

comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor,

Dated July 11, 1996.

Bob Sargis,

Acting Reports Clearance Officer.

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Food and Drug Administration

Sulfadimethoxine and Ormetoprim in Chukar Partridge Feed; Availability of Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of target animal safety and effectiveness data and environmental data to be used in support of a new animal drug application (NADA) or supplemental NADA for use of Type C medicated feed containing sulfadimethoxine and ormetoprim in chukar partridges, for the prevention of coccidiosis caused by *Eimeria kofoidi* and *E. legionensis*. The data, contained in Public Master File (PMF) 5157, were compiled under National Regional Support Project No. 7 (NRSP-7) (formerly the Interregional Research Project No. 4 (IR-4)), a national agricultural program for obtaining clearances for use of new drugs in minor animal species or in any animal species for control of diseases that occur infrequently or in limited geographical areas.

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, 301-827-3125.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1659.

SUPPLEMENTARY INFORMATION: The use of sulfadimethoxine and ormetoprim in chukar partridge feed is a new animal drug use 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, the combination of sulfadimethoxine/ormetoprim is subject to section 512 of the act (21 U.S.C. 360b) which requires that its use in chukar

partridges be the subject of an approved NADA or supplemental NADA.

Partridges are a minor species under § 514.1(d)(1)(ii) (21 CFR 514.1(d)(1)(ii)). The NRSP-7 Project, Northeastern Region, New York State College of Veterinary Medicine, Cornell University, Ithaca, NY 14853-6401, has filed data and information that demonstrate safety and effectiveness to chukar partridges consuming sulfadimethoxine/ormetoprim-containing feed for the prevention of coccidiosis caused by *E. kofoidi* and *E. legionensis*. NRSP-7 has also filed an environmental assessment (EA) that adequately addresses the potential impacts due to use of the drug product. Approval of an application based on the data and information in this file requires added information concerning the environmental impact of the manufacturing site. The EA will be displayed when the NADA is approved, so that the manufacturing site environmental impact can be included in the assessment. The EA may be seen at 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 use of the drug in chukar partridges has an inherent withdrawal period both when introduced into the game preserves and the period between dosing and maturity. Therefore, the Center for Veterinary Medicine has waived the requirements for conducting a tissue residue depletion study.

The data and information are contained in PMF 5157. Sponsors of NADA's or supplemental NADA's may, without further authorization, refer to the PMF 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 data needed for approval, such as manufacturing methods, facilities, and controls, and information addressing the potential environmental impacts (including occupational) of the manufacturing process. Persons desiring more information concerning the PMF or requirements for approval of an NADA may contact Naba K. Das (address above).

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and 21 CFR 514.11(e)(2)(ii), a summary of target animal safety and effectiveness data and information in the PMF submitted to support approval of an application may be seen in the Dockets Management

Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 11, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meeting

Pursuant to Pub.L. 92-463, notice is hereby given of a teleconference meeting of the Center for Substance Abuse Treatment (CSAT) National Advisory Council in July 1996.

The Council will discuss the Center's policy issues and current administrative, legislative and program development related to the Knowledge Development Application (KDA) Agenda for 1997. Public comments are welcome. Please contact the person listed below if you wish to participate in the meeting.

A summary of the meeting and roster of council members may be obtained from: Ms. Marjorie Cashion, Executive Secretary, National Advisory Council, CSAT, Rockwall II Building, Suite 840, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-3821.

Substantive program information may be obtained from the contact whose name and telephone number is listed below.

Committee Name: The Center for Substance Abuse Treatment, National Advisory Council.

Meeting Date/Time: July 23, 1996—1:00 p.m. to 2:30 p.m.

Place: Center for Substance Abuse Treatment, 5515 Security Lane, Rockwall II Building, Suite 615, Rockville, Maryland 20852.

Type: Open Session.

Contact: Marjorie M. Cashion, Rockwall II Building, Suite 840, Telephone (301) 443-3821, FAX: (301) 480-6077.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Dated: July 16, 1996.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

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