

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. * * *

Dated: February 2, 1998.

William B. Schultz,

Deputy Commissioner 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. Beaulieu,

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,

sibutramine, including its salts and optical isomers, into Schedule IV of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule IV will be applicable to the manufacture, distribution, importation and exportation of sibutramine and products containing sibutramine.

EFFECTIVE DATE: February 11, 1998.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION:

Sibutramine is an amphetamine analogue pharmacologically similar to other anorectic agents that produce central nervous system stimulation and amphetamine-like effects in humans and animals. Sibutramine hydrochloride will be marketed under the trade name of Meridia as an oral anorectic for the long-term management of obesity.

The Acting Deputy Administrator of the DEA received a letter dated November 12, 1997, from the Acting Assistant Secretary of Health, on behalf of the Secretary of the Department of Health and Human Services (DHHS), recommending that the substance, sibutramine, and its salts and isomers, be placed into Schedule IV of the CSA (21 U.S.C. 801 *et seq.*). Enclosed with the letter from the Assistant Secretary was a document prepared by the Food and Drug Administration (FDA) entitled "Basis for the Recommendation for Control of Sibutramine and its Salts in Schedule IV of the Controlled Substances Act (CSA)." The document contained a review of the factors which the CSA requires the Secretary to consider [21 U.S.C. 811(b)] and the summarized recommendations regarding the placement of sibutramine into Schedule IV of the CSA. The Acting Deputy Administrator of the DEA, in a December 8, 1997, **Federal Register** notice (62 FR 64526), proposed placement of sibutramine into Schedule IV of the CSA. The notice provided an opportunity for all interested persons to submit their comments, objections, or requests for hearing in writing to be received by the DEA on or before January 7, 1998. The DEA received no comments, objections or requests for hearing.

Based on the scientific and medical evaluation and the recommendation of the Assistant Secretary for Health, the FDA New Drug Application (NDA) approval on November 22, 1997, and a DEA review, the Acting Deputy Administrator of the DEA, pursuant to

sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Sibutramine has a low potential for abuse relative to the drugs or other substances in Schedule III.

(2) Sibutramine has a currently accepted medical use in treatment in the United States.

(3) Abuse of sibutramine may lead to limited physical and psychological dependence relative to drugs or other substances in Schedule III.

Based on these findings, the Acting Deputy Administrator of the DEA concludes that sibutramine, including its salts and isomers, warrants control in Schedule IV of the CSA. In order to make sibutramine pharmaceutical products available for medical use as soon as possible, the Schedule IV controls of sibutramine will be effective February 11, 1998. In the event that the regulations impose special hardships on the registrants, the DEA will entertain any justified request for an extension of time to comply with the Schedule IV regulations regarding sibutramine. The applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes, dispenses, imports or exports sibutramine or who engages in research or conducts instructional activities with sibutramine, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with Part 1301 of Title 21 of the Code of Federal Regulations.

2. *Security.* Sibutramine must be manufactured, distributed and stored in accordance with §§ 1301.71, 1301.72 (b), (c), and (d), 1301.73, 1301.74, 1301.75 (b) and (c) and 1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and Packaging.* All labels on commercial containers of, and all labeling of, sibutramine which is distributed shall comply with the requirements of §§ 1302.03-1302.07 of Title 21 of the Code of Federal Regulations.

4. *Inventory.* Registrants possessing sibutramine are required to take inventories pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations.

5. *Records.* All registrants must keep records pursuant to §§ 1304.03, 1304.04 and 1304.21-1304.23 of Title 21 of the Code of Federal Regulations.

6. *Prescriptions.* All prescriptions for sibutramine are to be issued pursuant to §§ 1306.03-1306.06 and 1306.21-1306.26 of Title 21 of the Code of Federal Regulation.

7. *Importation and Exportation.* All importation and exportation of sibutramine shall be in compliance with

Part 1312 of Title 21 of the Code of Federal Regulations.

8. *Criminal Liability.* Any activity with sibutramine not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful.

In accordance with the provisions of the CSA [21 U.S.C. 811(a)], this action is a formal rulemaking on the record after opportunity for a hearing. Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order (E.O.) 12866, Section 3(d)(1).

The Acting Deputy Administrator, in accordance with the Regulatory Flexibility Act [5 U.S.C. 605(b)], has reviewed this final rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small-business entities. Sibutramine is a new drug in the United States; recent approval of the product and its labeling by the FDA will allow it to be marketed once it is placed into Schedule IV of the CSA. This final rule, will allow these entities to have access to a new pharmaceutical product.

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with E.O. 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney general by section 201(a) of the CSA [21 U.S.C. 811(a)], and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100) and redelegated to the Deputy Administrator pursuant to 28 CFR 0.104, the Acting Deputy Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.14 is amended by redesignating the existing paragraph (e)(10) as (e)(11) and adding a new paragraph (e)(10) to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(e) * * *

(10) Sibutramine1675

* * * * *

Dated: February 5, 1998.

Peter F. Gruden,

Acting Deputy Administrator.

[FR Doc. 98-3439 Filed 2-10-98; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 397

Removal of Part

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: This document removes obsolete information in Title 32 of the Code of Federal Regulations addressing the organizational establishment of the Defense Printing Service. This part has served the purpose for which it was intended in the CFR and is no longer necessary.

EFFECTIVE DATE: February 11, 1998.

FOR FURTHER INFORMATION CONTACT: L. Bynum or Patricia Toppings, 703-697-4111.

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 397

Organization and functions.

PART 397—[REMOVED]

Accordingly, by the authority of 10 U.S.C. 301, 32 CFR part 397 is removed.

Dated: February 5, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98-3351 Filed 2-10-98; 8:45 am]

BILLING CODE 5000-04-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 412 and 413

[HCFA-1731-F]

RIN 0938-AG00

Medicare Program; Payment for Preadmission Services

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule responds to public comments on the January 12, 1994, interim final rule with comment period that provided that inpatient hospital operating costs include certain preadmission services furnished by the hospital (or by an entity that is wholly owned or operated by the hospital) to the patient up to 3 days before the date of the patient's admission to that hospital. These provisions implement amendments made to section 1886(a)(4) of the Social Security Act by section 4003 of the Omnibus Budget Reconciliation Act of 1990.

EFFECTIVE DATE: These regulations are effective on March 13, 1998.

FOR FURTHER INFORMATION CONTACT: Sandy Hetrick, (410) 786-4542.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1886 of the Social Security Act (the Act) addresses Medicare payment for hospital inpatient operating costs. Before the enactment of section 4003 of Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508), section 1886(a)(4) of the Act defined the operating costs of inpatient hospital services to include "all routine operating costs, ancillary service operating costs, and special care unit operating costs with respect to inpatient hospital services as such costs are determined on an average per admission or per discharge basis * * *." In 1966, the Medicare program established an administrative policy regarding payment for services furnished before

admission to a hospital. Specifically, if a beneficiary with coverage under Medicare Part A was furnished outpatient hospital services and was thereafter admitted as an inpatient of the same hospital before midnight of the next day, our longstanding policy provided that outpatient hospital services furnished to the beneficiary were treated as inpatient services and included in the hospital's Part A payment.

When the prospective payment system for hospitals was implemented in 1983, the costs related to the longstanding policy concerning the payment for preadmission outpatient services as inpatient services were included in the base year costs used to calculate the standardized payment amount and the diagnosis-related group (DRG) weighting factors. (Hospitals excluded from payment under the prospective payment system continue to be paid for inpatient hospital services they furnish, as well as for the preadmission services described above, on the basis of reasonable costs up to the ceiling on the allowable rate of the increase for Medicare hospital inpatient operating costs, as set forth in the Act.) Therefore, these preadmission services could not be billed separately from the covered inpatient admission that follows, since payment for them was included in the payment made under Part A for the inpatient stay (that is, the DRG payment for hospitals under the prospective payment system or, for excluded hospitals, the reasonable cost payment subject to the rate-of-increase limit).

Section 4003(a) of Pub. L. 101-508 amended the statutory definition of "operating costs of inpatient hospital services" at section 1886(a)(4) of the Act to include the costs of certain services furnished prior to admission. These preadmission services are to be included in the Part A payment for the subsequent inpatient stay. As amended, section 1886(a)(4) of the Act defines the operating costs of inpatient hospital services to include certain preadmission services furnished by the hospital (or by an entity that is wholly owned or operated by the hospital) to the patient up to 3 days before the date of the patient's admission to the hospital.

The provisions of section 4003(b) of Public Law 101-508 provided for implementation of the 3-day payment window in the following three phases:

- The first phase, effective from November 5, 1990 (the enactment date of Public Law 101-508) through September 30, 1991, included any services furnished during the day before the date of admission regardless of