who is accused of criminal activity receives due process of law in a criminal proceeding under the jurisdiction of the judicial branch of the Federal government.

(f) *In other circumstances.* We may disclose information to a court of competent jurisdiction in circumstances other than those stated in paragraph (e) of this section. We will make our decision regarding disclosure by balancing the needs of a court while preserving the confidentiality of information. For example, we may disclose information under a court order that restricts the use and redisclosure of the information by the participants in the proceeding; we may offer the information for inspection by the court *in camera* and under seal; or we may arrange for the court to exclude information identifying individuals from that portion of the record of the proceedings that is available to the public. We will make these determinations in accordance with § 401.140.

(g) *Other regulations on request for testimony, subpoenas and production of records in legal proceedings.* See 20 CFR part 403 of this chapter for additional rules covering disclosure of information and records governed by this part and requested in connection with legal proceedings.

[FR Doc. E7–7940 Filed 4–26–07; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. 2006N–0416]

Use of Ozone-Depleting Substances; Removal of Essential Use Designations; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of April 23, 2007, for the direct final rule that appeared in the **Federal Register** of December 7, 2006 (71 FR 70870). The direct final rule amends the regulation to remove beclomethasone, dexamethasone, fluticasone, bitolterol, salmeterol, ergotamine tartrate, and ipratropium bromide, used in oral pressurized metered-dose inhalers, from the list of essential uses of ozone-depleting substances. None of these products is currently being marketed. This document confirms the effective date of the direct final rule.

DATES: Effective date confirmed: April 23, 2007, except for the removal of § 2.125(e)(4)(v) (21 CFR 2.125(e)(4)(v)), which is effective August 1, 2007.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen or Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 7, 2006 (71 FR 70870), FDA solicited comments concerning the direct final rule for a 75-day period ending February 20, 2007. FDA stated that the effective date of the direct final rule would be on April 23, 2007, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period.

FDA received no significant adverse comments within the comment period. Therefore, under the Federal Food, Drug, and Cosmetic Act, the Clean Air Act, and under authority delegated to the Commissioner of Food and Drugs, after consultation with the Administrator of the Environmental Protection Agency, notice is given that no objections or requests for a hearing were filed in response to the December 7, 2006, direct final rule. Accordingly, FDA is confirming that the amendment issued thereby is effective April 23, 2007, except for the removal of § 2.125(e)(4)(v), which is effective August 1, 2007.

Dated: April 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–8043 Filed 4–26–07; 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; Diclazuril

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 Schering-Plough Animal Health Corp. The NADA provides for the veterinary prescription use of diclazuril oral pellets in horses for the treatment of equine protozoal myeloencephalitis.

DATES: This rule is effective April 27, 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: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, filed NADA 141–268 for the veterinary prescription use of PROTAZIL (1.56% diclazuril) Antiprotozoal Pellets in horses for the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona*. The NADA is approved as of March 29, 2007, and the regulations in 21 CFR part 520 are amended by adding new § 520.606 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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning March 29, 2007.

The agency 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, 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