PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

1. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371; 42 U.S.C. 262.

2. Section 312.33 is amended by revising paragraph (a)(2) to read as follows:

§ 312.33 Annual reports.

* * * * *

(a) * * *

(2) The total number of subjects initially planned for inclusion in the study; the number entered into the study to date, tabulated by age group, gender, and race; the number whose participation in the study was completed as planned; and the number who dropped out of the study for any reason.

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PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG OR AN ANTIBIOTIC DRUG

3. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371, 374, 379e.

4. Section 314.50 is amended by revising the second sentence and adding two new sentences after the second sentence in paragraph (d)(5)(v), and by adding two new sentences after the first sentence in paragraph (d)(5)(vi)(*a*) to read as follows:

§ 314.50 Content and format of an application.

* * * * *

(d) * * *

(5) * * *

(v) * * * Evidence is also required to support the dosage and administration section of the labeling, including support for the dosage and dose interval recommended. The effectiveness data shall be presented by gender, age, and racial subgroups and shall identify any modifications of dose or dose interval needed for specific subgroups. Effectiveness data from other subgroups of the population of patients treated, when appropriate, such as patients with renal failure or patients with different levels of severity of the disease, also shall be presented.

(vi) * * *

(*a*) * * * The safety data shall be presented by gender, age, and racial subgroups. When appropriate, safety data from other subgroups of the population of patients treated also shall be presented, such as for patients with renal failure or patients with different levels of severity of the disease. * * *

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Dated: February 2, 1998.

William B. Schultz,

Deputy Commisioner for Policy.

[FR Doc. 98–3422 Filed 2–10–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Monensin

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 (NADA's) filed by Elanco Animal Health, Division of Eli Lilly & Co. The supplemental NADA's provide for transferring the data and information in one NADA into another and withdrawing approval of the vacated NADA. The NADA's provide for use of monensin Type A medicated articles to make a free-choice Type C medicated feed/mineral granules for pastured cattle for increased rate of weight gain.

EFFECTIVE DATE: February 23, 1998.

FOR FURTHER INFORMATION CONTACT: Russell G. Arnold, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1674.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, is the sponsor of NADA's 95–735 and 119–823, both of which provide for use of a monensin Type A medicated article to make a monensin Type C medicated feed/free-choice mineral granules containing 810 milligrams monensin per pound (1,620 grams monensin per ton) to be fed free-choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) for increased rate of weight gain (see 21 CFR 520.1448b and 558.355(f)(3)(x)).

Elanco Animal Health, Division of Eli Lilly & Co. filed supplemental NADA's that provide for combining data and information in NADA 119–823 into NADA 95–735 and withdrawing approval of NADA 119–823. Supplemental NADA 95–735 is approved as of November 3, 1997, and the regulations are amended in part 520 (21 CFR part 520) by removing § 520.1448b to reflect the approval.

Approval of the supplemental NADA 95–735 or withdrawal of approval of NADA 119–823 does not require a freedom of information summary because the actions concern a change in status of existing applications and do not change the conditions of use of the products. This change does not affect the product's safety or effectiveness.

The agency has determined under 21 CFR 25.33(a)(1) and (g) 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 an environmental impact statement is required.

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.

§ 520.1448b [Removed]

2. Section 520.1448b *Monensin-mineral granules* is removed.

Dated: January 22, 1998.

Andrew J. Beaulieau,

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

[FR Doc. 98–3355 Filed 2–10–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA No. 173F]

Schedules of Controlled Substances: Placement of Sibutramine Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Acting Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance,