(3) *Limitations.* Do not use in horses intended for human consumption.

Dated: December 29, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–523 Filed 1–10–05; 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; Lincomycin Hydrochloride Soluble Powder

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 an abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The ANADA provides for oral use of lincomycin soluble powder to make medicated drinking water for administration to swine for the treatment of swine dysentery or to broiler chickens for the control of necrotic enteritis.

DATES: This rule is effective January 11, 2005.

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: *lonnie.luther@fda.gov*.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–377 for LINCOMED (lincomycin hydrochloride) Soluble Powder. The application provides for oral use of lincomycin soluble powder to make medicated drinking water for administration to swine for the treatment of swine dysentery or to broiler chickens for the control of necrotic enteritis. Cross Vetpharm Group Ltd.'s LINCOMED Soluble Powder is approved as a generic copy of Pharmacia & Upjohn Co.'s LINCOMIX Soluble Powder, approved under NADA 111–636. ANADA 200–377 is approved as of December 6, 2004, and the regulations are amended in 21 CFR 520.1263c to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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.

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 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.

■ 2. Section 520.1263c is amended by revising paragraph (b) to read as follows:

§ 520.1263c Lincomycin hydrochloride soluble powder.

* * * * *

(b) *Sponsors.* See Nos. 000009, 046573, 054925, 059130, and 061623 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

* * * * *

Dated: December 29, 2004 .

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–524 Filed 1–10–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1 and 3

[Docket No.: 2004–P–034]

RIN 0651–AB76

Changes To Implement the Cooperative Research and Technology Enhancement Act of 2004

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Interim rule.

SUMMARY: The Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act) amends the patent laws to provide that subject matter developed by another person shall be treated as owned by the same person or subject to an obligation of assignment to the same person for purposes of determining obviousness if three conditions are met: The claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made; the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement. The United States Patent and Trademark Office (Office) is revising the rules of practice in patent cases to implement the CREATE Act.

DATES: Effective Date: December 10, 2004.

Comment Deadline Date: To be ensured of consideration, written comments must be received on or before February 10, 2005. No public hearing will be held.

ADDRESSES: Comments should be sent by electronic mail message over the Internet addressed to: *ab76comments@uspto.gov*. Comments may also be submitted by mail addressed to: Box Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313–1450, or by facsimile to (571) 273–7735, marked to the attention of Robert A. Clarke. Although comments may be submitted by mail or facsimile, the Office prefers to receive comments via the Internet. If comments are submitted by mail, the Office prefers that the comments be submitted on a DOS formatted 3½ inch disk accompanied by a paper copy.

Comments may also be sent by electronic mail message over the Internet via the Federal eRulemaking Portal. See the Federal eRulemaking