

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 510 and 558
Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Agri Beef Co. to Elanco Animal Health, A Division of Eli Lilly and Co.

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT:

Benjamin Puyot, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8646.

SUPPLEMENTARY INFORMATION: Agri Beef Co., 2201 North 20th St., P. O. Box 47, Nampa, ID 83653, has informed FDA that it has transferred ownership of, and all rights and interests in, approved NADA 140-939 for Monensin/Tylosin liquid B feed to Elanco Animal Health, A Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285. Accordingly, the agency is amending the regulations in 21 CFR 558.355(f)(3)(ix) to reflect the change of sponsor. Also, FDA is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by removing Agri Beef Co. because the firm is no longer the sponsor of any approved NADA's.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:
Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry "Agri Beef Co." and in the table in paragraph (c)(2) by removing the entry "022941".

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.355 [Amended]

4. Section 558.355 *Monensin* is amended in paragraph (f)(3)(ix) by removing the number "022941" and adding in its place "000986".

Dated: January 7, 1993.

Robert C. Livingston,

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

[FR Doc. 93-803 Filed 1-13-92; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances: Placement of Cathinone and 2,5-Dimethoxy-4-ethylamphetamine Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration (DEA) places cathinone and 2,5-dimethoxy-4-ethylamphetamine (DOET) into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.). As a result of this rule, the regulatory controls and criminal sanctions of a Schedule I substance under the CSA will be applicable to the manufacture, distribution, and possession of cathinone and DOET. This action is taken to enable the United States to meet its obligations under the Convention on Psychotropic Substances.

EFFECTIVE DATE: February 16, 1993.

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

SUPPLEMENTARY INFORMATION: Cathinone and DOET are psychoactive substances which are regulated under Schedule I of the United Nations Convention on Psychotropic Substances, 1971. The United States is a signatory to that Convention. The CSA requires the Secretary of the Department of Health and Human Services (DHHS), should he concur with the scheduling decision of the United Nations Commission on Narcotic Drugs and should he determine that control measures under the CSA are not adequate to meet the requirements of the Convention, to recommend to the Attorney General that he initiate proceedings for scheduling the substance [see 21 U.S.C. 811(d)(3)(B)]. By letter dated July 2, 1987, the Assistant Secretary for Health, acting on behalf of the Secretary, recommended to the Administrator of the DEA that he initiate scheduling actions under the CSA to assure compliance with the international requirements. The Administrator proposed placing cathinone and DOET into Schedule I of the CSA in a notice which was published in the Federal Register (52 FR 41736, October 30, 1987). In response to the proposal, an individual requested a hearing if the placement of cathinone and DOET into Schedule I would affect his religious use of a number of psychoactive substances. Because the comment was not filed in a timely manner and the request for a hearing was not made in accordance with the procedures set forth in 21 CFR 1308.45, the request was denied.

The Administrator, by letter of December 13, 1988, requested a scientific and medical evaluation of the Assistant Secretary for Health [see 21 U.S.C. 811(b)]. The Assistant Secretary responded by letter of November 5, 1992 and recommended that cathinone and DOET be placed into Schedule I. Enclosed with the letter were documents which were entitled "Basis for the Recommendation for Control of Cathinone into Schedule I of the Controlled Substances Act" and "Basis for the Recommendation for Control of 2,5-Dimethoxy-4-ethylamphetamine (DOET) into Schedule I of the Controlled Substances Act". Each document presented an evaluation and scheduling recommendation which were based on a review of the factors which the CSA requires the Attorney General and the Secretary to consider [see 21 U.S.C. 811(c)]. The Assistant Secretary found that because cathinone's abuse potential is similar to those of the stimulants, amphetamine and methamphetamine, both of which have high potentials for abuse and are

controlled in Schedule II of the CSA, and because cathinone has not been accepted for medical use in treatment in the United States, cathinone should be controlled in Schedule I. In relation to DOET, the Assistant Secretary found that because its abuse potential is similar to that of the hallucinogens, mescaline, 2,5-dimethoxy-4-methylamphetamine and 2,5-dimethoxyamphetamine all of which are controlled in Schedule I of the CSA, 2,5-dimethoxy-4-ethylamphetamine (DOET) should be controlled similarly in Schedule I.

Cathinone is the major psychoactive component of the plant *Catha edulis* (khat). The young leaves of khat are chewed for a stimulant effect. Enactment of this rule results in the placement of any material which contains cathinone into Schedule I. When khat contains cathinone, khat is a Schedule I substance. During either the maturation or the decomposition of the plant material, cathinone is converted to cathine, a Schedule IV substance. In a previously published final rule, the Administrator stated that khat will be subject to the same Schedule IV controls as cathine, (see 53 FR 17459, May 17, 1988). When khat does not contain cathinone, but does contain cathine, khat is a Schedule IV substance.

While the clandestine synthesis of cathinone has not been encountered by the DEA, the illicit synthesis of the methyl analog, methcathinone, has been encountered at twelve clandestine laboratories. Methcathinone was placed into Schedule I on May 1, 1992 pursuant to 21 U.S.C. 811(h) (see 57 FR 18825, May 1, 1992). In January 1992, the DEA encountered a clandestine laboratory which had manufactured DOET.

Based on the information gathered and reviewed by the DEA, DHHS and the recommendation of the Assistant Secretary for Health, the Administrator of the DEA, pursuant to the provisions of 21 U.S.C. 811(a), finds that:

(A) Cathinone and DOET each have a high potential for abuse.

(B) Cathinone and DOET have no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of cathinone or DOET under medical supervision.

The above findings are consistent with placement of cathinone and DOET into Schedule I of the CSA.

Regulations that are effective on and after February 16, 1993, and imposed on cathinone and DOET are as follows:

1. **Registration.** Any person who manufactures, distributes, delivers,

imports or exports cathinone or DOET or who engages in research or conducts instructional activities with respect to these substances, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with parts 1301 and 1311 of title 21 of the Code of Federal Regulations.

2. **Security.** Cathinone and DOET must be manufactured, distributed and stored in accordance with §§ 1301.71–1301.76 of title 21 of the Code of Federal Regulations.

3. **Labeling and packaging.** All labels and labeling for commercial containers of cathinone and DOET must comply with the requirements of §§ 1302.03–1302.05, 1302.07 and 1302.08 of title 21 of the Code of Federal Regulations.

4. **Quotas.** All persons required to obtain quotas for cathinone or DOET shall submit applications pursuant to §§ 1303.12 and 1303.22 of title 21 of the Code of Federal Regulations.

5. **Inventory.** Every registrant required to keep records and who possesses any quantity of cathinone or DOET shall take an inventory pursuant to §§ 1304.11–1304.19 of title 21 of the Code of Federal Regulations of all stocks of these substances on hand.

6. **Records.** All registrants required to keep records pursuant to §§ 1304.21–1304.27 of title 21 of the Code of Federal Regulations shall maintain such records on cathinone and DOET.

7. **Reports.** All registrants required to submit reports pursuant to §§ 1304.34–1304.37 of title 21 of the Code of Federal Regulations shall do so regarding cathinone and DOET.

8. **Order Forms.** All registrants involved in the distribution of cathinone or DOET must comply with the order form requirements of §§ 1305.01–1305.16.

9. **Importation and Exportation.** All importation and exportation of cathinone or DOET shall be in compliance with part 1312 of title 21 of the Code of Federal Regulations.

10. **Criminal Liability.** Any activity with respect to cathinone or DOET not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the placement of cathinone and DOET into Schedule I will have no impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96–354). This drug control action relates to the control of substances that have no legitimate use or manufacturer in the United States.

This action has been analyzed in accordance with the principles and criteria contained in E.O. 12612, and it has been determined that this matter does not have sufficient federalism implications to require the preparation of a Federalism Assessment.

In accordance with the provisions of 21 U.S.C. 811(d), this scheduling action is a formal rulemaking that is required by United States obligations under an international convention, namely the Convention on Psychotropic Substances, 1971. Such formal proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, have been exempted from the consultation requirements of Executive Order 12291 (46 FR 13193). Accordingly, this action is not subject to those provisions of E.O. 12778 which are contingent upon review by OMB. Nevertheless, the Administrator has determined that this is not a "major rule," as that term is used in E.O. 12291, and that it would otherwise meet the applicable standards of sections 2(a) and 2(b)(2) of E.O. 12778.

List of Subjects in 21 CFR Part 1308

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

Based upon the notification of the Secretary-General of the United Nations and in accordance with the recommendations of the Assistant Secretary for Health of the Department of Health and Human Services and under the authority vested in the Attorney General by 21 U.S.C. 811(a) and delegated to the Administrator by the regulations of the Department of Justice (28 CFR 0.100), the Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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 1308.11 is amended by redesignating existing paragraphs (d)(3) through (d)(28) as (d)(4) through (d)(29) and adding new paragraph (d)(3) to read as follows:

* * * * *
 § 1308.11 **Schedule I.**
 (d) * * *

(3) 2,5-dimethoxy-4-ethylamphetamine.....7399

Some trade or other names: DOET
 * * * * *

3. Section 1308.11 is amended by redesignating paragraphs (f)(1) through (f)(4) as (f)(2) through (f)(5) and adding paragraph (f)(1) to read as follows:

§ 1308.11 Schedule I.

* * * * *
(f) * * *

(1) cathinone..... 1235

Some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone.

* * * * *

Dated: January 7, 1993.

Robert C. Bonner,

Administrator of Drug Enforcement.

[FR Doc. 93-877 Filed 1-13-93; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

24 CFR Part 990

[Docket No. N-93-3560; FR 3088-N-04]

Low-Income Public Housing—Project-Based Accounting

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Request for comment on estimated reporting and recordkeeping burden.

SUMMARY: This request for public comment is related to the final rule on project-based accounting for low-income public housing that was published on December 23, 1992. It deals with the subject of the burden of information collections contained in that rule. The Department has not changed the burden estimate, but it is inviting further comment from the public.

DATES: Comments are now being accepted by OMB and HUD.

ADDRESSES: Interested persons are invited to respond to this notice by sending comments on the reporting and recordkeeping burden of the project-based accounting requirement, in accordance with 24 CFR part 990, subpart C, to both of the following persons: HUD Rules Docket Clerk, room 10276, Office of General Counsel, Department of Housing and Development, 451 Seventh Street SW., Washington, DC 20410-0500; and HUD Desk Officer, Office of Information and Regulatory Affairs, Office of

Management and Budget, 725 Seventeenth Street NW., Washington, DC 20503. Communications should refer to the above docket number and title. A copy of each communication submitted will be available for inspection and copying during regular business hours (7:30 a.m.—5:30 p.m. Eastern Time) at the Seventh Street address.

FOR FURTHER INFORMATION CONTACT:

Mr. John T. Comerford, Director, Financial Management Division, Office of Management Operations, Public and Indian Housing, room 4212, U.S. Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410, telephone (202) 708-1872 (voice) or (202) 708-0850 (TDD). (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: In the final rule, published on December 23, 1992 (57 FR 61226), adding a subpart C to 24 CFR part 990, the Department mentioned that the estimated reporting and recordkeeping burden had been challenged by commenters. This Notice explains why the Department has not changed the burden estimate, while inviting further comment from the public.

Numerous objections were raised by commenters in response to the estimated reporting and recordkeeping burden of 1¼ hours per PHA for providing year-end information by project. Commenters argued that project-based accounting (PBA) would increase staff hours tremendously, require computer hardware and software redesign, staff training time, additional staff for handling accounting and reporting detail, increase accounting and auditing fees, and require the hiring of consultants.

The respondents who raised objections to the estimate of burden hours, in HUD's view, have misinterpreted the extent of the intended impact of project-based accounting on the PHA accounting system. For example, respondents assumed that the PBA requirement imposed a mandatory framework of accounting or reporting that would require extensive revision of their existing accounting systems; that separate operating budgets and/or HUD reporting forms would have to be prepared and submitted by project; that separate General Ledgers would have to be maintained by project; that PBA meant the assignment of specific staff to individual projects which would either require the hiring of additional staff or result in idle time for existing staff; that operating subsidy and operating

reserves would have to be calculated and maintained by project.

On the other hand, the estimate of burden hours was based on the assumption by the Department that many PHAs, particularly larger PHAs, have existing systems in place that provide for the accumulation and allocation of resources by management area; that little, if any, modification of existing systems would be required in order to further identify consolidated income/expense categories by project or cost center; that the only continuing additional time would be in the preparation of the required year-end information reports for the Board. The elimination in the final rule of the requirement to allocate indirect income/expense among projects/cost centers further ensures that the impact on existing accounting systems will be minimal, even for smaller PHAs. Therefore, the Department did not change the number of estimated burden hours because we believe that, on the average, the ongoing additional time required by the PHA will be limited to preparing the annual project/cost center reports for distribution to the Board.

The Office of Management and Budget is currently reviewing the reporting and recordkeeping burden imposed by the rule and would welcome additional comments concerning the new requirements by housing authorities, and entities that work with them, that have had experience with these new requirements. HUD plans to re-examine the burden estimates after the new PBA requirement is operational, and, therefore, also welcomes comments concerning the burden experienced by housing authorities, especially specific descriptions of the steps taken by the housing authorities, the type of staff or consultant employed for the task, and the time actually taken by each type of staff member to implement the requirements for each project or cost center.

Dated: January 5, 1993.

Grady J. Norris,

Assistant General Counsel for Regulations.

[FR Doc. 93-945 Filed 1-13-93; 8:45 am]

BILLING CODE 4210-33-M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 2602

Ethical Conduct of Employees

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.