comment.'' 5 U.S.C. 601(2). Since the rules are not being effected pursuant to section 553(b), they are not ''rules'' as defined in the RFA, and the analysis and certification process certified in that statute do not apply.

C. The Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501, *et seq.,* which imposes certain requirements on federal agencies, including the Commission, in connection with their conducting or sponsoring any collection of information as defined by the PRA, does not apply to these rule amendments because these rule amendments do not contain information collection requirements as defined by the PRA.

D. Cost-Benefit Analysis

Section 15 of the Act, as amended by section 119 of the CFMA, requires the Commission, before issuing a new regulation under the Act, to consider the costs and benefits of its action. The Commission understands that, by its terms, section 15 does not require the Commission to quantify the costs and benefits of a new regulation or to determine whether the benefits of the proposed regulation outweigh its costs.

Section 15 further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: (1) Protection of market participants and the public; (2) efficiency, competitiveness, and financial integrity of futures markets; (3) price discovery; (4) sound risk management practices; and (5) other public interest considerations. Accordingly, the Commission could in its discretion give greater weight to any one of the five enumerated areas of concern and could in its discretion determine that, notwithstanding its costs, a particular rule was necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the Act.

The Commission has considered the costs and benefits of this rule package in light of the specific areas of concern identified in section 15, at the time that the Commission delegated these responsibilities to the Division and the National Futures Association.

List of Subjects in 17 CFR Part 140

Authority delegations (Government agencies), Organization and functions (Government agencies).

PART 140—ORGANIZATION, FUNCTIONS, AND PROCEDURES OF THE COMMISSION

■ Accordingly, 17 CFR part 140 is corrected by making the following technical amendments:

■ 1. The authority citation for part 140 continues to read as follows:

Authority: 7 U.S.C. 2, 12a.

§ 140.93 [Corrected]

■ 2. In § 140.93:

■ a. Remove the words ''Trading and Markets'' in the title and add, in their place, ''Clearing and Intermediary Oversight.''

■ b. Remove paragraph (a)(2);

■ c. Redesignate paragraphs (a)(3) and (a)(4) as paragraphs (a)(2) and (a)(3), respectively;

■ d. Redesignate paragraph (a)(5) as paragraph (a)(4) and correct ''§ 4.5(c)(2)(v)'' in newly redesignated paragraph (a)(4) to read ''§ 4.5(c)(2)(ii)''; and

■ e. Redesignate paragraph (a)(6) as paragraph (a)(5).

* * * * *

Issued in Washington, DC, on January 11, 2005 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 05–817 Filed 1–14–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Melengestrol

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 Ivy Laboratories, Division of Ivy Animal Health, Inc. The ANADA provides for use of a melengestrol acetate liquid Type A medicated article to make Type C medicated feeds for heifers fed in confinement for slaughter and for heifers intended for breeding.

DATES: This rule is effective January 14, 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: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed ANADA 200–343 for use of HEIFERMAX 500 (melengestrol acetate) Liquid Premix, a liquid Type A medicated article used to make dry and liquid Type C medicated feeds for heifers fed in confinement for slaughter and for heifers intended for breeding. Ivy Laboratories' HEIFERMAX 500 Liquid Premix is approved as a generic copy of Pharmacia and Upjohn Co.'s MGA 500 (melengestrol acetate) Liquid Premix, approved under NADA 39–402. The application is approved as of December 3, 2004, and the regulations are amended in 21 CFR 558.342 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.

The agency 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 558

Animal drugs, Animal feeds.

■ 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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. Section 558.342 is amended by revising paragraph (b) and in the table in

paragraphs (e)(1)(i) and (e)(1)(ii) in the ''Sponsor'' column by adding in numerical sequence ''021641'' to read as follows:

§ 558.342 Melengestrol.

* * * * *

(b) *Approvals.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 000009 for use of products described in paragraph (a) of this section.

(2) No. 021641 for use of product described in paragraph (a)(2) of this section.

* * * * *

Dated: December 29, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–761 Filed 1–13–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Decoquinate

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 two supplemental new animal drug applications (NADAs) filed by Alpharma Inc. The supplemental NADAs provide for the use of single-ingredient decoquinate and chlortetracycline Type A medicated articles to make two-way Type B and Type C medicated feeds for cattle at a broader range of concentrations.

DATES: This rule is effective January 14, 2005.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: *janis.messenheimer@fda.gov*.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 141–147 for use of DECCOX (decoquinate) and CHLORMAX (chlortetracycline) Type A medicated articles to make two-way Type B and Type C medicated feeds for cattle at the broader range of concentrations. Alpharma Inc. also filed a supplement to NADA 141–185 for use of DECCOX and AUREOMYCIN (chlortetracycline) Type A medicated articles for the same revised conditions of use. The supplemental applications are approved as of December 16, 2004, and the regulations are amended in 21 CFR 558.195 to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor 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 558

Animal drugs, Animal feeds.

■ 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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. Section 558.195 is amended by redesignating paragraphs (e)(2)(ii), (e)(2)(iii), and (e)(2)(iv) as paragraphs (e)(2)(vi), (e)(2)(iv), and (e)(2)(iii) respectively; and by adding new paragraphs (e)(2)(ii) and (e)(2)(vii) to read as follows:

§ 558.195 Decoquinate.

* * * * *

(e) * * *

* * * * *

(2) *Cattle.*

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
(ii) 12.9 to 90.8	Chlortetracycline 500 to 4,000.	Calves, beef, and nonlactating dairy cattle: As in paragraph (e)(2)(i) of this section; for treatment of bacterial enteritis caused by *Escherichia coli*; and for treatment of bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.	Feed Type C feed to provide 22.7 mg decoquinate and 1 gram chlortetracycline per 100 lb body weight per day for not more than 5 days. When consumed, feed 22.7 mg decoquinate per 100 lb body weight/day for a total of 28 days to prevent coccidiosis. Withdraw 24 hours prior to slaughter when manufactured from CTC (chlortetracycline) Type A medicated articles under NADA 141–147. Zero withdrawal time when manufactured from AUREOMYCIN (chlortetracycline) Type A medicated articles under NADA 141–185. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not feed to animals producing milk for food. Chlortetracycline as provided by No. 046573 in § 510.600(c) of this chapter.	046573