

be available upon request from the Food and Drug Administration, Center for Devices and Radiological Health, Division of Mammography Quality and Radiation Programs, 10903 New Hampshire Ave., Bldg. 66, rm. 4521, Silver Spring, MD 20993-0002.

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PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

■ 33. The authority citation for 21 CFR part 1040 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360e-360j, 371, 381; 42 U.S.C. 263B-263n.

■ 34. Section 1040.10 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 1040.10 Laser products.

(a) * * *

(3) * * *

(i) Registers, and provides a listing by type of such laser products manufactured that includes the product name, model number and laser medium or emitted wavelength(s), and the name and address of the manufacturer. The manufacturer must submit the registration and listing to the Food and Drug Administration, Center for Devices and Radiological Health, Director, Office of Compliance, 10903 New Hampshire Ave., Bldg. 66, rm. 3521, Silver Spring, MD 20993-0002.

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■ 35. Section 1040.20 is amended by revising paragraph (d)(3)(iii) to read as follows:

§ 1040.20 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

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(d) * * *

(3) * * *

(iii) If the size, configuration, design, or function of the sunlamp product or ultraviolet lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, or would render the required label unnecessary, the Director, Office of Communication, Education, and Radiation Programs 10903 New Hampshire Ave., Bldg. 66, rm. 4312, Silver Spring, MD 20993-0002, Center for Devices and Radiological Health, on the center's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s), alternate wording for such label(s), or deletion, as applicable.

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Dated: April 12, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-8863 Filed 4-21-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2010-N-0002]

New Animal Drugs for Use in Animal Feeds; Melengestrol, Monensin, and Ractopamine

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 abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Div. of Ivy Animal Health, Inc. The supplemental NADA provides for an increased level of monensin in three-way combination Type C medicated feeds containing ractopamine, melengestrol, and monensin for heifers fed in confinement for slaughter.

DATES: This rule is effective April 22, 2010.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200-448 that provides for use of HEIFERMAX 500 (melengestrol acetate) Liquid Premix, OPTAFLEXX (ractopamine hydrochloride), and RUMENSIN (monensin, USP) single-ingredient Type A medicated articles to make dry and liquid, three-way combination drug Type C medicated feeds for heifers fed in confinement for slaughter. The supplemental ANADA provides for an increased level of monensin. The supplemental ANADA is approved as of February 16, 2010, and the regulations are amended in 21 CFR 558.500 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.

The agency has determined under 21 CFR 25.33 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.

§ 558.500 [Amended]

■ 2. In § 558.500, in paragraph (e)(2)(viii), in the "Limitations" column, remove "000009" and add in its place "000009 or 021641", and in the "Sponsor" column, remove "No. 000986" and add in its place "000986, 021641"; and remove paragraph (e)(2)(xii).

Dated: April 19, 2010.

Elizabeth Rettie,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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