. It is assumed that the applicant has made a reasonable effort to determine that no extraordinary circumstances exist.

Sponsors of NADA's or supplemental NADA's may, without further authorization, reference the PMF 5582 to support approval of an application filed under § 514.1(d). An NADA or supplemental NADA must include, in addition to reference to the PMF, animal drug labeling and other information needed for approval, such as: Data supporting extrapolation from a major species in which the drug is currently approved or authorized reference to such data; data concerning manufacturing methods, facilities, and controls; and information addressing potential environmental impacts of the manufacturing process. Persons desiring more information concerning the PMF or requirements for approval of an NADA or supplement may contact Gillian A. Comyn (address above).

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, from 9 a.m. to 4 p.m., Monday through Friday.

Dated: 3/20/00
March 20, 2000



Stephen F. Sundlof
Director
Center for Veterinary Medicine

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

