§ 1301.56 Final determination.

The General Counsel makes the final determination whether a demand for testimony or production of records or official testimony in a legal proceeding in which TVA is not a party shall be granted. All final determinations are within the sole discretion of the General Counsel. The General Counsel will notify the requesting party and, when necessary, the court or other authority of the final determination, the reasons for the grant or denial of the request, and any conditions that the General Counsel may impose on the production of testimony or records or official information.

§ 1301.57 Waiver.

The General Counsel may grant a waiver of any procedure described by this part where a waiver is considered necessary to promote a significant interest of TVA or the United States, or for other good cause.

Maureen H. Dunn,

General Counsel.

[FR Doc. E7–20907 Filed 10–24–07; 8:45 am]

BILLING CODE 8120–08–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Phenylbutazone Paste

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 a supplemental new animal drug application (NADA) filed by Luitpold Pharmaceuticals, Inc. The supplemental NADA provides for a revised human food safety warning for phenylbutazone paste, used in horses for relief of inflammatory conditions associated with the musculoskeletal system.

DATES: This rule is effective October 25, 2007.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967, filed a supplement to NADA 140–958 that provides for use of EQUIPHEN (phenylbutazone) Paste in horses for relief of inflammatory conditions associated with the musculoskeletal system. The supplemental NADA provides for a revised human food safety warning on product labeling. The supplemental NADA is approved as of September 26, 2007, and the regulations are amended in 21 CFR 520.1720c to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

FDA 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.

§ 520.1720c [Amended]

■ 2. In § 520.1720c, in paragraph (c)(3), remove ''Not for use in horses intended for food.'' and add in its place ''Do not use in horses intended for human consumption.''

Dated: October 17, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–21054 Filed 10–24–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Spinosad

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 a new animal drug application (NADA) filed by Elanco Animal Health. The NADA provides for veterinary prescription use of spinosad chewable tablets to kill fleas and for the prevention and treatment of flea infestations on dogs for 1 month.

DATES: This rule is effective October 25, 2007.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141–277 that provides for veterinary prescription use of COMFORTIS (spinosad) Chewable Tablets to kill fleas and for the prevention and treatment of flea infestations (*Ctenocephalides felis*) on dogs for 1 month. The NADA is approved as of September 25, 2007, and the regulations in 21 CFR part 520 are amended by adding § 520.2130 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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 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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

FDA has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,