

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

[Docket No. FDA-2011-N-0003]

**New Animal Drugs for Use in Animal Feeds; 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 a supplemental new animal drug application (NADA) filed by Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA provides for approval of free-choice feeds for growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers). **DATES:** This rule is effective January 27, 2012.

**FOR FURTHER INFORMATION CONTACT:** Suzanne Sechen, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276-8105, email: [suzanne.sechen@fda.hhs.gov](mailto:suzanne.sechen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 95-735 that provides for use of RUMENSIN 90 (monensin) Type A medicated article in free-choice feeds for growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers) for increased rate of weight gain and for prevention and control of coccidiosis. The supplemental NADA is approved as of November 18, 2011, and the regulations in 21 CFR 558.355 are amended to reflect the approval.

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.

■ 2. In § 558.355, add paragraph (f)(3)(iv); and in paragraph (f)(3)(x)(c), remove the last sentence.

The addition reads as follows:

**§ 558.355 Monensin.**

\* \* \* \* \*

(f) \* \* \*

(3) \* \* \*

(iv) *Amount.* Monensin at concentrations in free-choice Type C medicated feeds to provide 50 to 200 mg per head per day.

(a) *Indications for use.* Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.

(b) *Limitations.* During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated supplement before using the monensin medicated supplement. The product's effectiveness in cull cows and bulls has not been established. See paragraph (d) of this section for other required label warnings.

\* \* \* \* \*

Dated: January 23, 2012.

**William T. Flynn,**

*Acting Director, Center for Veterinary Medicine.*

[FR Doc. 2012-1755 Filed 1-26-12; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**21 CFR Parts 1300, 1303, 1304, 1305, 1306, 1308, 1309, 1310, 1312, 1313, 1314, 1316**

[Docket No. DEA-356]

**Technical Amendments and Corrections to DEA Regulations**

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** This final rule updates the Code of Federal Regulations pertaining to DEA by alphabetizing definitions and eliminating the numeric listings in those definitions in order to simplify future rulemakings where additional definitions are added or deleted. This rule also corrects typographic errors, reflects organizational changes, and updates cross-reference listings in the CFR. This action makes no substantive changes to the affected rules.

**DATES:** The effective date of this rule is January 27, 2012.

**FOR FURTHER INFORMATION CONTACT:** Rhea D. Moore, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone (202) 307-7165.

**SUPPLEMENTARY INFORMATION:**

**Background**

DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (CSIEA) (21 U.S.C. 801-971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 through 1321.

The Administrative Procedure Act (5 U.S.C. 553) does not require notice and the opportunity for public comment where the agency for good cause finds that notice and public comment are unnecessary, impracticable, or contrary to the public interest under 5 U.S.C. 553(b)(B) or on rules affecting agency organization, procedure, or practice under 5 U.S.C. 553(b)(A). This rule contains technical corrections and updates organizational changes in agency regulations; it imposes no new or substantive requirement on the public or DEA registrants. As such, DEA has determined that notice and

opportunity for public comment on this rule are unnecessary. This rule is also exempt from notice and comment because these changes involve rules of agency organization, procedure, or practice. Because this is not a substantive rule and as DEA finds good cause under 5 U.S.C. 553(d)(3) for the above reasons, this final rule shall take effect upon date of publication in the **Federal Register**.

#### Technical Amendments and Corrections

This rule removes the numbers for each definition in 21 CFR 1300.01 and 21 CFR 1300.02 and alphabetizes the definitions of each section so they can be easily referenced and so that additions and deletions can be made in future rulemakings without renumbering or causing confusion by placing definitions out of alphabetical order.

This rule also clarifies the regulations by correcting typographical errors and updating citation listings and organizational changes previously overlooked. Specifically, the changes are:

In § 1300.01(b), alphabetizing the definitions, italicization of defined terms, removing the numbered designations, standardization of subordinate definitions by placement in quotation marks, separating the term “manufacturer,” correcting the citation in “supplier” from 1305.08 to 1305.06, standardization of “a.k.a.” names for substances listed under “anabolic steroids,” and correcting the spelling of four of the chemical names for substances listed under “anabolic steroid”: boldenone, mesterolone, methyltrienolone, and 17 $\alpha$ -methyl- $\Delta$ 1-dihydrotestosterone;

In § 1300.02(b), alphabetizing the definitions, italicization of defined terms, removing the numbered designations, standardization of subordinate definitions by placement in quotation marks, and adding “Federal” at the beginning of “Food, Drug, and Cosmetic Act” in the definition of “Drug product”;

In the fifth sentence of § 1303.11(c), correcting the spelling of “nnt” to be “not”;

In the second sentence of § 1304.03(a), correcting the citation to be 1307.13 instead of 1307.15, and in the fifth sentence correcting the word “acquire” to be “require”;

In § 1305.03(d), updating the reference to reflect the new organization of § 1300.01;

In the heading for § 1306.24, correcting the spelling of “filing” to be “filling”;

In § 1308.11(d)(8), correcting the spelling of “mdthylenedioxy” to be “methylenedioxy”;

In § 1308.12(b)(4), correcting the spelling of “whhch” to be “which”;

In § 1308.13(b), correcting the spelling of “sxstem” to be “system” and correcting the term “position” to be “positional”;

In §§ 1309.21(a)(2), 1309.24(b)–(d), 1310.04(f)(1)(ii) and (g), 1310.05(d) and (f)(2), 1310.06(h)(5), 1310.09(b), 1310.10(a), 1310.14, 1313.21(c)(1), 1313.24(a), and 1314.115(a)(2), updating the references to reflect the new organization of § 1300.02;

In the second sentence of § 1309.62(a), correcting the spelling of “cases” to be “ceases”;

In the heading of § 1310.10, adding “Federal” at the beginning of “Food, Drug, and Cosmetic Act”;

In § 1312.18(d), correcting the citation from “paragraph (a)” to “paragraph (b)”;

In § 1312.21(c), correcting the spelling of “repuest” to be “request”;

In §§ 1312.25, 1312.28(c), 1313.12(d), and 1313.32(b)(2), updating the organizational listings of “Drug Operations Section,” “Drug Control Section,” and “Chemical Operations Section” to the correct “Import/Export Unit”;

In § 1313.14(c), correcting the spelling of “Sevice” to be “Service”;

In § 1313.31(b)(5), correcting the word “new” to be “net”;

In § 1314.45, correcting the citation from “1314.15” to “1314.30”;

In § 1316.03(d), correcting and updating the reference from “DEA Form 84” to “DEA Form 400”; and

In § 1316.42(g), correcting the spelling of “colmencing” to be “commencing.”

Finally, this rule would update sections of Parts 1310 and 1313 to accurately reflect how information is submitted to DEA by removing references to “telex number,” an outdated form of technology. This would occur by removing “telex” or “telex number” from 21 CFR 1310.06(e)(1), (e)(4), (f)(1) and (f)(4), 1313.13(c)(1), 1313.31(b)(11), and 1313.33(c)(1) and (c)(4).

#### Regulatory Analyses

##### Administrative Procedure Act

The Administrative Procedure Act (5 U.S.C. 553) does not require notice and the opportunity for public comment where the agency for good cause finds that notice and public procedure thereon is unnecessary, impracticable, or contrary to the public interest under 5 U.S.C. 553(b)(B) or on rules affecting agency organization, procedure, or practice under 5 U.S.C. 553(b)(A). This

rule contains technical corrections and updates organizational changes in agency regulations; it imposes no new or substantive requirement on the public or DEA registrants. As such, DEA finds good cause that notice and opportunity for public comment on this rule are unnecessary pursuant to 5 U.S.C. 553(b)(B). This rule is also exempt from notice and comment pursuant to 5 U.S.C. 553(b)(A) as these changes involve rules of agency organization, procedure, or practice.

Because this is not a substantive rule and as DEA finds good cause under 5 U.S.C. 553(d)(3) for the above reasons, this final rule is effective upon date of publication in the **Federal Register**.

##### Regulatory Flexibility Act

This rule has been reviewed in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Deputy Assistant Administrator certifies that this regulation will have no economic impact on a substantial number of small entities. This rulemaking only makes technical amendments and imposes no new requirements.

##### Executive Orders 12866 and 13563

The Deputy Assistant Administrator certifies that this is not a significant regulatory action within the meaning of Executive Order 12866 and the principles reaffirmed in Executive Order 13563, as it makes only technical amendments to the current regulations.

##### Executive Order 12988

This proposed regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards and reduce burden.

##### Executive Order 13132

This rulemaking does not preempt or modify any provision of State law, impose enforcement responsibilities on any State, or diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

##### Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$136,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no

actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

#### Paperwork Reduction Act of 1995

This action does not impose a collection of information requirement under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

#### Executive Order 13175

This proposed rule will not have tribal implications and will not impose substantial direct compliance costs on Indian tribal governments.

#### Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). 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 United States-based companies to compete with foreign-based companies in domestic and export markets.

#### List of Subjects

##### 21 CFR Part 1300

Chemicals, Drug traffic control.

##### 21 CFR Part 1303

Administrative practice and procedure, Drug traffic control.

##### 21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements.

##### 21 CFR Part 1305

Drug traffic control.

##### 21 CFR Part 1306

Drug traffic control, Prescription drugs.

##### 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

##### 21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

##### 21 CFR Part 1310

Drug traffic control, Exports, Imports, Security measures.

##### 21 CFR Parts 1312 and 1313

Administrative practice and procedure, Drug traffic control, Exports,

Imports, Reporting and recordkeeping requirements.

##### 21 CFR Part 1314

Drug traffic control, Reporting and recordkeeping requirements.

##### 21 CFR Part 1316

Administrative practice and procedure, Authority delegations (Government agencies), Drug traffic control, Research, Seizures and forfeitures.

For the reasons set out above, 21 CFR Parts 1300, 1303, 1304, 1305, 1306, 1308, 1309, 1310, 1312, 1313, 1314, and 1316 are amended to read as follows:

#### PART 1300—DEFINITIONS

■ 1. The authority citation for Part 1300 continues to read as follows:

**Authority:** 21 U.S.C. 802, 821, 829, 871(b), 951, 958(f).

■ 2. In § 1300.01, paragraph (b) is revised to read as follows:

##### § 1300.01 Definitions relating to controlled substances.

\* \* \* \* \*

(b) As used in parts 1301 through 1308 and part 1312 of this chapter, the following terms shall have the meanings specified:

*Act* means the Controlled Substances Act, as amended (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act, as amended (84 Stat. 1285; 21 U.S.C. 951).

*Administration* means the Drug Enforcement Administration.

*Administrator* means the Administrator of the Drug Enforcement Administration. The Administrator has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

*Anabolic steroid* means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes:

- (1) 3 $\beta$ ,17-dihydroxy-5 $\alpha$ -androstane
- (2) 3 $\alpha$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androstane
- (3) 5 $\alpha$ -androstane-3,17-dione
- (4) 1-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androst-1-ene)
- (5) 1-androstenediol (3 $\alpha$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androst-1-ene)
- (6) 4-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxy-androst-4-ene)
- (7) 5-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxy-androst-5-ene)
- (8) 1-androstenedione ([5 $\alpha$ ]-androst-1-en-3,17-dione)
- (9) 4-androstenedione (androst-4-en-3,17-dione)
- (10) 5-androstenedione (androst-5-en-3,17-dione)

- (11) bolasterone (7 $\alpha$ ,17 $\alpha$ -dimethyl-17 $\beta$ -hydroxyandrost-4-en-3-one)
- (12) boldenone (17 $\beta$ -hydroxyandrost-1,4-diene-3-one)
- (13) boldione (androsta-1,4-diene-3,17-dione)
- (14) calusterone (7 $\beta$ ,17 $\alpha$ -dimethyl-17 $\beta$ -hydroxyandrost-4-en-3-one)
- (15) clostebol (4-chloro-17 $\beta$ -hydroxyandrost-4-en-3-one)
- (16) dehydrochloromethyltestosterone (4-chloro-17 $\beta$ -hydroxy-17 $\alpha$ -methyl-androst-1,4-dien-3-one)
- (17) desoxymethyltestosterone (17 $\alpha$ -methyl-5 $\alpha$ -androst-2-en-17 $\beta$ -ol) (a.k.a. 'madol')
- (18)  $\Delta$ 1-dihydrotestosterone (a.k.a. '1-testosterone') (17 $\beta$ -hydroxy-5 $\alpha$ -androst-1-en-3-one)
- (19) 4-dihydrotestosterone (17 $\beta$ -hydroxy-androstan-3-one)
- (20) drostanolone (17 $\beta$ -hydroxy-2 $\alpha$ -methyl-5 $\alpha$ -androstan-3-one)
- (21) ethylestrenol (17 $\alpha$ -ethyl-17 $\beta$ -hydroxyestr-4-ene)
- (22) fluoxymesterone (9-fluoro-17 $\alpha$ -methyl-11 $\beta$ ,17 $\beta$ -dihydroxyandrost-4-en-3-one)
- (23) formebolone (2-formyl-17 $\alpha$ -methyl-11 $\alpha$ ,17 $\beta$ -dihydroxyandrost-1,4-dien-3-one)
- (24) furazabol (17 $\alpha$ -methyl-17 $\beta$ -hydroxyandrostano[2,3-c]-furazan)
- (25) 13 $\beta$ -ethyl-17 $\beta$ -hydroxygon-4-en-3-one
- (26) 4-hydroxytestosterone (4,17 $\beta$ -dihydroxy-androst-4-en-3-one)
- (27) 4-hydroxy-19-nortestosterone (4,17 $\beta$ -dihydroxy-estr-4-en-3-one)
- (28) mestanolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxy-5 $\alpha$ -androst-3-one)
- (29) mesterolone (1 $\alpha$ -methyl-17 $\beta$ -hydroxy-[5 $\alpha$ ]-androstan-3-one)
- (30) methandienone (17 $\alpha$ -methyl-17 $\beta$ -hydroxyandrost-1,4-dien-3-one)
- (31) methandriol (17 $\alpha$ -methyl-3 $\beta$ ,17 $\beta$ -dihydroxyandrost-5-ene)
- (32) methenolone (1-methyl-17 $\beta$ -hydroxy-5 $\alpha$ -androst-1-en-3-one)
- (33) 17 $\alpha$ -methyl-3 $\beta$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androstane
- (34) 17 $\alpha$ -methyl-3 $\alpha$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androstane
- (35) 17 $\alpha$ -methyl-3 $\beta$ ,17 $\beta$ -dihydroxyandrost-4-ene
- (36) 17 $\alpha$ -methyl-4-hydroxynandrolone (17 $\alpha$ -methyl-4-hydroxy-17 $\beta$ -hydroxyestr-4-en-3-one)
- (37) methyldienolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxyestra-4,9(10)-dien-3-one)
- (38) methyltrienolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxyestra-4,9,11-trien-3-one)
- (39) methyltestosterone (17 $\alpha$ -methyl-17 $\beta$ -hydroxyandrost-4-en-3-one)
- (40) mibolerone (7 $\alpha$ ,17 $\alpha$ -dimethyl-17 $\beta$ -hydroxyestr-4-en-3-one)
- (41) 17 $\alpha$ -methyl- $\Delta$ 1-dihydrotestosterone (17 $\beta$ -hydroxy-17 $\alpha$ -methyl-5 $\alpha$ -androst-1-en-3-one) (a.k.a. '17- $\alpha$ -methyl-1-testosterone')

- (42) nandrolone (17 $\beta$ -hydroxyestr-4-en-3-one)
- (43) 19-nor-4-androstenediol (3 $\beta$ , 17 $\beta$ -dihydroxyestr-4-ene)
- (44) 19-nor-4-androstenediol (3 $\alpha$ , 17 $\beta$ -dihydroxyestr-4-ene)
- (45) 19-nor-5-androstenediol (3 $\beta$ , 17 $\beta$ -dihydroxyestr-5-ene)
- (46) 19-nor-5-androstenediol (3 $\alpha$ , 17 $\beta$ -dihydroxyestr-5-ene)
- (47) 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione)
- (48) 19-nor-4-androstenedione (estr-4-en-3,17-dione)
- (49) 19-nor-5-androstenedione (estr-5-en-3,17-dione)
- (50) norbolethone (13 $\beta$ , 17 $\alpha$ -diethyl-17 $\beta$ -hydroxygon-4-en-3-one)
- (51) norclostebol (4-chloro-17 $\beta$ -hydroxyestr-4-en-3-one)
- (52) norethandrolone (17 $\alpha$ -ethyl-17 $\beta$ -hydroxyestr-4-en-3-one)
- (53) normethandrolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxyestr-4-en-3-one)
- (54) oxandrolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxy-2-oxa-[5 $\alpha$ ]-androstan-3-one)
- (55) oxymesterone (17 $\alpha$ -methyl-4,17 $\beta$ -dihydroxyandrost-4-en-3-one)
- (56) oxymetholone (17 $\alpha$ -methyl-2-hydroxymethylene-17 $\beta$ -hydroxy-[5 $\alpha$ ]-androstan-3-one)
- (57) stanozolol (17 $\alpha$ -methyl-17 $\beta$ -hydroxy-[5 $\alpha$ ]-androst-2-eno[3,2-c]-pyrazole)
- (58) stenbolone (17 $\beta$ -hydroxy-2-methyl-[5 $\alpha$ ]-androst-1-en-3-one)
- (59) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone)
- (60) testosterone (17 $\beta$ -hydroxyandrost-4-en-3-one)
- (61) tetrahydrogestrinone (13 $\beta$ , 17 $\alpha$ -diethyl-17 $\beta$ -hydroxygon-4,9,11-trien-3-one)
- (62) trenbolone (17 $\beta$ -hydroxyestr-4,9,11-trien-3-one)
- (63) Any salt, ester, or ether of a drug or substance described in this paragraph. Except such term does not include an anabolic steroid that is expressly intended for administration through implants to cattle or other nonhuman species and that has been approved by the Secretary of Health and Human Services for such administration. If any person prescribes, dispenses, or distributes such steroid for human use, the person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this paragraph.

*Automated dispensing system* means a mechanical system that performs operations or activities, other than compounding or administration, relative

to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.

*Basic class* means, as to controlled substances listed in Schedules I and II:

(1) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in § 1308.11(b) of this chapter;

(2) Each of the opium derivatives, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in § 1308.11(c) of this chapter;

(3) Each of the hallucinogenic substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in § 1308.11(d) of this chapter;

(4) Each of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(i) Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;

(ii) Apomorphine;

(iii) Codeine;

(iv) Etorphine hydrochloride;

(v) Ethylmorphine;

(vi) Hydrocodone;

(vii) Hydromorphone;

(viii) Metopon;

(ix) Morphine;

(x) Oxycodone;

(xi) Oxymorphone;

(xii) Thebaine;

(xiii) Mixed alkaloids of opium listed in § 1308.12(b)(2) of this chapter;

(xiv) Cocaine; and

(xv) Ecgonine;

(5) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in § 1308.12(c) of this chapter; and

(6) Methamphetamine, its salts, isomers, and salts of its isomers;

(7) Amphetamine, its salts, optical isomers, and salts of its optical isomers;

(8) Phenmetrazine and its salts;

(9) Methylphenidate;

(10) Each of the substances having a depressant effect on the central nervous

system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in § 1308.12(e) of this chapter.

*Central fill pharmacy* means a pharmacy which is permitted by the state in which it is located to prepare controlled substances orders for dispensing pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user. Such central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner.

*Commercial container* means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term commercial container does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of controlled substances.

*Compounder* means any person engaging in maintenance or detoxification treatment who also mixes, prepares, packages or changes the dosage form of a narcotic drug listed in Schedules II, III, IV or V for use in maintenance or detoxification treatment by another narcotic treatment program.

*Controlled substance* has the meaning given in section 802(6) of Title 21, United States Code (U.S.C.).

*Customs territory of the United States* means the several States, the District of Columbia, and Puerto Rico.

*Detoxification treatment* means the dispensing, for a period of time as specified below, of a narcotic drug or narcotic drugs in decreasing doses to an individual to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period of time. There are two types of detoxification treatment: Short-term detoxification treatment and long-term detoxification treatment.

(1) Short-term detoxification treatment is for a period not in excess of 30 days.

(2) Long-term detoxification treatment is for a period more than 30 days but not in excess of 180 days.

*Dispenser* means an individual practitioner, institutional practitioner, pharmacist or pharmacist who dispenses a controlled substance.

*Export* means, with respect to any article, any taking out or removal of such article from the jurisdiction of the United States (whether or not such taking out or removal constitutes an exportation within the meaning of the customs and related laws of the United States).

*Exporter* includes every person who exports, or who acts as an export broker for exportation of, controlled substances listed in any schedule.

*Freight forwarding facility* means a separate facility operated by a distributing registrant through which sealed, packaged controlled substances in unmarked shipping containers (i.e., the containers do not indicate that the contents include controlled substances) are, in the course of delivery to, or return from, customers, transferred in less than 24 hours. A distributing registrant who operates a freight forwarding facility may use the facility to transfer controlled substances from any location the distributing registrant operates that is registered with the Administration to manufacture, distribute, or import controlled substances, or, with respect to returns, registered to dispense controlled substances, provided that the notice required by § 1301.12(b)(4) of Part 1301 of this chapter has been submitted and approved. For purposes of this definition, a “distributing registrant” is a person who is registered with the Administration as a manufacturer, distributor, and/or importer.

*Hearing* means:

(1) In part 1301 of this chapter, any hearing held for the granting, denial, revocation, or suspension of a registration pursuant to sections 303, 304, and 1008 of the Act (21 U.S.C. 823, 824 and 958).

(2) In part 1303 of this chapter, any hearing held regarding the determination of aggregate production quota or the issuance, adjustment, suspension, or denial of a procurement quota or an individual manufacturing quota.

(3) In part 1308 of this chapter, any hearing held for the issuance, amendment, or repeal of any rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).

*Import* means, with respect to any article, any bringing in or introduction of such article into either the jurisdiction of the United States or the customs territory of the United States, and from the jurisdiction of the United States into the customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

*Importer* includes every person who imports, or who acts as an import broker for importation of, controlled substances listed in any schedule.

*Individual practitioner* means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

*Institutional practitioner* means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

*Interested person* means any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811).

*Inventory* means all factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).

*Isomer* means:

(1) The optical isomer, except as used in § 1308.11(d) and § 1308.12(b)(4) of this chapter. As used in § 1308.11(d) of this chapter, the term “isomer” means any optical, positional, or geometric isomer. As used in § 1308.12(b)(4) of this chapter, the term “isomer” means any optical or geometric isomer;

(2) As used in § 1308.11(d) of this chapter, the term “positional isomer” means any substance possessing the same molecular formula and core structure and having the same functional group(s) and/or substituent(s) as those found in the respective Schedule I hallucinogen, attached at any position(s) on the core structure, but in such manner that no new chemical functionalities are created and no

existing chemical functionalities are destroyed relative to the respective Schedule I hallucinogen. Rearrangements of alkyl moieties within or between functional group(s) or substituent(s), or divisions or combinations of alkyl moieties, that do not create new chemical functionalities or destroy existing chemical functionalities, are allowed i.e., result in compounds which are positional isomers. For purposes of this definition, the “core structure” is the parent molecule that is the common basis for the class; for example, tryptamine, phenethylamine, or ergoline. Examples of rearrangements resulting in creation and/or destruction of chemical functionalities (and therefore resulting in compounds which are not positional isomers) include, but are not limited to: Ethoxy to *alpha*-hydroxyethyl, hydroxy and methyl to methoxy, or the repositioning of a phenolic or alcoholic hydroxy group to create a hydroxyamine. Examples of rearrangements resulting in compounds which would be positional isomers include: *Tert*-butyl to *sec*-butyl, methoxy and ethyl to isopropoxy, N,N-diethyl to N-methyl-N-propyl, or *alpha*-methylamino to N-methylamino.

*Jurisdiction of the United States* means the customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and the Trust Territories of the Pacific Islands.

*Label* means any display of written, printed, or graphic matter placed upon the commercial container of any controlled substance by any manufacturer of such substance.

*Labeling* means all labels and other written, printed, or graphic matter:

(1) Upon any controlled substance or any of its commercial containers or wrappers, or

(2) Accompanying such controlled substance.

*Long Term Care Facility (LTCF)* means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

*Maintenance treatment* means the dispensing for a period in excess of twenty-one days, of a narcotic drug or narcotic drugs in the treatment of an individual for dependence upon heroin or other morphine-like drug.

*Manufacture* means the producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a

practitioner who, as an incident to his/her administration or dispensing such substance in the course of his/her professional practice, prepares, compounds, packages or labels such substance.

*Manufacturer* means a person who manufactures a drug or other substance, whether under a registration as a manufacturer or under authority of registration as a researcher or chemical analyst.

*Mid-level practitioner* means an individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists and physician assistants who are authorized to dispense controlled substances by the State in which they practice.

*Name* means the official name, common or usual name, chemical name, or brand name of a substance.

*Narcotic drug* means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

(1) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(2) Poppy straw and concentrate of poppy straw.

(3) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine and derivatives of ecgonine or their salts have been removed.

(4) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(5) Ecgonine, its derivatives, their salts, isomers and salts of isomers.

(6) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in paragraphs (1) through (5) of this definition.

*Narcotic treatment program* means a program engaged in maintenance and/or detoxification treatment with narcotic drugs.

*Net disposal* means, for a stated period, the quantity of a basic class of controlled substance distributed by the registrant to another person, plus the quantity of that basic class used by the registrant in the production of (or converted by the registrant into) another basic class of controlled substance or a noncontrolled substance, plus the quantity of that basic class otherwise disposed of by the registrant, less the quantity of that basic class returned to the registrant by any purchaser, and less the quantity of that basic class distributed by the registrant to another registered manufacturer of that basic class for purposes other than use in the production of, or conversion into, another basic class of controlled substance or a noncontrolled substance or in the manufacture of dosage forms of that basic class.

*Person* includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

*Pharmacist* means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

*Prescription* means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

*Proceeding* means all actions taken for the issuance, amendment, or repeal of any rule issued pursuant to section 201 of the Act (21 U.S.C. 811), commencing with the publication by the Administrator of the proposed rule, amended rule, or repeal in the **Federal Register**.

*Purchaser* means any registered person entitled to obtain and execute order forms pursuant to §§ 1305.04 and 1305.06.

*Readily retrievable* means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

*Register* and *registration* refer only to registration required and permitted by

sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).

*Registrant* means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

*Reverse distributor* means a registrant who receives controlled substances acquired from another DEA registrant for the purpose of—

(1) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or

(2) Where necessary, processing such substances or arranging for processing such substances for disposal.

*Supplier* means any registered person entitled to fill order forms pursuant to § 1305.06 of this chapter.

■ 3. In § 1300.02, paragraph (b) is revised to read as follows:

**§ 1300.02 Definitions relating to listed chemicals.**

\* \* \* \* \*

(b) As used in parts 1309, 1310, and 1313 of this chapter, the following terms shall have the meaning specified:

*Act* means the Controlled Substances Act, as amended (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act, as amended (84 Stat. 1285; 21 U.S.C. 951).

*Administration* means the Drug Enforcement Administration.

*Administrator* means the Administrator of the Drug Enforcement Administration. The Administrator has been delegated authority under the Act by the Attorney General (28 CFR 0.100).

*At retail*, with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively.

*Broker and trader* mean any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical by—

(1) Negotiating contracts;

(2) Serving as an agent or intermediary; or

(3) Fulfilling a formal obligation to complete the transaction by bringing together a buyer and seller, a buyer and transporter, or a seller and transporter, or by receiving any form of compensation for so doing.

*Chemical export* means transferring ownership or control, or the sending or taking of threshold quantities of listed chemicals out of the United States (whether or not such sending or taking out constitutes an exportation within the meaning of the customs and related laws of the United States).

*Chemical exporter* is a regulated person who, as the principal party in

interest in the export transaction, has the power and responsibility for determining and controlling the sending of the listed chemical out of the United States.

*Chemical import* means with respect to a listed chemical, any bringing in or introduction of such listed chemical into either the jurisdiction of the United States or into the customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States).

*Chemical importer* is a regulated person who, as the principal party in interest in the import transaction, has the power and responsibility for determining and controlling the bringing in or introduction of the listed chemical into the United States.

*Chemical mixture* means a combination of two or more chemical substances, at least one of which is not a listed chemical, except that such term does not include any combination of a listed chemical with another chemical that is present solely as an impurity or which has been created to evade the requirements of the Act.

*Combination ephedrine product* means a drug product containing ephedrine or its salts, optical isomers, or salts of optical isomers, and therapeutically significant quantities of another active medicinal ingredient.

*Customs territory of the United States* means the several States, the District of Columbia, and Puerto Rico.

*Drug product* means an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Federal Food, Drug, and Cosmetic Act for distribution in the United States.

*Encapsulating machine* means any manual, semi-automatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, semi-solid, or liquid material.

*Established business relationship* means the regulated person has imported or exported a listed chemical at least once within the past six months, or twice within the past twelve months from or to a foreign manufacturer, distributor, or end user of the chemical that has an established business with a fixed street address. A person or business that functions as a broker or intermediary is not a customer for purposes of this definition.

*Established record as an importer* means that the regulated person has imported a listed chemical at least once within the past six months, or twice within the past twelve months from a foreign supplier.

*Hearing* means any hearing held for the granting, denial, revocation, or suspension of a registration pursuant to sections 303, 304, and 1008 of the Act (21 U.S.C. 823, 824 and 958).

*International transaction* means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

*Jurisdiction of the United States* means the customs territory of the United States, the Virgin Islands, the Canal Zone, Guam, American Samoa, and the Trust Territories of the Pacific Islands.

*Listed chemical* means any List I chemical or List II chemical.

*List I chemical* means a chemical specifically designated by the Administrator in § 1310.02(a) of this chapter that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act and is important to the manufacture of a controlled substance.

*List II chemical* means a chemical, other than a List I chemical, specifically designated by the Administrator in § 1310.02(b) of this chapter that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the Act.

*Mobile retail vendor* means a person or entity that makes sales at retail from a stand that is intended to be temporary or is capable of being moved from one location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes).

*Name* means the official name, common or usual name, chemical name, or brand name of a substance.

*Person* includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

*Readily retrievable* means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

*Register and registration* refer only to registration required and permitted by sections 303 or 1007 of the Act (21 U.S.C. 823 or 957).

*Registrant* means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

*Regular customer* means a person with whom the regulated person has an established business relationship for a specified listed chemical or chemicals that has been reported to the Administration subject to the criteria established in part 1313 of this chapter.

*Regular importer* means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Administrator.

*Regulated person* means any individual, corporation, partnership, association, or other legal entity who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine, or who acts as a broker or trader for an international transaction involving a listed chemical, tableting machine, or encapsulating machine.

*Regulated seller* means a retail distributor (including a pharmacy or a mobile retail vendor), except that the term does not include an employee or agent of the distributor.

*Regulated transaction* means:

(1) A distribution, receipt, sale, importation, or exportation of a listed chemical, or an international transaction involving shipment of a listed chemical, or if the Administrator establishes a threshold amount for a specific listed chemical, a threshold amount as determined by the Administrator, which includes a cumulative threshold amount for multiple transactions, of a listed chemical, except that such term does not include:

(i) A domestic lawful distribution in the usual course of business between agents or employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person;

(ii) A delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this paragraph does not relieve a distributor, importer, or exporter from compliance with parts 1309, 1310, 1313, and 1315 of this chapter;

(iii) Any category of transaction or any category of transaction for a specific

listed chemical or chemicals specified by regulation of the Administrator as excluded from this definition as unnecessary for enforcement of the Act;

(iv) Any transaction in a listed chemical that is contained in a drug other than a scheduled listed chemical product that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act, subject to paragraph (1)(v) of this definition, unless—

(A) The Administrator has determined pursuant to the criteria in § 1310.10 of this chapter that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(B) The quantity of the listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical;

(v) Any transaction in a scheduled listed chemical product that is a sale at retail by a regulated seller or a distributor required to submit reports under § 1310.03(c) of this chapter; or

(vi) Any transaction in a chemical mixture designated in §§ 1310.12 and 1310.13 of this chapter that the Administrator has exempted from regulation.

(2) A distribution, importation, or exportation of a tableting machine or encapsulating machine except that such term does not include a domestic lawful distribution in the usual course of business between agents and employees of a single regulated person; in this context, agents or employees means individuals under the direct management and control of the regulated person.

*Retail distributor* means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine or phenylpropranolamine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. Also for the purposes of this paragraph, a “grocery store” is an entity within Standard Industrial Classification (SIC) code 5411, a “general merchandise store” is an entity within SIC codes 5300 through 5399 and 5499, and a “drug store” is an entity within SIC code 5912.

*Scheduled listed chemical product* means:

(1) A product that contains ephedrine, pseudoephedrine, or phenylpropranolamine and may be marketed or distributed lawfully in the

United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug, Ephedrine, pseudoephedrine, and phenylpropranolamine include their salts, optical isomers, and salts of optical isomers.

(2) Scheduled listed chemical product does not include any product that is a controlled substance under part 1308 of this chapter. In the absence of such scheduling by the Attorney General, a chemical specified in paragraph (1) of this definition may not be considered to be a controlled substance.

*Tableting machine* means any manual, semi-automatic, or fully automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets.

*Valid prescription* means a prescription that is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner’s professional practice.

#### PART 1303—QUOTAS

■ 4. The authority citation for Part 1303 continues to read as follows:

**Authority:** 21 U.S.C. 821, 826, 871(b).

■ 5. In § 1303.11, the fifth sentence of paragraph (c) is revised to read as follows:

##### § 1303.11 Aggregate production quotas.

\* \* \* \* \*

(c) \* \* \* In the event the Administrator decides to hold such a hearing, he shall publish notice of the hearing in the **Federal Register**, which notice shall summarize the issue s to be heard and shall set the time for the hearing which shall not be less than 30 days after the date of publication of the notice. \* \* \*

#### PART 1304—RECORDS AND REPORTS OF REGISTRANTS

■ 6. The authority citation for Part 1304 continues to read as follows:

**Authority:** 21 U.S.C. 821, 827, 831, 871(b), 958(e), 965, unless otherwise noted.

■ 7. In § 1304.03, the second and fifth sentences of paragraph (a) are revised to read as follows:

##### § 1304.03 Persons required to keep records and file reports.

(a) \* \* \* Any registrant who is authorized to conduct other activities without being registered to conduct

those activities, either pursuant to § 1301.22(b) of this chapter or pursuant to §§ 1307.11–1307.13 of this chapter, shall maintain the records and inventories and shall file the reports required by this part for persons registered to conduct such activities. \* \* \* Also, the Administration does not wish to require separate stocks of the same substance to be purchased and stored for separate activities. \* \* \*

#### PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES

■ 8. The authority citation for Part 1305 continues to read as follows:

**Authority:** 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

■ 9. In § 1305.03, paragraph (d) is revised to read as follows:

##### § 1305.03 Distributions requiring a Form 222 or a digitally signed electronic order.

\* \* \* \* \*

(d) Delivery from a central fill pharmacy, as defined in § 1300.01 of this chapter, to a retail pharmacy.

#### PART 1306—PRESCRIPTIONS

■ 10. The authority citation for Part 1306 continues to read as follows:

**Authority:** 21 U.S.C. 821, 829, 831, 871(b), unless otherwise noted.

■ 11. In § 1306.24, the section heading is revised to read as follows:

##### § 1306.24 Labeling of substances and filling of prescriptions.

\* \* \* \* \*

#### PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 12. The authority citation for Part 1308 continues to read as follows:

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

■ 13. In § 1308.11, paragraph (d)(8) is revised to read as follows:

##### § 1308.11 Schedule I.

\* \* \* \* \*

(d) \* \* \*

(8) 5-methoxy-3,4-methylenedioxy-amphetamine 7401

\* \* \* \* \*

■ 14. In § 1308.12, paragraph (b)(4) is revised to read as follows:

##### § 1308.12 Schedule II.

\* \* \* \* \*

(b) \* \* \*

(4) Coca leaves (9040) and any salt, compound, derivative or preparation of coca leaves (including cocaine (9041)

and ecgonine (9180) and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.

\* \* \* \* \*

■ 15. In § 1308.13, paragraph (b) introductory text is revised to read as follows:

§ 1308.13 Schedule III.

\* \* \* \* \*

(b) *Stimulants*. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, positional, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

\* \* \* \* \*

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

■ 16. The authority citation for Part 1309 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 952, 958.

■ 17. In § 1309.21, paragraph (a)(2) is revised to read as follows:

§ 1309.21 Persons required to register.

(a) \* \* \*

(2) Every person who distributes or exports or proposes to distribute or export any List I chemical, other than those List I chemicals contained in a product exempted under paragraph (1)(iv) of the definition of regulated transaction in § 1300.02 of this chapter.

\* \* \* \* \*

■ 18. In § 1309.24, paragraphs (b), (c), and (d) are revised to read as follows:

§ 1309.24 Waiver of registration requirement for certain activities.

\* \* \* \* \*

(b) The requirement of registration is waived for any person who manufactures or distributes a scheduled listed chemical product or other product containing a List I chemical that is described and included in paragraph (1)(iv) of the definition of regulated

transaction in § 1300.02 of this chapter, if that person is registered with the Administration to engage in the same activity with a controlled substance.

(c) The requirement of registration is waived for any person who imports or exports a scheduled listed chemical product or other product containing a List I chemical that is described and included in paragraph (1)(iv) of the definition of regulated transaction in § 1300.02 of this chapter, if that person is registered with the Administration to engage in the same activity with a controlled substance.

(d) The requirement of registration is waived for any person who only distributes a prescription drug product containing a List I chemical that is regulated pursuant to paragraph (1)(iv) of the definition of regulated transaction in § 1300.02 of this chapter.

\* \* \* \* \*

■ 19. In § 1309.62, the second sentence of paragraph (a) is revised to read as follows:

§ 1309.62 Termination of registration.

(a) \* \* \* Any registrant who ceases legal existence or discontinues business or professional practice shall promptly notify the Special Agent in Charge of the Administration in the area in which the person is located of such fact and seek authority and instructions to dispose of any List I chemicals obtained under the authority of that registration.

\* \* \* \* \*

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

■ 20. The authority citation for Part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 827(h), 830, 871(b), 890.

■ 21. In § 1310.04, paragraph (f)(1)(ii) and the first sentence of paragraph (g) are revised to read as follows:

§ 1310.04 Maintenance of records.

\* \* \* \* \*

(f) \* \* \*

(1) \* \* \*

(ii) For List I chemicals that are contained in scheduled listed chemical products as defined in § 1300.02 of this chapter, the thresholds established in paragraph (g) of this section apply only to non-retail distribution, import, and export. Sales of these products at retail are subject to the requirements of part 1314 of this chapter.

\* \* \* \* \*

(g) For listed chemicals for which no thresholds have been established, the size of the transaction is not a factor in

determining whether the transaction meets the definition of a regulated transaction as set forth in § 1300.02 of this chapter. \* \* \*

\* \* \* \* \*

■ 22. In § 1310.05, the fifth sentence of paragraph (d) and paragraph (f)(2) are revised to read as follows:

§ 1310.05 Reports.

\* \* \* \* \*

(d) \* \* \* This reporting requirement does not apply to drug or other products which are exempted under paragraphs (1)(iv) or (1)(v) of the definition of regulated transaction in § 1300.02 of this chapter except as set forth in § 1310.06(h)(5). \* \* \*

\* \* \* \* \*

(f) \* \* \*

(2) Distributions of drug products by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as defined in § 1300.02 of this chapter, except that this paragraph does not apply to sales of scheduled listed chemical products at retail.

\* \* \* \* \*

■ 23. In § 1310.06, paragraphs (e)(1), (e)(4), (f)(1), (f)(4), and (h)(5) are revised to read as follows:

§ 1310.06 Content of records and reports.

\* \* \* \* \*

(e) \* \* \*

(1) The name, address, telephone number, and, where available, the facsimile number of the regulated person; the name, address, telephone number, and, where available, the facsimile number of the import broker or forwarding agent, if any:

\* \* \* \* \*

(4) The name, address, telephone number, and, where available, the facsimile number of the consignor in the foreign country of exportation.

(f) \* \* \*

(1) The name, address, telephone number, and, where available, the facsimile number of the regulated person; the name, address, telephone number, and, where available, the facsimile number of the export broker, if any:

\* \* \* \* \*

(4) The name, address, telephone number, and, where available, the facsimile number of the consignee in the country where the shipment is destined; the name(s) and address(es) of any intermediate consignee(s).

\* \* \* \* \*

(h) \* \* \*

(5) The aggregate quantity of each listed chemical manufactured which

becomes a component of a product exempted from paragraphs (1)(iv) or (1)(v) of the definition of regulated transaction in § 1300.02 of this chapter during the preceding calendar year.

\* \* \* \* \*

■ 24. In § 1310.09, the first sentence of paragraph (b) is revised to read as follows:

**§ 1310.09 Temporary exemption from registration.**

\* \* \* \* \*

(b) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a drug product that contains pseudoephedrine or phenylpropanolamine that is regulated pursuant to paragraph (1)(iv) of the definition of regulated transaction in § 1300.02 of this chapter is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before December 3, 1997.

\* \* \* \* \*

■ 25. In § 1310.10, the section heading and first sentence of paragraph (a) is revised to read as follows:

**§ 1310.10 Removal of the exemption of drugs distributed under the Federal Food, Drug and Cosmetic Act.**

(a) The Administrator may remove from exemption under paragraph (1)(iv) of the definition of regulated transaction in § 1300.02 of this chapter any drug or group of drugs that the Administrator finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance.

\* \* \* \* \*

■ 26. In § 1310.14, the introductory paragraph is revised to read as follows:

**§ 1310.14 Removal of exemption from definition of regulated transaction.**

The Administrator finds that the following drugs or groups of drugs are being diverted to obtain a listed chemical for use in the illicit production of a controlled substance and removes the drugs or groups of drugs from exemption under paragraph (1)(iv) of the definition of regulated transaction in § 1300.02 of this chapter pursuant to the criteria listed in § 1310.10 of this part:

\* \* \* \* \*

**PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES**

■ 27. The authority citation for Part 1312 continues to read as follows:

**Authority:** 21 U.S.C. 952, 953, 954, 957, 958.

■ 28. In § 1312.18, paragraph (d) is revised to read as follows:

**§ 1312.18 Contents of import declaration.**

\* \* \* \* \*

(d) Notwithstanding the time limitations included in paragraph (b) of this section, an applicant may obtain a special waiver of these time limitations in emergency or unusual instances, provided that a specific confirmation is received from the Administrator or his delegate advising the registrant to proceed pursuant to the special waiver.

■ 29. In § 1312.21, paragraph (c) is revised to read as follows:

**§ 1312.21 Requirement of authorization to export.**

\* \* \* \* \*

(c) A separate authorization request is obtained for each consignment of such controlled substances to be exported.

■ 30. In § 1312.25, the second sentence is revised to read as follows:

**§ 1312.25 Expiration date.**

\* \* \* Any unused export permit shall be returned by the permittee to the Import/Export Unit for cancellation.

■ 31. In § 1312.28, paragraph (c) is revised to read as follows:

**§ 1312.28 Distribution of special controlled substances invoice.**

\* \* \* \* \*

(c) Copy 3 shall accompany the shipment and will be detached by the District Director of the U.S. Customs Service at the port of exportation, who shall sign and date the certification of customs on such Copy 3, noting any changes from the entries made by the exporter, and shall then promptly forward Copy 3 to the Import/Export Unit of the Administration.

\* \* \* \* \*

**PART 1313—IMPORTATION AND EXPORTATION OF LIST I AND LIST II CHEMICALS**

■ 32. The authority citation for Part 1313 continues to read as follows:

**Authority:** 21 U.S.C. 802, 830, 871(b), 971.

■ 33. In § 1313.12, paragraph (d) is revised to read as follows:

**§ 1313.12 Requirement of authorization to import.**

\* \* \* \* \*

(d) For imports where advance notification is waived pursuant to paragraph (c)(1) of this section, the DEA Form 486 must be received by the Drug Enforcement Administration, Import/Export Unit, on or before the date of importation through use of the mailing

address listed in § 1313.12(b) or through use of electronic facsimile media.

\* \* \* \* \*

■ 34. In § 1313.13, paragraph (c)(1) is revised to read as follows:

**§ 1313.13 Contents of import declaration.**

\* \* \* \* \*

(c) \* \* \*

(1) The name, address, telephone number, and, where available, the facsimile number of the chemical importer; the name, address, telephone number, and, where available, the facsimile number of the broker or forwarding agent (if any); and

\* \* \* \* \*

■ 35. In § 1313.14, paragraph (c) is revised to read as follows:

**§ 1313.14 Distribution of import declaration.**

\* \* \* \* \*

(c) Copy 3 shall be presented to the U.S. Customs Service along with the customs entry. If the import is a regulated transaction for which the 15-day advance notice requirement has been waived, the regulated person shall declare this information to the U.S. Customs Service Official by checking the block on the DEA Form 486 designated for this purpose.

■ 36. In § 1313.21, paragraph (c)(1) is revised to read as follows:

**§ 1313.21 Requirement of authorization to export.**

\* \* \* \* \*

(c) \* \* \*

(1) Any regulated person who has satisfied the requirements of § 1313.24 for reporting to the Administration an established business relationship, as defined in § 1300.02 of this chapter, with a foreign customer.

\* \* \* \* \*

■ 37. In § 1313.24, paragraph (a) is revised to read as follows:

**§ 1313.24 Waiver of 15-day advance notice for chemical exporters.**

(a) Each regulated person shall provide to the Administration the identity and information listed in the definition of established business relationship in § 1300.02 of this chapter for an established business relationship with a foreign customer not later than August 31, 1989.

\* \* \* \* \*

■ 38. In § 1313.31, paragraphs (b)(5) and (b)(11) are revised to read as follows:

**§ 1313.31 Advance notice of importation for transshipment or transfer.**

\* \* \* \* \*

(b) \* \* \*

(5) The net weight of each listed chemical given in kilograms or parts thereof;

\* \* \* \* \*

(11) The name, address, business, telephone number, and, where available, the facsimile number of the importer, transferor, or transshipper;

\* \* \* \* \*

■ 39. In § 1313.32, paragraph (b)(2) is revised to read as follows:

§ 1313.32 Requirement of authorization for international transactions.

\* \* \* \* \*

(b) \* \* \*

(2) A copy of the DEA Form 486 may be transmitted directly to the Drug Enforcement Administration, Import/Export Unit, through electronic facsimile media not later than 15 days prior to the exportation.

\* \* \* \* \*

■ 40. In § 1313.33, paragraphs (c)(1) and (c)(4) are revised to read as follows:

§ 1313.33 Contents of an international transaction declaration.

\* \* \* \* \*

(c) \* \* \*

(1) The name, address, telephone number, and, where available, the facsimile number of the chemical exporter; the name, address, telephone number, and, where available, the facsimile number of the chemical importer;

\* \* \* \* \*

(4) The name, address, telephone number, and, where available, the facsimile number of the consignee in the country where the chemical shipment is destined; the name(s) and address(es) of any intermediate consignee(s).

PART 1314—RETAIL SALE OF SCHEDULED LISTED CHEMICAL PRODUCTS

■ 41. The authority citation for Part 1314 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 842, 871(b), 875, 877, 886a.

■ 42. In § 1314.45, the introductory paragraph is revised to read as follows:

§ 1314.45 Privacy protections.

To protect the privacy of individuals who purchase scheduled listed chemical products, the disclosure of information in logbooks under § 1314.30 is restricted as follows:

\* \* \* \* \*

■ 43. In § 1314.115, paragraph (a)(2) is revised to read as follows:

§ 1314.115 Distributions not subject to reporting requirements.

(a) \* \* \*

(2) Distributions by retail distributors that may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in the definition of retail distributor in § 1300.02 of this chapter, except that this paragraph (a)(2) does not apply to sales of scheduled listed chemical products at retail.

\* \* \* \* \*

PART 1316—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

■ 44. The authority citation for Subpart A of Part 1316 continues to read as follows:

Authority: 21 U.S.C. 822(f), 830(a), 871(b), 880, 958(f), 965.

■ 45. In § 1316.03, paragraph (d) is revised to read as follows:

§ 1316.03 Authority to make inspections.

\* \* \* \* \*

(d) Collecting samples of controlled substances or listed chemicals (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples on DEA Form 400 to the owner, operator, or agent in charge of the premises);

\* \* \* \* \*

■ 46. The authority citation for Subpart D of Part 1316 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 875, 958(d), 965.

■ 47. In § 1316.42, paragraph (g) is revised to read as follows:

§ 1316.42 Definitions.

\* \* \* \* \*

(g) The term *proceeding* means all actions involving a hearing, commencing with the publication by the Administrator of the notice of proposed rulemaking or the issuance of an order to show cause.

\* \* \* \* \*

Dated: January 13, 2012.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

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DEPARTMENT OF STATE

22 CFR Part 8

RIN 1400-AC64

[Public Notice 7773]

Advisory Committee Management

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This final rule removes regulations which implement the Federal Advisory Committee Act (FACA) for the Department of State. The Department of State implementation of FACA is now governed by the rules promulgated by GSA and internal policy guidance in the Foreign Affairs Manual.

DATES: Effective Date: This rule is effective on February 27, 2012.

FOR FURTHER INFORMATION CONTACT: Alice Kottmyer, Office of the Legal Adviser, who may be reached at (202) 647-2318.

SUPPLEMENTARY INFORMATION: Pursuant to Section 8(a) of the Federal Advisory Committee Act (FACA), 5 U.S.C. Appendix, agency heads are required to establish uniform administrative guidelines and management controls for advisory committees established by that agency.

The Department of State first finalized its rules, codified at 22 CFR Part 8, in 1975. Since then, GSA has promulgated comprehensive guidance at 41 CFR Part 102-3, and the Department recently published updated internal guidance that implements FACA and the GSA regulations. The Department guidance is in Volume 11 of the Foreign Affairs Manual, and can be found at: http://www.state.gov/documents/organization/176811.pdf. The provisions of Part 8 are obsolete and are hereby removed.

Regulatory Analyses

Administrative Procedure Act

Removing 22 CFR part 8 is a decision regarding the Department's organization, procedure, or practice and is not subject to the notice-and-comment procedures of 5 U.S.C. 553(b).

Regulatory Flexibility Act/Executive Order 13272: Small Business

The Department certifies that this rulemaking is not expected to have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act, 5 U.S.C. 601-612, and Executive Order 13272, section 3(b).