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. legonensis. 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 EPA 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)(1)(ii). 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.

Bob Sargis, Acting Reports Clearance Officer.

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