disclosure of this information from $5,000 to $50,000 annually? Are there other options that allow retention of the provision but effectively narrow its scope?

These issues will be discussed at the March 29, 1996, advisory committee meeting. Because FDA wants to provide adequate time for the submission of all relevant information related to this important public health issue, FDA is reopening the comment period.

Interested persons may, on or before April 29, 1996, submit to Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

For further information on the administrative procedure for holding the Science Board to the Food and Drug Administration meeting and the general function of this advisory committee, see the document entitled ''Advisory Committee; notice of meeting,'' that published in the Federal Register of February 26, 1996 (61 FR 7117).

Dated: February 27, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–5116 Filed 3–4–96; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1302, 1303, 1304, 1305, 1306, 1307, 1308, 1309, 1310, 1311, 1312, 1313, and 1316

[DEA Number 139P]

RIN Number 1117–AA33

Consolidation, Elimination, and Clarification of Various Regulations

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule.

SUMMARY: DEA proposes to amend the language in title 21, Code of Federal Regulations, parts 1300 through 1316. In concert with the President's National Performance Review, Regulatory Reinvention Initiative (NPR), DEA proposes to consolidate, eliminate, and clarify many of its regulations to address areas of confusion frequently raised by the pharmaceutical, chemical, and health care industries; and to correct inaccurate citations, office designations, and typographical errors.

DATES: Written comments or objections must be received by July 3, 1996.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION: A comprehensive review has been conducted of title 21, Code of Federal Regulations (21 CFR), parts 1300 through 1316. Title 21 contains the rules and regulations by which DEA implements the Controlled Substances Act, the Narcotic Addict Treatment Act, the Controlled Substances Import/Export Act, the Chemical Diversion and Trafficking Act, and the Domestic Chemical Diversion Control Act. These regulations are designed to detect and deter the diversion of controlled substances and listed chemicals. DEA undertook this review to update, simplify, and consolidate its regulations in concert with the President's Regulatory Reform Initiative under the NPR; to clarify areas of confusion which have been raised by the pharmaceutical, chemical, and health care industries; and to correct inaccurate citations, office designations and typographical errors. In this effort, DEA intends to reduce some of the regulatory burden on the affected industries. The changes proposed herein build upon DEA's longstanding commitment to internal self-examination, to respond to technological advances, and to work with industry to develop the most effective and least intrusive methods of preventing and detecting the diversion of controlled substances and listed chemicals.

Among the changes being proposed, which are further described below, are the consolidation into a chart of the frequency of registration, coincident activities, and fee schedules; allowing manufacturers more latitude to set individual labeling standards; reducing the frequency of ARCOS reports from monthly to quarterly, and reducing the number of transactions to be reported by manufacturers; permitting some pharmacies to file prescriptions without marking them with a red ''C'', to transfer prescriptions for refill purposes more than once, and to retain faxed prescriptions as original documents for patients in home hospice care; and combining and streamlining various reporting, recordkeeping, and inventory requirements.

The following summarizes the changes proposed to be made to each part of the regulations:

Part 1300

DEA is proposing to move the definitions set out in 21 CFR parts 1301 through 1313 into a new part 1300. This will provide a single source for definition of the terms used in 21 CFR parts 1301 through 1313, avoiding the need for duplicate definitions in the various parts. The definitions set out in Part 1316 will remain listed in that part due to the specificity of the definitions to the subject matter of the part.

Part 1301

DEA is proposing to amend 21 CFR, part 1301 to provide a simple and clear set of requirements concerning the registration of manufacturers, distributors, dispensers, importers and exporters of controlled substances. In this regard, DEA is proposing to incorporate into 21 CFR, part 1301 the requirements relating to the registration of importers and exporters which were previously set out in 21 CFR, part 1311.

In order to provide easier reference to the primary regulations regarding registration (including separate registration for independent activities, coincident activities, the application forms and fees required for registration and reregistration, and the registration period for the various activities) DEA is proposing to amend 21 CFR, part 1301 to list such requirements in table form. Use of the table form allows for ''at-a-glance'' reference to the fundamental regulations concerning the registration requirements, rather than requiring reference to multiple pages of text in separate sections.

In addition to revising the format of 21 CFR, part 1301, DEA is proposing to transfer the definitions previously listed in § 1301.02 to the proposed new part 1300, and to remove §§ 1301.27, 1301.29, and 1301.53, relating to civil defense authorities, provisional registration of narcotic treatment programs (NTP), and waiver and modification of rules in hearings, respectively. Sections 1301.27 and 1301.29 are obsolete and § 1301.53 is duplicated by § 1316.44. With respect to civil defense authorities, DEA will continue to work with the appropriate Federal and state agencies to insure that the proper policies and procedures are in place to deal with the availability and

security of controlled substances during emergencies. Further, the fee exemption provisions (formerly in § 1301.13 and now in § 1301.21) and the provision regarding when a registrant may apply for reregistration (formerly in § 1301.31(b) and now in § 1301.13(b)) have been amended. The fee exemption provision has been amended to provide that Federal, state or local officials who must obtain an individual practitioner registration in order to carry out their official duties are exempted from the fees for registration and reregistration. This action is being taken to insure that those individual government practitioners who are not able to practice under the registration number of a hospital or clinic are subject to the same exemption as those government physicians carrying out official duties in such facilities. The reregistration provision has been amended to allow that a person registered as either a bulk manufacturer of Schedule I or II controlled substances or an importer of Schedule I or II controlled substances may apply to be reregistered no more than 120 days prior to the expiration date of his/her registration. The current limitation of no more than 60 days prior to the expiration date does not allow sufficient time prior to the applicant's expiration date to satisfy the notice and comment and hearing procedures required under §§ 1301.33 and 1301.34 of this chapter. The additional 60 days should provide sufficient time to allow for satisfaction of those requirements for most applications prior to the expiration date. However, in no circumstances will DEA grant such an applicant reregistration more than 60 days prior to the applicant's registration expiration date.

DEA is also proposing to incorporate the language found in § 1307.12 of this chapter into the coincident activities table and the language found in § 1307.14 into § 1301.62. Additionally, DEA is proposing to combine §§ 1301.62 and 1301.63 into one section and revise the new section to allow that a registration cannot be assigned or transferred unless specific, written authority has been granted by the Administration.

The proposed changes will result in a substantial restructuring of part 1301, including the redesignation of most of the sections within the part. Only the sections relating to the Security Requirements (§ 1301.71–1301.76) and Employee Screening—Non-Practitioners (§ 1301.90–1301.93) are unchanged. For the sake of clarity, DEA is proposing in the regulatory text to remove the old §§ 1301.11 through 1301.63 and replace them with new §§ 1301.11 through 1301.52. While the appearance of the new sections is significantly changed, readers should keep in mind that there are only minor changes to the specific regulatory requirements contained in the old parts 1301 and 1311.

Part 1302

This part contains the requirements governing the labeling and packaging of controlled substances pursuant to sections 305 and 1008(e) of the Act (21 U.S.C. 825 and 958(e)). The proposed changes made in part 1302 would move the definitions into Part 1300 for ease of reference and, in general, allow more latitude to the registrant in the design of labels for products which contain controlled substances. While continuing to require an identifiable marking on labels of a commercial container which contains a controlled substance, the proposed changes would allow the registrant to meet the requirement by its own design of a label and placement of the required symbol. Further, language regarding labeling requirements at the inception of the Controlled Substances Act (on May 1, 1971) has been proposed to be removed as no longer necessary. The effective date for implementing the labeling requirements for substances transferred or added to a schedule is proposed to be established in the final order. Finally, the requirement for sealing of a commercial package is proposed to be amended to include all controlled substances, making it consistent with the Federal Food, Drug, and Cosmetic Act, and to allow more latitude in the design of the seal, while retaining the primary purpose of a seal which is to detect tampering of the commercial package.

Part 1303

This part contains the procedures governing the establishment of production and manufacturing quotas for basic classes of controlled substances listed in Schedules I and II. Changes are being proposed in this part to correct inaccurate citations and typographical errors and to move the definitions to part 1300 for ease of reference.

Part 1304

This part sets forth inventory and recordkeeping requirements for registrants who handle controlled substances. In accordance with 21 U.S.C. 827 and 958(e), registrants who manufacture, distribute, or dispense controlled substances must maintain complete and accurate records of such substances manufactured, received, sold, delivered or otherwise disposed of. Modifications to several sections of part 1304 are being proposed to eliminate the requirement for reports which are outdated, to remove redundancies in recordkeeping and inventory requirements, to change obsolete references, and to correct typographical errors.

Section 1304.02 is proposed to be revised to remove all definitions to Part 1300.

Section 1304.03 is proposed to be revised to combine researcher activities into one paragraph, thereby eliminating redundancies in the recordkeeping requirements.

Section 1304.04 is proposed to be revised to correct a typographical error in paragraph (a), to update language in paragraph (e), and amend paragraph (h)(2) to permit pharmacies with automatic data processing systems to file Schedule III–V prescriptions without marking them with a red ''C''.

Section 1304.11 is proposed to be revised to combine all general requirements for inventories thereby eliminating redundancies. Paragraphs (b) and (c) were combined and the frequency statement was revised to permit the biennial inventory to be taken on any date as long as it is within two years of the previous biennial inventory; the requirements contained in §§ 1304.12, 1304.13, 1304.14, 1304.15, 1304.16, 1304.17, 1304.18 and 1304.19 were combined and included in 1304.11. In § 1304.12, the reference to the May 1, 1971 date is proposed to be deleted. Paragraph references are proposed to be changed to reflect revisions.

Section 1304.21 paragraph (a): The May 1, 1971 date is proposed to be deleted and paragraph references changed to reflect revisions.

Sections 1304.22, 1304.23, 1304.24, 1304.25 and 1304.26 are proposed to be combined. Paragraph references are proposed to be changed to reflect revisions.

Sections 1304.31 through 1304.38 are proposed to be revised, combined, or removed to delete obsolete forms and references, and reflect changes to manufacturer reporting from existing regulations to conform with current practice. Reporting requirements are proposed to be revised to reflect changes in frequency of reporting (from monthly to quarterly) and to reduce the number of transactions (i.e., quality control samples, manufacturing waste, etc.) required to be reported by manufacturers.

Part 1305

This part contains the procedures governing the issuance, use, and preservation of order forms pursuant to

section 308 of the Act (21 U.S.C. 828). The changes proposed to be made in part 1305, in general, delete redundant requirements and move the definitions into part 1300 for ease of reference. Section 1305.05, Power of Attorney, is amended only to correct certain citations; however, the existing Power of Attorney format is repeated in its entirety. Additionally, the Official Order Form for Schedule I & II Controlled Substances contains instructions that need not be repeated in the regulations. Regulations requiring reporting of lost or stolen Order Forms are modified to standardize reporting to local DEA offices of responsibility.

Part 1306

This part contains the specific regulatory requirements for the issuance, filling, and filing of prescriptions. Changes to this part are being proposed to reduce regulatory requirements for pharmacies. Additional changes are being made to correct typographical errors in the existing text.

Section 1306.02 contains a number of definitions which are proposed to be moved to part 1300 for ease of reference.

Section 1306.11 establishes the requirements for prescriptions for controlled substances listed in Schedule II. Under § 1306.11, the length of time a pharmacy is permitted to obtain a written prescription to cover an emergency oral prescription for a Schedule II controlled substance is 72 hours. Many pharmacists have expressed the view that there often is not enough time to meet their obligation within the time permitted. DEA is therefore proposing to extend the time allowed to obtain the written prescription from 72 hours to 7 days.

This same section permits pharmacists to dispense Schedule II narcotics to patients in Long Term Care Facilities (LTCFs) pursuant to prescriptions transmitted by facsimile. The facsimile then acts as the original written prescription for recordkeeping purposes. DEA is proposing to add a paragraph to § 1306.11 to give pharmacies the same authority to fill Schedule II narcotic prescriptions transmitted by facsimile for patients in a home hospice setting as exists for patients in LTCFs. The physician issuing the prescription will be required to note that the patient is a hospice patient on the face of the faxed prescription.

Section 1306.13 contains the rules for the partial filling of Schedule II prescriptions. A prescription for a Schedule II controlled substance written for a patient in a LTCF or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. Section 1306.13(b) requires that prior to any subsequent partial filling the pharmacist must determine that the additional partial fillings are necessary. DEA is proposing to remove this requirement.

The requirements for Schedule III and IV controlled substances are currently delineated separately from those in Schedule V. In order to more clearly differentiate those requirements that are identical from those that are not, where appropriate, identical rules affecting the controlled substances in Schedule V are proposed to be merged with those for Schedule III and IV. DEA is proposing to add Schedule V references to § 1306.21 and delete the corresponding § 1306.31. The language in these two sections is virtually identical and, therefore, will have no effect on the requirements currently in place.

Several typographical errors and an obsolete term are proposed to be corrected in § 1306.22.

Section 1306.23, which currently allows for the partial filling of Schedule III and IV prescriptions, is proposed to be expanded to add Schedule V controlled substances.

Section 1306.25, which refers to the rules for filing Schedule III and IV prescriptions contained in § 1304.04(h), is proposed to be removed and replaced by a new paragraph (§ 1306.24(c)).

Section 1306.26 establishes the rules for the transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes. A principal requirement for transferring prescription information is that the original prescription may be transferred on a one time basis only. This limitation was and is extremely important in preventing illegal and unauthorized refills from being dispensed. The prevention of diversion through unauthorized refills is significantly impacted by the ability of pharmacists and investigators to locate and confirm the authenticity of original prescription records. However, in situations where the prescription information, to include the entire refill history, is immediately accessible to the pharmacist, some exceptions to the one time only rule are proposed.

DEA is proposing to permit pharmacies sharing a real-time, on-line electronic database, to transfer prescription information for refill purposes for Schedule III, IV, and V controlled substances as often as refills are authorized by law and the original prescription. In addition to the requirements currently imposed on prescription transfers, it is proposed that a pharmacy filling a transferred prescription will be required to record the dates of all previous refills.

Part 1307

This part is a miscellaneous part which addresses the application of state law and other Federal Law, exceptions to regulations, special exceptions for manufacture and distribution of controlled substances, disposal of controlled substances, and special exempt persons. Changes to this part are being proposed to correct citation errors and omissions and to consolidate similar requirements. Section 1307.01 contains a definition which is proposed to be moved to part 1300. DEA proposes to remove § 1307.12 and include its provisions in the chart of coincident activities contained in Part 1301. DEA proposes to incorporate § 1307.14, Distribution upon discontinuance or transfer of business, with the redesignated § 1301.52, Transfer of registration. Section 1307.21 is proposed to be amended so that the requirements for reporting controlled substances to be disposed of will be uniform for all registrants regardless of whether or not they file reports to ARCOS.

Part 1308

This part sets forth the schedules of controlled substances and mechanisms for scheduling, rescheduling, or decontrolling a substance. Section 1308.04 is proposed to be removed as unnecessary since it is outdated. The following tables are proposed to be removed which contain information given out routinely to the industry and is available upon request: Section 1308.24—Exempt Chemical Preparations; § 1308.26—Excluded Veterinary Anabolic Steroid Implant Products; § 1308.32—Exempted prescription products; and § 1308.34—Exempt Anabolic Steroid Products. The sections will contain a reference on the procedure to request a copy of the tables.

Sections 1308.43, 1308.46, and 1308.47 relating to hearings are proposed to be removed as their requirements are already contained in part 1316. Proposed to be added to Section 1308.42 is a sentence which provides information on where to locate additional information on hearings related to this part.

Part 1309

Part 1309 is proposed to be amended by moving the definitions set out in § 1309.02 into part 1300. This will

provide a centralized source for all definitions for parts 1301 through 1313.

Further, §§ 1309.53 and 1309.57 are proposed to be removed, as they duplicate § 1316.44 and 1316.67 respectively. Sections 1309.54 through 1309.56 are proposed to be redesignated as §§ 1309.53 through 1309.55. In addition, §§ 1309.21 (a) and (b), 1309.25 (a) and (b), and 1309.71(a)(2) are proposed to be amended to change the citation from § 1310.01(f)(1)(iv) to § 1300.01(c)(28)(i)(D).

Part 1310

Part 1310 is proposed to be amended by moving the definitions set out in § 1310.01 into part 1300. Sections 1310.05 and 1310.08 will be amended to remove references to definitions in § 1310.01. Section 1310.10(a) is proposed to be amended to change the citation from § 1310.01(f)(1)(iv) to § 1300.01(c)(28)(i)(D) and §§ 1310.14(a) and 1310.15(d) are proposed to be amended to change the citation from § 1310.01(f)(1)(iv)(A) to § 1300.01(c)(28)(i)(D)(1). Finally, § 1310.09 is proposed to be removed, as this section was applicable only during the initial chemical registration period.

Part 1311

This part is proposed to be removed and reserved. The requirements contained in part 1311 have been incorporated into the proposed revisions to part 1301.

Part 1312

This part contains the procedures governing the importation, exportation, transshipment, and intransit shipment of controlled substances. Changes are being proposed in this part to correct inaccurate citations and typographical errors, to update office designations and addresses, and to move the definitions to part 1300 for ease of reference.

Part 1313

Part 1313 is proposed to be amended by moving the definitions set out in § 1313.02 into part 1300. In addition, §§ 1313.15, 1313.21 and 1313.24 are proposed to be amended to remove references to the definitions in § 1313.02.

Part 1316

This part contains the regulatory requirements and authorities related to Administrative Inspections, Protection of Researchers and Research Subjects, Enforcement Proceedings, Administrative Hearings, Seizure, Forfeiture, and Disposition of Property and Expedited Forfeiture Proceedings for Certain Property. Changes to this part are being proposed to correct citation errors and omissions and to consolidate similar requirements. DEA proposes to revise § 1316.13 to replace the present schedule of inspections with a system where the frequency of inspections will be determined by the history of the registrant, potential for diversion, or the amount of controlled substances found in the illicit market. DEA will focus inspection resources on diversion prevention and problem areas, reducing the intended frequency of inspections of registrants with a demonstrated record of compliance. This revision only applies to distributors of controlled substances listed in Schedules II through V and manufacturers of controlled substances listed in Schedules III through V. The yearly inspection for manufacturers of controlled substances listed in Schedules I and II and distributors of controlled substances listed in Schedule I remains unchanged. This proposal is intended to reduce the expenditure of time and effort, both on the part of DEA and the registrants who have shown a history of compliance in the past and continue to comply with the requirements of the CSA.

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this proposed regulation and by approving it certifies that this proposed regulation will not have a significant economic impact on a substantial number of small entities. This proposed regulation will streamline the current regulations set out in title 21, Code of Federal Regulations, parts 1300 to end and to provide regulatory relief to registrants.

This proposed regulation has been drafted in accordance with Executive Order 12866, section 1(b), Principles of Regulation. The Office of Managment and Budget has reviewed this proposed rule and determined that it is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review.

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

List of Subjects in 21 CFR Parts 1300–1316

Administrative practice and procedure, Drug traffic control, Security measures, Exports, Imports, Labeling, Packaging and containers, Reporting requirements, Prescription drugs, Narcotics, List I and List II chemicals, Research, Seizures and forfeitures.

21 CFR Part 1300 is proposed to be added to read as follows:

PART 1300—DEFINITIONS

Sec.

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

§ 1300.01 Definitions relating to controlled substances.

(a) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802), except that certain terms used in part 1316 of this chapter are defined at the beginning of each subpart of that part.

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

(1) The term *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).

(2) The term *Administration* means the Drug Enforcement Administration.

(3) The term *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).

(4) The term *anabolic steroid* means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, and includes:

(i) Boldenone;

(ii) Chlorotestosterone (4-chlortestosterone);

(iii) Clostebol;

(iv) Dehydrochlormethyltestosterone;

(v) Dihydrotestosterone (4-dihydrotestosterone);

(vi) Drostanolone;

(vii) Ethylestrenol;

(viii) Fluoxymesterone;

(ix) Formebulone (formebolone);

(x) Mesterolone;

(xi) Methandienone;

(xii) Methandranone;

(xiii) Methandriol;

(xiv) Methandrostenolone;

(xv) Methenolone;
(xvi) Methyltestosterone;
(xvii) Mibolerone;
(xviii) Nandrolone;
(xix) Norethandrolone;
(xx) Oxandrolone;
(xxi) Oxymesterone;
(xxii) Oxymetholone;
(xxiii) Stanolone;
(xxiv) Stanozolol;
(xxv) Testolactone;
(xxvi) Testosterone;
(xxvii) Trenbolone; and
(xxviii) Any salt, ester, or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth. Except such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which 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, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this paragraph.

(5) The term *basic class* means, as to controlled substances listed in Schedules I and II:

(i) 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;

(ii) 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;

(iii) 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;

(iv) 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:

(A) Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;
(B) Apomorphine;
(C) Codeine;
(D) Etorphine hydrochloride;
(E) Ethylmorphine;
(F) Hydrocodone;
(G) Hydromorphone;
(H) Metopon;
(I) Morphine;
(J) Oxycodone;
(K) Oxymorphone;
(L) Thebaine;
(M) Mixed alkaloids of opium listed in Section 1308.12(b)(2) of this chapter;
(N) Cocaine; and
(O) Ecgonine;

(v) 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

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

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

(viii) Phenmetrazine and its salts;

(ix) Methylphenidate;

(x) 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.

(6) The term *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.

(7) The term *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.

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

(9) The term *customs territory* of the United States means the several States, the District of Columbia, and Puerto Rico.

(10) The term *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.

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

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

(11) The term *dispenser* means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

(12) The term *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).

(13) The term *exporter* includes every person who exports, or who acts as an export broker for exportation of, controlled substances listed in any schedule.

(14) The term *hearing* means:

(i) 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).

(ii) 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.

(iii) 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).

(15) The term *home infusion pharmacy* means a pharmacy which compounds solutions for direct administration to a patient in a private residence, Long Term Care Facility or hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion.

(16) The term *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).

(17) The term *importer* includes every person who imports, or who acts as an import broker for importation of, controlled substances listed in any schedule.

(18) The term *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.

(19) The term *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.

(20) The term *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).

(21) The term *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).

(22) The term *isomer* means the optical isomer, except as used in § 1308.11(d) and § 1308.12(b)(4). As used in § 1308.11(d), the term isomer means the optical, positional, or geometric isomer. As used in § 1308.12(b)(4), the term isomer means the optical or geometric isomer.

(23) The term *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.

(24) The term *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.

(25) The term labeling means all labels and other written, printed, or graphic matter:

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

(ii) accompanying such controlled substance.

(26) The term *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.

(27) The term *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.

(28) The term *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. The term 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.

(29) The term *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.

(30) The term *name* means the official name, common or usual name, chemical name, or brand name of a substance.

(31) The term *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:

(i) 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.

(ii) Poppy straw and concentrate of poppy straw.

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

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

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

(vi) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in paragraphs (b)(31) (i) through (v) of this section.

(32) The term *narcotic treatment program* means a program engaged in maintenance and/or detoxification treatment with narcotic drugs.

(33) The term *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.

(34) The term *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.

(35) The term *person* includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(36) The term *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.)

(37) The term *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.

(38) The term *purchaser* means any registered person entitled to obtain and execute order forms pursuant to § 1305.04 and 1305.06.

(39) The term *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.

(40) The terms *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).

(41) The term 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).

(42) The term *supplier* means any registered person entitled to fill order forms pursuant to § 1305.08.

§ 1300.02 Definitions relating to listed chemicals.

(a) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802), except that certain terms used in part 1316 of this chapter are defined at the beginning of each subpart of that part.

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

(1) The term *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) as amended.

(2) The term *Administration* means the Drug Enforcement Administration.

(3) The term *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).

(4) The terms *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—

(i) Negotiating contracts;

(ii) Serving as an agent or intermediary; or

(iii) 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.

(5) The term *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).

(6) The term *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.

(7) The term *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).

(8) The term *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.

(9) The term *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.

(10) The term *customs territory of the United States* means the several States, the District of Columbia, and Puerto Rico.

(11) The term *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.

(12) The term *established business relationship with a foreign customer* means the regulated person has exported a listed chemical at least once within the past six months, or twice within the past twelve months to a foreign manufacturer, distributor, or end user of the chemical that has an established business in the foreign country with a fixed street address. A person or business which functions as a broker or intermediary is not a customer within the meaning of this section. The term also means that the regulated person has provided the Administration with the following information in accordance with the Waiver of 15-day advance notice requirements of § 1313.24 of this chapter:

(i) The name and street address of the chemical exporter and of each regular customer;

(ii) The telephone number, telex number, contact person, and where available, the facsimile number for the chemical exporter and for each regular customer;

(iii) The nature of the regular customer's business (i.e., importer, exporter, distributor, manufacturer, etc.), and if known, the use to which the listed chemical or chemicals will be applied;

(iv) The duration of the business relationship;

(v) The frequency and number of transactions occurring during the preceding 12-month period;

(vi) the amounts and the listed chemical or chemicals involved in regulated transactions between the chemical exporter and regular customer;

(vii) The method of delivery (direct shipment or through a broker or forwarding agent); and

(viii) Other information that the chemical exporter considers relevant for determining whether a customer is a regular customer.

(13) The term *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. The term also means that the regulated person has provided the Administration with the following information in accordance with the waiver of the 15-day advance notice requirements of § 1313.15 of this chapter:

(i) The name, DEA registration number (where applicable), street address, telephone number, telex number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and

(ii) The frequency and number of transactions occurring during the preceding 12 month period.

(14) The term *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).

(15) The term *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.

(16) The term *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.

(17) The term *listed chemical* means any List I chemical or List II chemical.

(18) The term *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.

(19) The term *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.

(20) The term *name* means the official name, common or usual name, chemical name, or brand name of a substance.

(21) The term *person* includes any individual, corporation, government or governmental subdivision or agency, business trust, partnership, association, or other legal entity.

(22) The term *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.

(23) The terms *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).

(24) The term *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).

(25) The term *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 § 1300.01(b)(12).

(26) The term *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.

(27) The term *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.

(28) The term *regulated transaction* means:

(i) 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:

(A) 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;

(B) 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 this part or parts 1309 and 1313 of this chapter;

(C) 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;

(D) Any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act unless—

(*1*) The drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient. For purposes of this paragraph, the term ''therapeutically insignificant quantities'' shall apply if the product formulation (i.e., the qualitative and quantitative composition of active ingredients within the product) is not listed in any of the following compendiums: *American Pharmaceutical Association (Apha) Handbook of Nonprescription Drugs; Drug Facts and Comparisons* (published by Wolters Kluwer Company); or *USP DI* (published by authority of the United States Pharmacopeial Convention, Inc.); or the product is not listed in § 1310.15 of this chapter as an exempt drug product. For drug products having formulations not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in § 1310.14 of this chapter, whether the active medicinal ingredients are present in quantities considered therapeutically significant for purposes of this paragraph; or

(*2*) The Administrator has determined pursuant to the criteria in § 1310.10 of this chapter that:

(*i*) 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

(*ii*) The quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Administrator;

(E) Any transaction in a chemical mixture listed in § 1310.13 of this chapter.

(ii) 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.

(29) The term retail distributor means a distributor whose List I chemical activities are restricted to the sale of drug products that are regulated as List I chemicals pursuant to § 1300.01(b)(28)(i)(D), directly to walk-in customers for personal use.

(30) The term *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.

PART 1301—[AMENDED]

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877, 952, 956, 957, 958, unless otherwise noted.

2. Section 1301.01 is proposed to be revised to read as follows:

§ 1301.01 Scope of part 1301.

Procedures governing the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances pursuant to sections 301–304 and 1007–1008 of the Act (21 U.S.C. 821–824 and 957–958) are set forth generally by those sections and specifically by the sections of this part.

3. Section 1301.02 is proposed to be revised to read as follows:

§ 1301.02 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or Part 1300 of this chapter.

4. As set forth in the Preamble, part 1301 is also proposed to be amended by revising §§ 1301.11 through 1301.52 and the undesignated center headings and by removing §§ 1301.53 through 1301.63 and the undesignated center headings:

Registration

§ 1301.11 Persons required to register.

(a) Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§ 1301.22–1301.26. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

§ 1301.12 Separate registrations for separate locations.

(a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of subsection 302(c)(2) or subsection 1007(b)(1)(B) of the Act (21 U.S.C. 822(c)(2) or 957(b)(1)(B));

(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and

(3) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

(a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Administrator to such person.

(b) Any person who is registered may apply to be reregistered not more than 60 days before the expiration date of his/her registration, except that a bulk manufacturer of Schedule I or II controlled substances or an importer of Schedule I or II controlled substances may apply to be reregistered no more than 120 days before the expiration date of their registration.

(c) At the time a manufacturer, distributor, researcher, analytical lab, importer, exporter or narcotic treatment program is first registered, that business activity shall be assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last date of the month designated for that group. In assigning any of the above business activities to a group, the Administration may select a group the expiration date of which is less than one year from the date such business activity was registered. If the business activity is assigned to a group which has an expiration date less than three months from the date of which the business activity is registered, the registration shall not expire until one year from that expiration date; in all other cases, the registration shall expire on the expiration date following the date on which the business activity is registered.

(d) At the time a retail pharmacy, hospital/clinic, practitioner or teaching institution is first registered, that business activity shall be assigned to one of twelve groups, which shall correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last day of the month designated for that group. In assigning any of the above business activities to a group, the Administration may select a group the expiration date of which is not less than 28 months nor more than 39 months from the date such business activity was registered. After the initial registration period, the registration shall expire 36 months from the initial expiration date.

(e) Any person who is required to be registered and who is not so registered, shall make application for registration for one of the following groups of controlled substances activities, which are deemed to be independent of each other. Application for each registration shall be made on the indicated form, and shall be accompanied by the indicated fee. Fee payments shall be made in the form of a personal, certified, or cashier's check or money order made payable to the ''Drug Enforcement Administration''. The application fees are not refundable. Any person, when registered to engage in the activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he/she complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities. Any person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided in this paragraph under coincident activities. A single registration to engage in any group of independent activities listed below may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in Schedule I may conduct research with any substances listed in Schedule I for which he/she has filed and had approved a research protocol.

(1)

Business activity	Controlled substances	DEA application forms	Application fee	Registration period	Coincident activities allowed
(i) Manufacturing	Schedules I through V.	New—225 Renewal—225a.	$875 875	1 year	Schedules I through V: May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered. Schedules II through V: May conduct chemical analysis and preclinical research (including quality control analysis) with substances listed in those schedules for which authorization as a manufacturer was issued.
(ii) Distributing	Schedules I through V.	New—225 Renewal—225a.	438 438	1 year.	
(iii) Dispensing or Instructing (Includes Practitioner Hospital/Clinic, Retail Pharmacy, Teaching Institution).	Schedules II through V.	New—224 Renewal—224a.	210 210	3 years	May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under state statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in Schedule II through V in a proportion not exceeding 20 percent of the complete solution, compound, or mixture.
(iv) Research or Instructing	Schedule I	New—225 Renewal—225a.	70 70	1 year	A researcher may manufacture or import the basic class of substance or substances for which registration was issued, provided that such manufacture or import is set forth in the protocol required in Section 1301.18 and to distribute such class to persons registered or authorized to conduct research with such class of substance or registered or authorized to conduct chemical analysis with controlled substances.
(v) Research	Schedules II through V.	New—225 Renewal—225a.	70 70	1 year	May conduct chemical analysis with controlled substances in those schedules for which registration was issued; manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration or reregistration; import such substances for research purposes; distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances, and to persons exempted from registration pursuant to Section 1301.24, and to conduct instructional activities with controlled substances.
(vi) Narcotic Treatment Program (including compounder).	Narcotic Drugs in Schedules II through V.	New—363 Renewal—363a.	70 70	1 year.	
(vii) Importing	Schedules I through V.	New—225 Renewal—225a.	438 438	1 year	May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered.
(viii) Exporting	Schedules I through V.	New—225 Renewal—225a.	438 438	1 year.	
(ix) Chemical Analysis	Schedules I through V.	New—225 Renewal—225a.	70 70	1 year	May manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to Section 1301.24; may export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries, and to conduct instructional activities with controlled substances.

(2) DEA Forms 224, 225, and 363 may be obtained at any area office of the Administration or by writing to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005.

(3) DEA Forms 224a, 225a, and 363a will be mailed, as applicable, to each registered person approximately 60 days before the expiration date of his/her registration; if any registered person does not receive such forms within 45 days before the expiration date of his/her registration, he/she must promptly give notice of such fact and request such forms by writing to the Registration Unit of the Administration at the foregoing address.

(f) Each application for registration to handle any basic class of controlled substance listed in Schedule I (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substance listed in Schedule II shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each basic class to be covered by such registration.

(g) Each application for registration to import or export controlled substances shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each controlled substance whose importation or exportation is to be authorized by such registration. Registration as an importer or exporter shall not entitle a registrant to import or export any controlled substance not specified in such registration.

(h) Each application for registration to conduct research with any basic class of controlled substance listed in Schedule II shall include the Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, for each such basic class to be manufactured or imported as a coincident activity of that registration. A statement listing the quantity of each such basic class or controlled substance to be imported or manufactured during the registration period for which application is being made shall be included with each such application. For purposes of this paragraph only, manufacturing is defined as the production of a controlled substance by synthesis, extraction or by agricultural/horticultural means.

(i) Each application shall include all information called for in the form, unless the item is not applicable, in which case this fact shall be indicated.

(j) Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity. An applicant may authorize one or more individuals, who would not otherwise be authorized to do so, to sign applications for the applicant by filing with the Registration Unit of the Administration a power of attorney for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications under this paragraph and shall contain the signature of the individual being authorized to sign applications. The power of attorney shall be valid until revoked by the applicant.

§ 1301.14 Filing of application; acceptance for filing; defective applications.

(a) All applications for registration shall be submitted for filing to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. The appropriate registration fee and any required attachments must accompany the application.

(b) Any person required to obtain more than one registration may submit all applications in one package. Each application must be complete and should not refer to any accompanying application for required information.

(c) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the Administrator may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within 10 days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time; the Administrator shall accept for filing any application upon resubmission by the applicant, whether complete or not.

(d) Accepting an application for filing does not preclude any subsequent request for additional information pursuant to § 1301.15 and has no bearing on whether the application will be granted.

§ 1301.15 Additional Information.

The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he/she deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

§ 1301.16 Amendments to and withdrawal of applications.

(a) An application may be amended or withdrawn without permission of the Administrator at any time before the date on which the applicant receives an order to show cause pursuant to § 1301.37. An application may be amended or withdrawn with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

§ 1301.17 Special procedures for certain applications.

(a) If, at the time of application for registration of a new pharmacy, the pharmacy has been issued a license from the appropriate State licensing agency, the applicant may include with his/her application an affidavit as to the existence of the State license in the following form:

Affidavit for New Pharmacy

I, _____, the _____ (Title of officer, official, partner, or other position) of _____ (Corporation, partnership, or sole proprietor), doing business as _____ (Store name) at _____ (Number and Street), _____ (City) _____ (State) _____ (Zip code), hereby certify that said store was issued a pharmacy permit No. _____ by the _____ (Board of Pharmacy or Licensing Agency) of the State of _____ on _____ (Date).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number. I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety. I further understand that any false information

contained in this affidavit may subject me personally and the above-named corporation/partnership/business to prosecution under 21 U.S.C. 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than $30,000 or both.

_____

Signature (Person who signs Application for Registration) State of _____

County of_____ _____

Subscribed to and sworn before me this _____ day of _____, 19____.

_____

Notary Public

(b) Whenever the ownership of a pharmacy is being transferred from one person to another, if the transferee owns at least one other pharmacy licensed in the same State as the one the ownership of which is being transferred, the transferee may apply for registration prior to the date of transfer. The Administrator may register the applicant and authorize him to obtain controlled substances at the time of transfer. Such registration shall not authorize the transferee to dispense controlled substances until the pharmacy has been issued a valid State license. The transferee shall include with his/her application the following affidavit:

Affidavit for Transfer of Pharmacy

I, _____, the _____ (Title of officer, official, partner or other position) of _____ (Corporation, partnership, or sole proprietor), doing business as _____ (Store name) hereby certify:

(1) That said company was issued a pharmacy permit No. _____ by the _____ (Board of Pharmacy of Licensing Agency) of the State of _____ and a DEA Registration Number _____ for a pharmacy located at _____ (Number and Street) _____ (City) _____ (State) _____ (Zip Code); and

(2) That said company is acquiring the pharmacy business of _____ (Name of Seller) doing business as _____ with DEA Registration Number _____ on or about _____ (Date of Transfer) and that said company has applied (or will apply on _____ (Date) for a pharmacy permit from the board of pharmacy (or licensing agency) of the State of _____ to do business as _____ (Store name) at _____ (Number and Street) _____ (City) _____ (State) _____ (Zip Code).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number.

I understand that if a DEA registration number is issued, the pharmacy may acquire controlled substances but may not dispense them until a pharmacy permit or license is issued by the State board of pharmacy or licensing agency.

I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally to prosecution under 21 U.S.C. 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than $30,000 or both.

_____

Signature (Person who signs Application for Registration)

State of _____

County of _____

Subscribed to and sworn before me this _____ day of _____, 19____.

_____

Notary Public

(c) The Administrator shall follow the normal procedures for approving an application to verify the statements in the affidavit. If the statements prove to be false, the Administrator may revoke the registration on the basis of section 304(a)(1) of the Act (21 U.S.C. 824(a)(1)) and suspend the registration immediately by pending revocation on the basis of section 304(d) of the Act (21 U.S.C. 824(d)). At the same time, the Administrator may seize and place under seal all controlled substances possessed by the applicant under section 304(f) of the Act (21 U.S.C. 824(f)). Intentional misuse of the affidavit procedure may subject the applicant to prosecution for fraud under section 403(a)(4) of the Act (21 U.S.C. 843(a)(4)), and obtaining controlled substances under a registration fraudulently gotten may subject the applicant to prosecution under section 403(a)(3) of the Act (21 U.S.C. 843(a)(3)). The penalties for conviction of either offense include imprisonment for up to 4 years, a fine not exceeding $30,000 or both.

§ 1301.18 Research protocols.

(a) A protocol to conduct research with controlled substances listed in Schedule I shall be in the following form and contain the following information where applicable:

(1) Investigator:

(i) Name, address, and DEA registration number; if any.

(ii) Institutional affiliation.

(iii) Qualifications, including a curriculum vitae and an appropriate bibliography (list of publications).

(2) Research project:

(i) Title of project.

(ii) Statement of the purpose.

(iii) Name of the controlled substances or substances involved and the amount of each needed.

(iv) Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.

(v) Location where the research will be conducted.

(vi) Statement of the security provisions for storing the controlled substances (in accordance with § 1301.75) and for dispensing the controlled substances in order to prevent diversion.

(vii) If the investigator desires to manufacture or import any controlled substance listed in paragraph (a)(2)(iii) of this section, a statement of the quantity to be manufactured or imported and the sources of the chemicals to be used or the substance to be imported.

(3) Authority:

(i) Institutional approval.

(ii) Approval of a Human Research Committee for human studies.

(iii) Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number).

(iv) Indication of an approved funded grant (number), if any.

(b) In the case of a clinical investigation with controlled substances listed in Schedule I, the applicant shall submit three copies of a Notice of Claimed Investigational Exemption for a New Drug (IND) together with a statement of the security provisions (as prescribed in paragraph (a)(2)(v) of this section for a research protocol) to, and have such submission approved by, the Food and Drug Administration as required in 21 U.S.C. 355(i) and § 130.3 of this title. Submission of this Notice and statement to the Food and Drug Administration shall be in lieu of a research protocol to the Administration as required in paragraph (a) of this section. The applicant, when applying for registration with the Administration, shall indicate that such notice has been submitted to the Food and Drug Administration by submitting to the Administration with his/her DEA Form 225 three copies of the following certificate:

I hereby certify that on _____ (Date), pursuant to 21 U.S.C. 355(i) and 21 CFR 130.3, I, _____ _____ _____ (Name and Address of IND Sponsor) submitted a Notice of Claimed Investigational Exemption for a New Drug (IND) to the Food and Drug Administration for:

_____
(Name of Investigational Drug).
_____ (Date)

_____
(Signature of Applicant).

(c) In the event that the registrant desires to increase the quantity of a controlled substance used for an approved research project, he/she shall submit a request to the Registration Unit, Drug Enforcement Administration, Post Office Box 28083, Central Station, Washington, DC 20005, by registered mail, return receipt requested. The request shall contain the following information: DEA registration number; name of the controlled substance or substances and the quantity of each authorized in the approved protocol; and the additional quantity of each desired. Upon return of the receipt, the registrant shall be authorized to purchase the additional quantity of the controlled substance or substances specified in the request. The Administration shall review the letter and forward it to the Food and Drug Administration together with the Administration comments. The Food and Drug Administration shall approve or deny the request as an amendment to the protocol and so notify the registrant. Approval of the letter by the Food and Drug Administration shall authorize the registrant to use the additional quantity of the controlled substance in the research project.

(d) In the event the registrant desires to conduct research beyond the variations provided in the registrant's approved protocol (excluding any increase in the quantity of the controlled substance requested for his/her research project as outlined in paragraph (c) of this section), he/she shall submit three copies of a supplemental protocol in accordance with paragraph (a) of this section describing the new research and omitting information in the supplemental protocol which has been stated in the original protocol. Supplemental protocols shall be processed and approved or denied in the same manner as original research protocols.

Exceptions To Registration and Fees

§ 1301.21 Exemption from fees.

(a) The Administrator shall exempt from payment of an application fee for registration or reregistration:

(1) Any hospital or other institution which is operated by an agency of the United States (including the U.S. Army, Navy, Marine Corps., Air Force, and Coast Guard), of any State, or any political subdivision or agency thereof.

(2) Any individual practitioner who is required to obtain an individual registration in order to carry out his or her duties as an official of an agency of the United States (including the U.S. Army, Navy, Marine Corps., Air Force, and Coast Guard), of any State, or any political subdivision or agency thereof.

(b) In order to claim exemption from payment of a registration or reregistration application fee, the registrant shall have completed the certification on the appropriate application form, wherein the registrant's superior (if the registrant is an individual) or officer (if the registrant is an agency) certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess, or handle controlled substances.

(c) Exemption from payment of a registration or reregistration application fee does not relieve the registrant of any other requirements or duties prescribed by law.

§ 1301.22 Exemption of agents and employees; affiliated practitioners.

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his/her business or employment.

(b) An individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.

(c) An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that:

(1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice;

(2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing;

(3) The hospital or other institution by whom he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction;

(4) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution;

(5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO 123456–10 or APO123456–A12); and

(6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

§ 1301.23 Exemption of certain military and other personnel.

(a) The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of his/her official duties. Such officials shall follow procedures set forth in part 1306 of this chapter regarding prescriptions, but shall state the branch of service or agency (e.g., ''U.S. Army'' or ''Public Health Service'') and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a Public Health Service employee is his/her Social Security identification number.

(b) The requirement of registration is waived for any official or agency of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, or Public Health Service who or which is authorized to import or export controlled substances in the course of his/her official duties.

(c) If any official exempted by this section also engages as a private individual in any activity or group of activities for which registration is required, such official shall obtain a registration for such private activities.

§ 1301.24 Exemption of law enforcement officials.

(a) The requirement of registration is waived for the following persons in the circumstances described in this section:

(1) Any officer or employee of the Administration, any officer of the U.S. Customs Service, any officer or employee of the United States Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs or customs, and is duly authorized to possess or to import or export controlled substances in the course of his/her official duties; and

(2) Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his/her official duties.

(b) Any official exempted by this section may, when acting in the course of his/her official duties, procure any controlled substance in the course of an inspection, in accordance with § 1316.03(d) of this chapter, or in the course of any criminal investigation involving the person from whom the substance was procured, and may possess any controlled substance and distribute any such substance to any other official who is also exempted by this section and acting in the course of his/her official duties.

(c) In order to enable law enforcement agency laboratories, including laboratories of the Administration, to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories shall obtain annually a registration to conduct chemical analysis. Such laboratories shall be exempted from payment of a fee for registration. Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials exempted by this section and within the activity described in section 515(d) of the Act (21 U.S.C. 885(d)). For purposes of this paragraph, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this section.

(d) In addition to the activities authorized under a registration to conduct chemical analysis pursuant to § 1301.13(e)(1)(ix), laboratories of the Administration shall be authorized to manufacture or import controlled substances for any lawful purpose, to distribute or export such substances to any person, and to import and export such substances in emergencies without regard to the requirements of part 1312 of this chapter if a report concerning the importation or exportation is made to the Drug Operations Section of the Administration within 30 days of such importation or exportation.

§ 1301.25 Registration regarding ocean vessels, aircraft, and other entities.

(a) If acquired by and dispensed under the general supervision of a medical officer described in paragraph (b) of this section, or the master or first officer of the vessel under the circumstances described in paragraph (d) of this section, controlled substances may be held for stocking, be maintained in, and dispensed from medicine chests, first aid packets, or dispensaries:

(1) On board any vessel engaged in international trade or in trade between ports of the United States and any merchant vessel belonging to the U.S. Government;

(2) On board any aircraft operated by an air carrier under a certificate of permit issued pursuant to the Federal Aviation Act of 1958 (49 U.S.C. 1301); and

(3) In any other entity of fixed or transient location approved by the Administrator as appropriate for application of this section (e.g., emergency kits at field sites of an industrial firm).

(b) A medical officer shall be:

(1) Licensed in a state as a physician;

(2) Employed by the owner or operator of the vessel, aircraft or other entity; and

(3) Registered under the Act at either of the following locations:

(i) The principal office of the owner or operator of the vessel, aircraft or other entity or

(ii) At any other location provided that the name, address, registration number and expiration date as they appear on his/her Certificate of Registration (DEA Form 223) for this location are maintained for inspection at said principal office in a readily retrievable manner.

(c) A registered medical officer may serve as medical officer for more than one vessel, aircraft, or other entity under a single registration, unless he/she serves as medical officer for more than one owner or operator, in which case he/she shall either maintain a separate registration at the location of the principal office of each such owner or operator or utilize one or more registrations pursuant to paragraph (b)(3)(ii) of this section.

(d) If no medical officer is employed by the owner or operator of a vessel, or in the event such medical officer is not accessible and the acquisition of controlled substances is required, the master or first officer of the vessel, who shall not be registered under the Act, may purchase controlled substances from a registered manufacturer or distributor, or from an authorized pharmacy as described in paragraph (f) of this section, by following the procedure outlined below:

(1) The master or first officer of the vessel must personally appear at the vendor's place of business, present proper identification (e.g., Seaman's photographic identification card) and a written requisition for the controlled substances.

(2) The written requisition must be on the vessel's official stationery or purchase order form and must include the name and address of the vendor, the name of the controlled substance, description of the controlled substance (dosage form, strength and number or volume per container) number of containers ordered, the name of the vessel, the vessel's official number and country of registry, the owner or operator of the vessel, the port at which the vessel is located, signature of the vessel's officer who is ordering the controlled substances and the date of the requisition.

(3) The vendor may, after verifying the identification of the vessel's officer requisitioning the controlled substances, deliver the control substances to that officer. The transaction shall be documented, in triplicate, on a record of sale in a format similar to that outlined in paragraph (d)(4) of this section. The vessel's requisition shall be attached to copy 1 of the record of sale and filed with the controlled substances records of the vendor, copy 2 of the record of sale shall be furnished to the officer of the vessel and retained aboard the vessel, copy 3 of the record of sale shall be forwarded to the nearest DEA Division Office within 15 days after the end of the month in which the sale is made.

(4) The vendor's record of sale should be similar to, and must include all the information contained in, the below listed format.

Sale of Controlled Substances to Vessels

(Name of registrant)

_____

(Address of registrant)

_____

(DEA registration number)

_____

* * * TABLE START * * *

Line No.	Number of packages ordered	Size of packages	Name of product	Packages distributed	Date distributed
1					
2					
3					

FOOTNOTE: Line numbers may be continued according to needs of the vendor.

* * * TABLE END * * *

Number of lines completed

_____

Name of vessel

_____

Vessel's official number

_____

Vessel's country of registry

_____

Owner or operator of the vessel

_____

Name and title of vessel's officer who presented the requisition

_____

Signature of vessel's officer who presented the requisition

_____

(e) Any medical officer described in paragraph (b) of this section shall, in addition to complying with all requirements and duties prescribed for registrants generally, prepare an annual report as of the date on which his/her registration expires, which shall give in detail an accounting for each vessel, aircraft, or other entity, and a summary accounting for all vessels, aircraft, or other entities under his/her supervision for all controlled substances purchased, dispensed or disposed of during the year. The medical officer shall maintain this report with other records required to be kept under the Act and, upon request, deliver a copy of the report to the Administration. The medical officer need not be present when controlled substances are dispensed, if the person who actually dispensed the controlled substances is responsible to the medical officer to justify his/her actions.

(f) Any registered pharmacy which wishes to distribute controlled substances pursuant to this section shall be authorized to do so, provided that:

(1) The registered pharmacy notifies the nearest Division Office of the Administration of its intention to so distribute controlled substances prior to the initiation of such activity. This notification shall be by registered mail and shall contain the name, address, and registration number of the pharmacy as well as the date upon which such activity will commence; and

(2) Such activity is authorized by state law; and

(3) The total number of dosage units of all controlled substances distributed by the pharmacy during any calendar year in which the pharmacy is registered to dispense does not exceed the limitations imposed upon such distribution by § 1307.11(a) (4) and (b) of this chapter.

(g) Owners or operators of vessels, aircraft, or other entities described in this section shall not be deemed to possess or dispense any controlled substance acquired, stored and dispensed in accordance with this section. Additionally, owners or operators of vessels, aircraft, or other entities described in this section or in Article 32 of the Single Convention on Narcotic Drugs, 1961, or in Article 14 of the Convention on Psychotropic Substances, 1971, shall not be deemed to import or export any controlled substances purchased and stored in accordance with that section or applicable article.

(h) The Master of a vessel shall prepare a report for each calendar year which shall give in detail an accounting for all controlled substances purchased, dispensed, or disposed of during the year. The Master shall file this report with the medical officer employed by the owner or operator of his/her vessel, if any, or, if not, he/she shall maintain this report with other records required to be kept under the Act and, upon request, deliver a copy of the report to the Administration.

(i) Controlled substances acquired and possessed in accordance with this section shall not be distributed to persons not under the general supervision of the medical officer employed by the owner or operator of the vessel, aircraft, or other entity, except in accordance with § 1307.21 of this chapter.

§ 1301.26 Exemptions from import or export requirements for personal medical use.

Any individual who has in his/her possession a controlled substance listed in schedules II, III, IV, or V, which he/she has lawfully obtained for his/her personal medical use, or for administration to an animal accompanying him/her, may enter or depart the United States with such substance notwithstanding sections 1002–1005 of the Act (21 U.S.C. 952–955), providing the following conditions are met:

(a) The controlled substance is in the original container in which it was dispensed to the individual; and

(b) The individual makes a declaration to an appropriate official of the U.S. Customs Service stating:

(1) That the controlled substance is possessed for his/her personal use, or for an animal accompanying him/her; and

(2) The trade or chemical name and the symbol designating the schedule of the controlled substance if it appears on the container label, or, if such name does not appear on the label, the name and address of the pharmacy or practitioner who dispensed the substance and the prescription number, if any.

Action on Applications for Registration: Revocation or Suspension of Registration

§ 1301.31 Administrative review generally.

The Administrator may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to subpart A of part 1316 of this chapter. The Administrator shall review, the application for registration and other information gathered by the Administrator regarding an applicant in order to determine whether the applicable standards of section 303 of the Act (21 U.S.C. 823) or section 1008 (21 U.S.C. 958) have been met by the applicant.

§ 1301.32 Action on applications for research in Schedule I substances.

(a) In the case of an application for registration to conduct research with controlled substances listed in Schedule I, the Administrator shall process the application and protocol and forward a copy of each to the Secretary within 7 days after receipt. The Secretary shall determine the qualifications and competency of the applicant, as well as the merits of the protocol (and shall notify the Administrator of his/her determination) within 21 days after receipt of the application and complete protocol, except that in the case of a clinical investigation, the Secretary shall have 30 days to make such determination and notify the Administrator. The Secretary, in determining the merits of the protocol,

shall consult with the Administrator as to effective procedures to safeguard adequately against diversion of such controlled substances from legitimate medical or scientific use.

(b) An applicant whose protocol is defective shall be notified by the Secretary within 21 days after receipt of such protocol from the Administrator (or in the case of a clinical investigation within 30 days), and he/she shall be requested to correct the existing defects before consideration shall be given to his/her submission.

(c) If the Secretary determines the applicant qualified and competent and the research protocol meritorious, he/she shall notify the Administrator in writing of such determination. The Administrator shall issue a certificate of registration within 10 days after receipt of this notice, unless he/she determines that the certificate of registration should be denied on a ground specified in section 304(a) of the Act (21 U.S.C. 824(a)). In the case of a supplemental protocol, a replacement certificate of registration shall be issued by the Administrator.

(d) If the Secretary determines that the protocol is not meritorious and/or the applicant is not qualified or competent, he/she shall notify the Administrator in writing setting forth the reasons for such determination. If the Administrator determines that grounds exist for the denial of the application, he/she shall within 10 days issue an order to show cause pursuant to § 1301.37 and, if requested by the applicant, hold a hearing on the application pursuant to § 1301.41. If the grounds for denial of the application include a determination by the Secretary, the Secretary or his duly authorized agent shall furnish testimony and documents pertaining to his determination at such hearing.

(e) Supplemental protocols will be processed in the same manner as original research protocols. If the processing of an application or research protocol is delayed beyond the time limits imposed by this section, the applicant shall be so notified in writing.

§ 1301.33 Application for bulk manufacture of Schedule I and II substances.

(a) In the case of an application for registration or reregistration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II, the Administrator shall, upon the filing of such application, publish in the Federal Register a notice naming the applicant and stating that such applicant has applied to be registered as a bulk manufacturer of a basic class of narcotic or nonnarcotic controlled substance, which class shall be identified. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of that basic class and to any other applicant therefor. Any such person may, within 60 days from the date of publication of the notice in the Federal Register, file with the Administrator written comments on or objections to the issuance of the proposed registration.

(b) In order to provide adequate competition, the Administrator shall not be required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply.

(c) This section shall not apply to the manufacture of basic classes of controlled substances listed in Schedules I or II as an incident to research or chemical analysis as authorized in § 01.13(e)(1).

§ 1301.34 Application for importation of Schedule I and II substances.

(a) In the case of an application for registration or reregistration to import a controlled substance listed in Schedule I or II, under the authority of section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)), the Administrator shall, upon the filing of such application, publish in the Federal Register a notice naming the applicant and stating that such applicant has applied to be registered as an importer of a Schedule I or II controlled substance, which substance shall be identified. A copy of said notice shall be mailed simultaneously to each person registered as a bulk manufacturer of that controlled substance and to any other applicant therefor. Any such person may, within 30 days from the date of publication of the notice in the Federal Register, file written comments on or objections to the issuance of the proposed registration, and may, at the same time, file a written request for a hearing on the application pursuant to § 1301.43. If a hearing is requested, the Administrator shall hold a hearing on the application in accordance with § 1301.41. Notice of the hearing shall be published in the Federal Register, and shall be mailed simultaneously to the applicant and to all persons to whom notice of the application was mailed. Any such person may participate in the hearing by filing a notice of appearance in accordance with § 1301.43 of this chapter. Notice of the hearing shall contain a summary of all comments and objections filed regarding the application and shall state the time and place for the hearing, which shall not be less than 30 days after the date of publication of such notice in the Federal Register. A hearing pursuant to this section may be consolidated with a hearing held pursuant to §§ 1301.35 or 1301.36 of this part.

(b) The Administrator shall register an applicant to import a controlled substance listed in Schedule I or II if he/she determines that such registration is consistent with the public interest and with U.S. obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in Schedule I or II compounded therefrom into other than legitimate medical, scientific research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) Compliance with applicable State and local law;

(3) Promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) Past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion;

(6) That the applicant will be permitted to import only:

(i) Such amounts of crude opium, poppy straw, concentrate of poppy straw, and coca leaves as the Administrator finds to be necessary to provide for medical, scientific, or other legitimate purposes; or

(ii) Such amounts of any controlled substances listed in Schedule I or II as the Administrator shall find to be necessary to provide for the medical, scientific, or other legitimate needs of the United States during an emergency in which domestic supplies of such substances are found by the Administrator to be inadequate; or

(iii) Such amounts of any controlled substance listed in Schedule I or II as the Administrator shall find to be necessary to provide for the medical, scientific, or other legitimate needs of the United States in any case in which

the Administrator finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 303 of the Act (21 U.S.C. 823); or

(iv) Such limited quantities of any controlled substance listed in Schedule I or II as the Administrator shall find to be necessary for scientific, analytical or research uses; and

(7) Such other factors as may be relevant to and consistent with the public health and safety.

(c) In determining whether the applicant can and will maintain effective controls against diversion within the meaning of paragraph (b) of this section, the Administrator shall consider among other factors:

(1) Compliance with the security requirements set forth in §§ 1301.71–1301.76 and

(2) Employment of security procedures to guard against in-transit losses within and without the jurisdiction of the United States.

(d) In determining whether competition among the domestic manufacturers of a controlled substance is adequate within the meaning of paragraphs (b)(1) and (b)(6)(iii) of this section, as well as section 1002(a)(2)(B) of the Act (21 U.S.C. 952(a)(2)(B)), the Administrator shall consider:

(1) The extent of price rigidity in the light of changes in:

(i) Raw materials and other costs and

(ii) Conditions of supply and demand;

(2) The extent of service and quality competition among the domestic manufacturers for shares of the domestic market including:

(i) Shifts in market shares and

(ii) Shifts in individual customers among domestic manufacturers;

(3) The existence of substantial differentials between domestic prices and the higher of prices generally prevailing in foreign markets or the prices at which the applicant for registration to import is committed to undertake to provide such products in the domestic market in conformity with the Act. In determining the existence of substantial differentials hereunder, appropriate consideration should be given to any additional costs imposed on domestic manufacturers by the requirements of the Act and such other cost-related and other factors as the Administrator may deem relevant. In no event shall an importer's offering prices in the United States be considered if they are lower than those prevailing in the foreign market or markets from which the importer is obtaining his/her supply;

(4) The existence of competitive restraints imposed upon domestic manufacturers by governmental regulations; and

(5) Such other factors as may be relevant to the determinations required under this paragraph.

(e) In considering the scope of the domestic market, consideration shall be given to substitute products which are reasonably interchangeable in terms of price, quality and use.

(f) The fact that the number of existing manufacturers is small shall not demonstrate, in and of itself, that adequate competition among them does not exist.

§ 1301.35 Certificate of registration; denial of registration.

(a) The Administrator shall issue a Certificate of Registration (DEA Form 223) to an applicant if the issuance of registration or reregistration is required under the applicable provisions of sections 303 or 1008 of the Act (21 U.S.C. 823 and 958). In the event that the issuance of registration or reregistration is not required, the Administrator shall deny the application. Before denying any application, the Administrator shall issue an order to show cause pursuant to § 1301.37 and, if requested by the applicant, shall hold a hearing on the application pursuant to § 1301.41.

(b) If a hearing is requested by an applicant for registration or reregistration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II, notice that a hearing has been requested shall be published in the Federal Register and shall be mailed simultaneously to the applicant and to all persons to whom notice of the application was mailed. Any person entitled to file comments or objections to the issuance of the proposed registration pursuant to § 1301.33(a) may participate in the hearing by filing notice of appearance in accordance with § 1301.43. Such persons shall have 30 days to file a notice of appearance after the date of publication of the notice of a request for a hearing in the Federal Register.

(c) The Certificate of Registration (DEA Form 223) shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the schedules and/or Administration Controlled Substances Code Number (as set forth in part 1308 of this chapter) of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption), and the expiration date of the registration. The registrant shall maintain the certificate of registration at the registered location in a readily retrievable manner and shall permit inspection of the certificate by any official, agent or employee of the Administration or of any Federal, State, or local agency engaged in enforcement of laws relating to controlled substances.

§ 1301.36 Suspension or revocation of registration; suspension of registration pending final order; extension of registration pending final order.

(a) For any registration issued under section 303 of the Act (21 U.S.C. 823), the Administrator may:

(1) Suspend the registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)) for any period of time.

(2) Revoke the registration pursuant to section 304(a) of the Act (21 U.S.C. 824(a)).

(b) For any registration issued under section 1008 of the Act (21 U.S.C. 958), the Administrator may:

(1) Suspend the registration pursuant to section 1008(d) of the Act (21 U.S.C. 958(d)) for any period of time.

(2) Revoke the registration pursuant to section 1008(d) of the Act (21 U.S.C. 958(d)) if he/she determines that such registration is inconsistent with the public interest as defined in section 1008 or with the United States obligations under international treaties, conventions, or protocols in effect on October 12, 1984.

(c) The Administrator may limit the revocation or suspension of a registration to the particular controlled substance, or substances, with respect to which grounds for revocation or suspension exist.

(d) Before revoking or suspending any registration, the Administrator shall issue an order to show cause pursuant to § 1301.37 and, if requested by the registrant, shall hold a hearing pursuant to § 13.01.41.

(e) The Administrator may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where he/she finds that there is an imminent danger to the public health or safety. If the Administrator so suspends, he/she shall serve with the order to show cause pursuant to § 1301.37 an order of immediate suspension which shall contain a statement of his findings regarding the danger to public health or safety.

(f) Upon service of the order of the Administrator suspending or revoking registration, the registrant shall immediately deliver his/her Certificate of Registration, any order forms, and

any import or export permits in his/her possession to the nearest office of the Administration. The suspension or revocation of a registration shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant pursuant to part 1303 of this chapter and any import or export permits issued to the registrant pursuant to part 1312 of this chapter. Also, upon service of the order of the Administrator revoking or suspending registration, the registrant shall, as instructed by the Administrator:

(1) Deliver all controlled substances in his/her possession to the nearest office of the Administration or to authorized agents of the Administration; or

(2) Place all controlled substances in his/her possession under seal as described in sections 304(f) or 1008(d)(6) of the Act (21 U.S.C. 824(f) or 958(d)(6)).

(g) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required to be paid for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration and, if appropriate, any order forms in his/her possession to the nearest office of the Administration. The suspension or revocation of a registration, when limited to a particular basic class or classes of controlled substances, shall suspend or revoke any individual manufacturing or procurement quota fixed for the registrant for such class or classes pursuant to part 1303 of this chapter and any import or export permits issued to the registrant for such class or classes pursuant to part 1312 of this chapter. Also, upon service of the order of the Administrator revoking or suspending registration, the registrant shall, as instructed by the Administrator:

(1) Deliver to the nearest office of the Administration or to authorized agents of the Administration all of the particular controlled substance or substances affected by the revocation or suspension which are in his/her possession; or

(2) Place all of such substances under seal as described in sections 304(f) or 958(d)(6) of the Act (21 U.S.C. 824(f) or 958(d)(6)).

(h) Any suspension shall continue in effect until the conclusion of all proceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Administrator or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under paragraph (e) of this section may request a hearing on the revocation or suspension of his/her registration at a time earlier than specified in the order to show cause pursuant to § 1301.37, which request shall be granted by the Administrator, who shall fix a date for such hearing as early as reasonably possible.

(i) In the event that an applicant for reregistration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least 45 days before the date on which the existing registration is due to expire, and the Administrator has issued no order on the application on the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Administrator so issues his/her order. The Administrator may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least 45 days before expiration of the existing registration, with or without request by the registrant, if the Administrator finds that such extension is not inconsistent with the public health and safety.

§ 1301.37 Order to show cause.

(a) If, upon examination of the application for registration from any applicant and other information gathered by the Administration regarding the applicant, the Administrator is unable to make the determinations required by the applicable provisions of section 303 and/or section 1008 of the Act (21 U.S.C. 823 and 958) to register the applicant, the Administrator shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information gathered by the Administration regarding any registrant, the Administrator determines that the registration of such registrant is subject to suspension or revocation pursuant to section 304 or section 1008 of the Act (21 U.S.C. 824 and 958), the Administrator shall serve upon the registrant an order to show cause why the registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Administrator at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) Upon receipt of an order to show cause, the applicant or registrant must, if he/she desires a hearing, file a request for a hearing pursuant to § 1301.43. If a hearing is requested, the Administrator shall hold a hearing at the time and place stated in the order, pursuant to § 1301.41.

(e) When authorized by the Administrator, any agent of the Administration may serve the order to show cause.

Hearings

§ 1301.41 Hearings generally.

(a) In any case where the Administrator shall hold a hearing on any registration or application therefor, the procedures for such hearing shall be governed generally by the adjudication procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by §§ 303, 304, and 1008 of the Act (21 U.S.C. 823–824 and 958), by §§ 1301.42–1301.46 of this part, and by the procedures for administrative hearings under the Act set forth in §§ 1316.41–1316.67 of this chapter.

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act or any other law of the United States.

§ 1301.42 Purpose of hearing.

If requested by a person entitled to a hearing, the Administrator shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration, and the granting of any application for registration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II. Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law.

§ 1301.43 Request for hearing or appearance; waiver.

(a) Any person entitled to a hearing pursuant to §§ 1301.32 or 1301.34–1301.36 and desiring a hearing shall, within 30 days after the date of receipt of the order to show cause (or the date of publication of notice of the application for registration in the Federal Register in the case of

§ 1301.34), file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) Any person entitled to participate in a hearing pursuant to § 1301.34 or § 1301.35(b) and desiring to do so shall, within 30 days of the date of publication of notice of the request for a hearing in the Federal Register, file with the Administrator a written notice of intent to participate in such hearing in the form prescribed in § 1316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance.

(c) Any person entitled to a hearing or to participate in a hearing pursuant to § 1301.32 or §§ 1301.34–1301.36 may, within the period permitted for filing a request for a hearing or a notice of appearance, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding such person's position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any person entitled to a hearing or to participate in a hearing pursuant to §§ 1301.32 or 1301.34–1301.36 fails to file a request for a hearing or a notice of appearance, or if such person so files and fails to appear at the hearing, such person shall be deemed to have waived the opportunity for a hearing or to participate in the hearing, unless such person shows good cause for such failure.

(e) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his/her final order pursuant to § 1301.46 without a hearing.

§ 1301.44 Burden of proof.

(a) At any hearing on an application to manufacture any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to section 303(a) of the Act (21 U.S.C. 823(a)) are satisfied. Any other person participating in the hearing pursuant to § 1301.35(b) shall have the burden of proving any propositions of fact or law asserted by such person in the hearing.

(b) At any hearing on the granting or denial of an applicant to be registered to conduct a narcotic treatment program or as a compounder, the applicant shall have the burden of proving that the requirements for each registration pursuant to section 303(g) of the Act (21 U.S.C. 823(g)) are satisfied.

(c) At any hearing on the granting or denial of an application to be registered to import or export any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements for such registration pursuant to sections 1008 (a) and (d) of the Act (21 U.S.C. 958 (a) and (d)) are satisfied. Any other person participating in the hearing pursuant to § 1301.34 shall have the burden of proving any propositions of fact or law asserted by him/her in the hearings.

(d) At any other hearing for the denial of a registration, the Administration shall have the burden of proving that the requirements for such registration pursuant to section 303 or section 1008 (c) and (d) of the Act (21 U.S.C. 823 or 958 (c) and (d)) are not satisfied.

(e) At any hearing for the revocation or suspension of a registration, the Administration shall have the burden of proving that the requirements for such revocation or suspension pursuant to section 304(a) or section 1008(d) of the Act (21 U.S.C. 824(a) or 958(d)) are satisfied.

§ 1301.45 Time and place of hearing.

The hearing will commence at the place and time designated in the order to show cause or notice of hearing published in the Federal Register (unless expedited pursuant to § 1301.36(h)) but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 1301.46 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his/her order on the granting, denial, revocation, or suspension of registration. In the event that an application for registration to manufacture in bulk a basic class of any controlled substance listed in Schedule I or II is granted, or any application for registration is denied, or any registration is revoked or suspended, the order shall include the findings of fact and conclusions of law upon which the order is based. The order shall specify the date on which it shall take effect. The Administrator shall serve one copy of his/her order upon each party in the hearing.

Modification, Transfer and Termination of Registration

§ 1301.51 Modification in registration.

Any registrant may apply to modify his/her registration to authorize the handling of additional controlled substances or to change his/her name or address, by submitting a letter of request to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. The letter shall contain the registrant's name, address, and registration number as printed on the certificate of registration, and the substances and/or schedules to be added to his/her registration or the new name or address and shall be signed in accordance with § 1301.13(j). If the registrant is seeking to handle additional controlled substances listed in Schedule I for the purpose of research or instructional activities, he/she shall attach three copies of a research protocol describing each research project involving the additional substances, or two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate. No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration. If the modification in registration is approved, the Administrator shall issue a new certificate of registration (DEA Form 223) to the registrant, who shall maintain it with the old certificate of registration until expiration.

§ 1301.52 Termination of registration; transfer of registration; distribution upon discontinuance of business.

(a) Except as provided in paragraph (b) of this section, the registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice. Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Administrator promptly of such fact.

(b) No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Administration may specifically designate and then only pursuant to written consent. Any person seeking authority to transfer a registration shall submit a written request, providing full details regarding the proposed transfer of registration, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration,

Department of Justice, Washington, DC 20537.

(c) Any registrant desiring to discontinue business activities altogether or with respect to controlled substances (without transferring such business activities to another person) shall return for cancellation his/her certificate of registration, and any unexecuted order forms in his/her possession, to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. Any controlled substances in his/her possession may be disposed of in accordance with § 1307.21 of this chapter.

(d) Any registrant desiring to discontinue business activities altogether or with respect to controlled substance (by transferring such business activities to another person) shall submit in person or by registered or certified mail, return receipt requested, to the Special Agent in Charge in his/her area, at least 14 days in advance of the date of the proposed transfer (unless the Special Agent in Charge waives this time limitation in individual instances), the following information:

(1) The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor);

(2) The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);

(3) Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed);

(4) Whether the registrant-transferor has a quota to manufacture or procure any controlled substance listed in Schedule I or II (if so, the basic class or class of the substance should be indicated); and

(5) The date on which the transfer of controlled substances will occur.

(e) Unless the registrant-transferor is informed by the Special Agent in Charge, before the date on which the transfer was stated to occur, that the transfer may not occur, the registrant-transferor may distribute (without being registered to distribute) controlled substances in his/her possession to the registrant-transferee in accordance with the following:

(1) On the date of transfer of the controlled substances, a complete inventory of all controlled substances being transferred shall be taken in accordance with § 1304.11 of this chapter. This inventory shall serve as the final inventory of the registrant-transferor and the initial inventory of the registrant-transferee, and a copy of the inventory shall be included in the records of each person. It shall not be necessary to file a copy of the inventory with the Administration unless requested by the Special Agent in Charge. Transfers of any substances listed in Schedule I or II shall require the use of order forms in accordance with part 1305 of this chapter.

(2) On the date of transfer of the controlled substances, all records required to be kept by the registrant-transferor with reference to the controlled substances being transferred, under part 1304 of this chapter, shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

(3) In the case of registrants required to make reports pursuant to part 1304 of this chapter, a report marked ''Final'' will be prepared and submitted by the registrant-transferor showing the disposition of all the controlled substances for which a report is required; no additional report will be required from him, if no further transactions involving controlled substances are consummated by him. The initial report of the registrant-transferee shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor-registrant and the substances transferred to him shall be reported as receipts in his/her initial report.

§ 1301.75 Physical security controls for practitioners.

* * * * *

(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

* * * * *

6. Section 1301.76 is proposed to be amended by revising paragraph (c) to read as follows:

§ 1301.76 Other security controls for practitioners.

* * * * *

(c) Whenever the registrant distributes a controlled substance (without being registered as a distributor, as permitted in § 1301.13(e)(1) and/or §§ 1307.11–1307.12) he/she shall comply with the requirements imposed on nonpractitioners in § 1301.74 (a), (b), and (e).

§ 1301.72 [Amended]

7. In 21 CFR 1301.72(b)(4)(i)(b) remove the word ''lay'' and add, in its place, the word ''lag''.

PART 1302—[AMENDED]

1. The authority citation for part 1302 continues to read as follows:

Authority: 21 U.S.C. 821, 825, 871(b), 958 (e).

2. Section 1302.02 is proposed to be revised to read as follows:

§ 1302.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or Part 1300 of this chapter.

3. Section 1302.04 is proposed to be revised to read as follows:

§ 1302.04 Location and size of symbol on label and labeling.

The symbol shall be prominently located on the label or the labeling of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance. The symbol on labels shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf. The symbol on all other labeling shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

§ 1302.05 [Removed]

4. Section 1302.05 is proposed to be removed.

5. Section 1302.06 is proposed to be redesignated as Section 1302.05 and revised to read as follows:

§ 1302.05 Effective dates of labeling requirements.

All labels on commercial containers of, and all labeling of, a controlled substance which either is transferred to another schedule or is added to any schedule shall comply with the requirements of § 1302.03, on or before the effective date established in the final order for the transfer or addition.

6. Section 1302.07 is proposed to be redesignated as § 1302.06 and revised to read as follows:

§ 1302.06 Sealing of controlled substances.

On each bottle, multiple dose vial, or other commercial container of any

controlled substance, there shall be securely affixed to the stopper, cap, lid, covering, or wrapper or such container a seal to disclose upon inspection any tampering or opening of the container.

7. Section 1302.08 is proposed to be redesignated as § 1302.07, and revised to read as follows:

§ 1302.07 Labeling and packaging requirements for imported and exported substances.

(a) The symbol requirements of §§ 1302.03–1302.05 apply to every commercial container containing, and to all labeling of, controlled substances imported into the jurisdiction of and/or the customs territory of the United States.

(b) The symbol requirements of §§ 1302.03–1302.05 do not apply to any commercial containers containing, or any labeling of, a controlled substance intended for export from the jurisdiction of the United States.

(c) The sealing requirements of § 1302.06 apply to every bottle, multiple dose vial, or other commercial container of any controlled substance listed in schedule I or II, or any narcotic controlled substance listed in schedule III or IV, imported into, exported from, or intended for export from, the jurisdiction of and/or the customs territory of the United States.

PART 1303—[AMENDED]

1. The authority citation for part 1303 continues to read as follows:

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

2. Section 1303.02 is proposed to be revised to read as follows:

§ 1303.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

3. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1303.12(b)	(or BND) each place it appears.	
1303.12(b)	Drug Control Section	Drug & Chemical Evaluation Section.
1303.12(d)	Drug Control Section	Drug & Chemical Evaluation Section.
1303.12(e)(1)	subsance	substance.
1303.12(e)(3)	1301.22(b)	1301.13.
1303.21(a)	1301.45 and 1301.46	1301.36.
1303.22	(or BND) each place it appears.	
1303.22	Drug Control Section	Drug & Chemical Evaluation Section.
1303.26	1301.45 or 1301.46	1301.36.
1303.27	Drug Control Section	Drug & Chemical Evaluation Section.
1303.32(b)	1301.45 or 1301.46	1301.36.
1303.35(a)	aggregrate	aggregate.

PART 1304—[AMENDED]

1. The authority citation for part 1304 is proposed to be corrected to read as follows:

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

2. Section 1304.02 is proposed to be revised to read as follows:

§ 1304.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

3. Section 1304.03 is proposed to be amended by removing paragraphs (g) and (h), and revising paragraph (f) to read as follows:

§ 1304.03 Persons required to keep records and file reports.

* * * * *

(f) Registered persons using any controlled substances while conducting preclinical research, in teaching at a registered establishment which maintains records with respect to such substances or conducting research in conformity with an exemption granted under section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a registered establishment which maintains records in accordance with either of those sections are not required to keep records if he/she notifies the Administration of the name, address, and registration number of the establishment maintaining such records. This notification shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

4. Section 1304.04 is proposed to be amended by removing ''executed'' in paragraph (a) and by adding ''executed'' and by revising paragraphs (e) and (h) to read as follows:

§ 1304.04 Maintenance of records and inventories.

* * * * *

(e) All central recordkeeping permits previously issued by the Administration expired September 30, 1980.

* * * * *

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in a separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter ''C'' no less than 1-inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances. However, if a pharmacy employs an ADP system or other electronic recordkeeping system for prescriptions which permits

identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red ''C'' is waived.

5. Section 1304.11 is proposed to be revised to read as follows:

§ 1304.11 Inventory requirements.

(a) *General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be ''on hand'' if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) *Initial inventory date.* Every person required to keep records, shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on the day of the year on which the initial inventory was taken or on any other fixed date which does not vary by more than 6 months from the biennial date that would otherwise apply. If the registrant elects to take the biennial inventory on another fixed date, he/she shall notify the Administration of this election and of the date on which the biennial inventory will be taken.

(d) *Inventory date for newly controlled substances.* On the effective date of a rule by the Administrator pursuant to §§ 1308.45, 1308.46, or § 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

(e) *Inventories of manufacturers, distributors, dispensers, researchers, importers, exporters and chemical analysts.* Each person registered or authorized (by §§ 1301.13 or §§ 1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records pursuant to § 1304.03 shall include in the inventory the information listed below.

(1) *Inventories of manufacturers.* Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) the name of the substance and

(B) the total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;

(B) the quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number;

(C) the physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

(B) each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(C) the number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(D) the number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;

(B) the total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(C) the reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

(2) *Inventories of distributors.* Each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section.

(3) *Inventories of dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(i) If the substance is listed in Schedule I or II, make an exact count or measure of the contents or

(ii) if the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(4) *Inventories of importers and exporters.* Each person registered or

authorized to import or export controlled substances shall include in the inventory, the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

(5) *Inventories of chemical analysts.* Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

§§ 1304.12—1304.19 [Removed]

6. Sections 1304.12, 1304.13, 1304.14, 1304.15, 1304.16, 1304.17, 1304.18 and 1304.19 are proposed to be removed.

7. Section 1304.21 is proposed to be amended by revising paragraphs (a) and (c) to read as follows:

§ 1304.21 General requirements for continuing records.

(a) Every registrant required to keep records pursuant to Section 1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.

(b) * * *

(c) Separate records shall be maintained by a registrant for each independent activity for which he/she is registered, except as provided in § 1304.22(d).

* * * * *

8. Section 1304.22 is proposed to be revised to read as follows:

1304.22 Records for manufacturers, distributors, dispensers, researchers, importers and exporters.

Each person registered or authorized (by § 1301.13(e) or §§ 1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export or conduct research with controlled substances shall maintain records with the information listed below.

(a) *Records for manufacturers.* Each person registered or authorized to manufacture controlled substances shall maintain records with the following information:

(1) For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,

(i) The name of the substance;

(ii) The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

(iii) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

(iv) The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him/her, including the date, quantity, and import permit or declaration number for each importation;

(v) The quantity used to manufacture the same substance in finished form, including:

(A) The date and batch or other identifying number of each manufacture;

(B) The quantity used in the manufacture;

(C) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);

(D) The number of units of finished form manufactured;

(E) The quantity used in quality control;

(F) The quantity lost during manufacturing and the causes therefore, if known;

(G) The total quantity of the substance contained in the finished form;

(H) The theoretical and actual yields; and

(I) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(vi) The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph (a)(1)(v) of this section;

(vii) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

(viii) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;

(ix) The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed;

(x) The originals of all written certifications of available procurement quotas submitted by other persons (as required by § 1303.12(f) of this chapter) relating to each order requiring the distribution of a basic class of controlled substance listed in Schedule I or II.

(2) For each controlled substance in finished form,

(i) The name of the substance;

(ii) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(iii) The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to paragraph (a)(1)(v) of this section;

(iv) The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address, and registration number of the person from whom the units were received;

(v) The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation.

(vi) The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

(A) The date and batch or other identifying number of each manufacture;

(B) The operation performed (e.g., repackaging or relabeling);

(C) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes for such losses, if known; and

(D) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(vii) The number of commercial containers distributed to other persons, including the date of and number of containers in each distribution, and the name, address, and registration number of the person to whom the containers were distributed;

(viii) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(ix) The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

(b) *Records for distributors.* Each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2) (i), (ii), (iv), (v), (vii), (viii) and (ix) of this section.

(c) *Records for dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2) (i), (ii), (iv) and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.

(d) *Records for importers and exporters.* Each person registered or authorized to import or export controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2) (i), (iv), (v) and (vii) of this section. In addition, the quantity disposed of in any other manner by the registrant (except quantities used in manufacturing by an importer under a registration as a manufacturer), which quantities are to be recorded pursuant to paragraphs (a)(1) (iv) and (v) of this section; and the quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume), and the export permit or declaration number for each exportation, but excluding all quantities (and number of units and volumes) manufactured by an exporter under a registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to paragraphs (a)(1)(xiii) or (a)(2)(xiii) of this section.

§§ 1304.23—1304.26 [Removed]

9. Sections 1304.23 through 1304.26 are proposed to be removed.

§ 1304.27 [Redesignated as § 1304.23]

10. Section 1304.27 is proposed to be redesignated as § 1304.23.

§ 1304.28 [Redesignated as § 1304.24 and amended]

11. Section 1304.28 is proposed to be redesignated as § 1304.24 and reference in § 1304.28(b) to ''§ 1304.24'' is proposed to be revised to read ''§ 1304.22'', and in paragraph (d), the words ''part 1401 of this title'' are proposed to be revised to read ''42 CFR Part 2.''

§ 1304.29 [Redesignated as § 1304.25]

12. Section 1304.29 is proposed to be redesignated as § 1304.25.

13. Section 1304.31 is proposed to be revised to read as follows:

§ 1304.31 Reports from manufacturers importing narcotic raw material.

(a) Every manufacturer which imports or manufactures from narcotic raw material (opium, poppy straw, and concentrate of poppy straw), shall submit information which accounts for the importation and for all manufacturing operations performed between importation and the production in bulk or finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary or other recognized medical standards. Reports shall be signed by the authorized official and submitted quarterly on company letterhead to the Drug Enforcement Administration, Drug and Chemical Evaluation Section, Washington, D.C. 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The following information shall be submitted for each type of narcotic raw material (quantities are expressed as grams of anhydrous morphine alkaloid):

(1) Beginning inventory;

(2) Gains on reweighing;

(3) Imports;

(4) Other receipts;

(5) Quantity put into process;

(6) Losses on reweighing;

(7) Other dispositions and

(8) Ending inventory.

(c) The following information shall be submitted for each narcotic raw material derivative including morphine, codeine, thebaine, oxycodone, hydrocodone, medicinal opium, manufacturing opium, crude alkaloids and other derivatives (quantities are expressed as grams of anhydrous base or anhydrous morphine alkaloid for manufacturing opium and medicinal opium):

(1) Beginning inventory;

(2) Gains on reweighing;

(3) Quantity extracted from narcotic raw material;

(4) Quantity produced/manufactured/synthesized;

(5) Quantity sold;

(6) Quantity returned to conversion processes for reworking;

(7) Quantity used for conversion;

(8) Quantity placed in process;

(9) Other dispositions;

(10) Losses on reweighing and

(11) Ending inventory.

(d) The following information shall be submitted for importation of each narcotic raw material:

(1) Import permit number;

(2) Date shipment arrived at the United States port of entry;

(3) Actual quantity shipped;

(4) Assay (percent) of morphine, codeine and thebaine and

(5) Quantity shipped, expressed as anhydrous morphine alkaloid.

(e) Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer in the manner and according to the method specified in the U.S. Pharmacopoeia. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(f) Where factory procedure is such that partial withdrawals of opium are

made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.

(g) All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it must no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

14. Section 1304.32 is proposed to be revised to read as follows:

§ 1304.32 Reports of manufacturers importing coca leaves.

(a) Every manufacturer importing or manufacturing from raw coca leaves shall submit information accounting for the importation and for all manufacturing operations performed between the importation and the manufacture of bulk or finished products standardized in accordance with U.S. Pharmacopoeia, National Formulary, or other recognized standards. The reports shall be submitted quarterly on company letterhead to the Drug Enforcement Administration, Drug and Chemical Evaluation Section, Washington, DC 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The following information shall be submitted for raw coca leaf, ecgonine, ecgonine for conversion or further manufacture, benzoylecgonine, manufacturing coca extracts (list for tinctures and extracts; and others separately), other crude alkaloids and other derivatives (quantities should be reported as grams of actual quantity involved and the cocaine alkaloid content or equivalency):

(1) Beginning inventory;
(2) Imports;
(3) Gains on reweighing;
(4) Quantity purchased;
(5) Quantity produced;
(6) Other receipts;
(7) Quantity returned to processes for reworking;
(8) Material used in purification for sale;
(9) Material used for manufacture or production;
(10) Losses on reweighing;
(11) Material used for conversion;
(12) Other dispositions and
(13) Ending inventory.

(c) The following information shall be submitted for importation of coca leaves:

(1) Import permit number;
(2) Date the shipment arrived at the United States port of entry;
(3) Actual quantity shipped;
(4) Assay (percent) of cocaine alkaloid and
(5) Total cocaine alkaloid content.

(d) Upon importation of coca leaves, samples will be selected and assays made by the importing manufacturer in accordance with recognized chemical procedures. These assays shall form the basis of accounting for such coca leaves, which shall be accounted for in terms of their cocaine alkaloid content or equivalency or their total anhydrous coca alkaloid content. Where final assay data is not determined at the time of submission, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(e) Where factory procedure is such that partial withdrawals of medicinal coca leaves are made from individual containers, there shall be attached to the container a stock record card on which shall be kept a complete record of withdrawals therefrom.

(f) All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it must no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

§ 1304.33 [Removed]

15. Section 1304.33 is proposed to be removed.

§ 1304.34 [Redesignated as § 1304.33]

16. Section 1304.34 is proposed to be redesignated as § 1304.33 and revised to read as follows:

§ 1304.33 Reports to ARCOS.

(a) *Reports generally.* All reports required by this section shall be filed with the ARCOS Unit, PO/ 28293, Central Station, Washington, DC 20005 on DEA Form 333, or on media which contains the data required by DEA Form 333 and which is acceptable to the ARCOS Unit.

(b) *Frequency of reports.* Acquisition/ Distribution transaction reports shall be filed every quarter not later than the 15th day of the month succeeding the quarter for which it is submitted; except that a registrant may be given permission to file more frequently, (but not more frequently than monthly), depending on the number of transactions being reported each time by that registrant. Inventories shall provide data on the stocks of each reported controlled substance on hand as of the close of business on December 31 of each year. These reports shall be filed not later than January 15 of the following year. Manufacturing transaction reports shall be filed annually for each calendar year not later than January 15 of the following year.

(c) *Persons reporting.* For controlled substances in Schedules I, II or narcotic controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or package, repackage, label or relabel and each person who is registered to distribute shall report acquisition/ distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, and on each psychotropic controlled substance listed in Schedules III and IV as identified in paragraph (d) of this section.

(d) *Substances covered.* Manufacturing and acquisition/ distribution transaction reports shall include data on each controlled substance listed in Schedules I and II and on each narcotic controlled substance listed in Schedule III (but not on any material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V). Additionally, reports on manufacturing transactions shall include the following psychotropic controlled substances listed in Schedules III and IV:

Schedule III

(1) Benzphetamine;
(2) Cyclobarbital;
(3) Methyprylon; and
(4) Phendimetrazine.

Schedule IV

(1) Barbital;
(2) Diethylpropion (Amfepramone);
(3) Ethchlorvynol;
(4) Ethinamate;
(5) Lefetamine (SPA);
(6) Mazindol;
(7) Meprobamate;
(8) Methylphenobarbital;
(9) Phenobarbital;
(10) Phentermine; and
(11) Pipradrol.

Data shall be presented in such a manner as to identify the particular

form, strength, and trade name, if any, of the product containing the controlled substance for which the report is being made. For this purpose, persons filing reports shall utilize the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration.

(e) *Transactions reported.* Acquisition/distribution transaction reports shall provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies). Manufacturing reports shall provide data on material manufactured, manufacture from other material, use in manufacturing other material and use in producing dosage forms.

(f) *Exceptions.* A registered institutional practitioner who repackages or relabels exclusively for distribution or who distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the registrant may be exempted from filing reports under this section by applying to the ARCOS Unit of the Administration.

(Approved by the Office of Management and Budget under control number 1117–0003)

§§ 1304.35—1304.38 [Removed]

17. Sections 1304.35 through 1304.38 are proposed to be removed.

PART 1305—[AMENDED]

1. The authority citation for part 1305 continues to read as follows:

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

2. Section 1305.02 is proposed to be revised to read as follows:

§ 1305.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or Part 1300 of this chapter.

3. Section 1305.03 is proposed to be revised to read as follows:

§ 1305.03 Distributions requiring order forms.

An order form (DEA Form 222) is required for each distribution of a Schedule I or II controlled substance except to persons exempted from registration under part 1301 of this chapter; which are exported from the United States in conformity with the Act; or for delivery to a registered analytical laboratory, or its agent approved by DEA.

4. Section 1305.06 is proposed to be amended to read as follows:

§ 1305.06 Procedure for executing order forms.

(a) Order forms shall be prepared and executed by the purchaser simultaneously in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms shall be prepared by use of a typewriter, pen, or indelible pencil.

(b) Only one item shall be entered on each numbered line. An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The last line completed shall be noted on that form at the bottom of the form, in the space provided. Order forms for carfentanil, etorphine hydrochloride, and diprenorphine shall contain only these substances.

(c) The name and address of the supplier from whom the controlled substances are being ordered shall be entered on the form. Only one supplier may be listed on any form.

(d) Each order form shall be signed and dated by a person authorized to sign an application for registration. The name of the purchaser, if different from the individual signing the order form, shall also be inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of such location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

5. Section 1305.07 is proposed to be amended to read as follows:

§ 1305.07 Power of attorney.

Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a power of attorney for each such individual. The power of attorney shall be signed by the same person who signed the most recent application for registration or reregistration and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the executed order forms of the purchaser, and shall be retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a notice of revocation, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, whoever signed the most recent application for registration or reregistration, and filing it with the power of attorney being revoked. The form for the power of attorney and notice of revocation shall be similar to the following:

Power of Attorney for DEA Order Forms

_____

(Name of registrant)

_____

(Address of registrant)

(DEA registration number) _____

I, _____ (name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint

(name of attorney-in-fact), _____ my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

_____

(Signature of person granting power)

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

_____

(Signature of attorney-in-fact)

Witnesses:

1. _____.

2. _____.

Signed and dated on the _____ day of _____, (year), at _____.

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act of the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

_____

(Signature of person revoking power)

Witnesses:

1. _____.

2. _____.

Signed and dated on the _____ day of _____, (year) , at _____.

6. Section 1305.12 is proposed to be amended by revising paragraph (b) to read as follows:

§ 1305.12 Lost or stolen order forms.

* * * * *

(b) Whenever any used or unused order forms are stolen or lost (otherwise than in the course of transmission) by any purchaser or supplier, he/she shall immediately upon discovery of such theft or loss, report the same to the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, he/she shall report the date or approximate date of receipt thereof and the names and addresses of the purchasers. If an entire book of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms contained therein, he/she shall report, in lieu of the numbers of the forms contained in such book, the date or approximate date of issuance thereof. If any unused order form reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located shall immediately be notified.

7. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1305.04(b)	his	his/her.
1305.05(b)	him (twice) ...	him/her.
1305.08(a)	he	he/she.
1305.08(a)	his (twice)	his/her.
1305.09(b)	he	he/she.
1305.09(d)	his ovn	his/her own.
1305.10(a)	hall	shall.
1305.10(a)	he	he/she.
1305.13(a)	He	He/She.
1305.13(b)	he	he/she.
1305.13(c)	he	he/she.
1305.13(c)	1305.06(e) ...	1305.06(d).
1305.14	he (twice)	he/she.
1305.14	1301.45 or 1301.46.	1301.36.
1305.16(b)	he	he/she.

PART 1306—[AMENDED]

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

Authority: 21 U.S.C. 821, 829, 871(b).

2. Section 1306.02 is proposed to be revised to read as follows:

§ 1306.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

3. Section 1306.11 is proposed to be amended by revising paragraphs (a) and (d)(4), and adding a new paragraph (g) to read as follows:

§ 1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with § 1304.04(h) of this chapter.

* * * * *

(d) * * *

(4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 1306.05, the prescription shall have written on its face ''Authorization for Emergency Dispensing,'' and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7 day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

* * * * *

(g) A prescription prepared in accordance with § 1306.05 written for a Schedule II narcotic substance for a patient released by a registered institution to a home hospice setting which continues to provide daily skilled nursing care to the home hospice setting may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with § 1304.04(h) of this chapter.

4. Section 1306.13 is proposed to be amended by revising paragraph (b) to read as follows:

§ 1306.13 Partial filling of prescriptions.

* * * * *

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. The pharmacist must record on the prescription whether the patient is ''terminally ill'' or an ''LTCF patient.'' Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is ''terminally ill'' or an ''LTCF patient.'' A prescription that is partially filled and does not contain the notation ''terminally ill'' or ''LTCF patient'' shall be deemed to have been filled in violation of the Act. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

* * * * *

5. Section 1306.14 is proposed to be amended by revising the heading and adding a new paragraph (c) to read as follows:

§ 1306.14 Labeling of substances and filing of prescriptions.

* * * * *

(c) All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of § 1304.04(h) of this chapter.

6. Section 1306.15 is proposed to be removed.

7. The center undesignated heading preceding § 1306.21 and § 1306.21 are proposed to be revised to read as follows:

Controlled Substances Listed in Schedules III, IV, and V

§ 1306.21 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 1306.05, except for the signature of the practitioner.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III, IV, or V in the course of his/her professional practice without a prescription, subject to § 1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a written prescription signed by an individual practitioner, or pursuant to a facsimile of a written prescription or order for medication transmitted by the practitioner or the practitioner's agent to the institutional practitioner-pharmacist, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in § 1306.05 except for the signature of the individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to § 1306.07.

8. Section 1306.23 is proposed to be amended by revising the introductory text to read as follows:

§ 1306.23 Partial filling of prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible, provided that:

* * * * *

9. Section 1306.24 is proposed to be revised to read as follows:

§ 1306.24 Labeling of substances and filing of prescriptions.

(a) The pharmacist filling a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.

(b) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule III, IV, or V is prescribed for administration to an ultimate user who is institutionalized: provided, that:

(1) Not more than a 34-day supply or 100 dosage units, whichever is less, of the controlled substance listed in Schedule III, IV or V is dispensed at one time;

(2) The controlled substance listed in Schedule III, IV or V is not in the possession of the ultimate user prior to administration;

(3) The institution maintains appropriate safeguards and records the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule III, IV or V; and

(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

(c) All prescriptions for controlled substances listed in Schedules III, IV and V shall be kept in accordance with § 1304.04(h) of this chapter.

§ 1306.25 [Removed]

10. Section 1306.25 is proposed to be removed.

§ 1306.26 [Redesignated as § 1306.25 and amended]

11. Section 1306.26 is proposed to be redesignated as § 1306.25 and amended by revising paragraphs (a) and (b) to read as follows:

§ 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.

(a) The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

(1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:

(i) Write the word ''VOID'' on the face of the invalidated prescription.

(ii) Record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information.

(iii) Record the date of the transfer and the name of the pharmacist transferring the information.

(b) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(1) Write the word ''transfer'' on the face of the transferred prescription.

(2) Provide all information required to be on a prescription pursuant to 21 CFR 1306.05 and include:

(i) Date of issuance of original prescription;

(ii) Original number of refills authorized on original prescription;

(iii) Date of original dispensing;

(iv) Number of valid refills remaining and date(s) and locations of previous refill(s);

(v) Pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;

(vi) Name of pharmacist who transferred the prescription.

(vii) Pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled;

(3) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

* * * * *

§ Undesignated center heading and § 1306.31 [Removed]

12. The undesignated heading preceding § 1306.31 and § 1306.31 are proposed to be removed.

§ 1306.32 [Redesignated as § 1306.26 and amended]

13. Section 1306.32 is proposed to be redesignated as § 1306.26 and the introductory text and paragraph (a) are revised to read as follows:

§ 1306.26 Dispensing without prescription.

A controlled substance listed in Schedules II, III, IV or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

(a) Such dispensing is made only by a pharmacist (as defined in Part 1300 of this chapter), and not by a nonpharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);

* * * * *

14. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1306.03(a)(2)	1301.24(c)	1301.22(c).
1306.03(a)(2)	1301.25	1301.23.
1306.05(b)	1301.24(c)	1301.22(c).
1306.05(c)	1301.25	1301.22(c).
1306.22(a)(2)	practioner	practitioner.
1306.22(b)	retrival	retrieval.
1306.22(b)(2)	duing	during.
1306.22(b)(4)	Compliance ..	Diversion.

PART 1307—[AMENDED]

1. The authority citation for part 1307 continues to read as follows:

Authority: 21 U.S.C. 821, 822(d), 871(b).

2. Section 1307.01 is proposed to be revised to read as follows:

§ 1307.01 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or Part 1300 of this chapter.

3. Section 1307.02 is proposed to be revised to read as follows:

§ 1307.02 Application of State law and other Federal law.

Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such act nor shall compliance with such parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

4. Section 1307.03 is proposed to be revised to read as follows:

§ 1307.03 Exceptions to regulations.

Any person may apply for an exception to the application of any provision of this chapter by filing a written request stating the reasons for such exception. Requests shall be filed with the Administrator, Drug Enforcement Administration, Department of Justice, Washington, DC 20537. The Administrator may grant an exception in his discretion, but in no case shall he/she be required to grant an exception to any person which is otherwise required by law or the regulations cited in this section.

§ 1307.12 [Removed]

5. Section 1307.12 is proposed to be removed.

§ 1307.13 [Redesignated as § 1307.12]

6. Section 1307.13 is proposed to be redesignated as § 1307.12.

§ 1307.14 [Removed]

7. Section 1307.14 is proposed to be removed.

§ 1307.15 [Redesignated as § 1307.13]

8. Section 1307.15 is proposed to be redesignated as § 1307.13.

9. Section 1307.21 is proposed to be amended by revising paragraph (a) to read as follows:

§ 1307.21 Procedure for disposing of controlled substances.

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Special Agent in Charge of the Administration in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:

(1) If the person is a registrant, he/she shall list the controlled substance or substances which he/she desires to dispose of on DEA Form 41, and submit three copies of that form to the Special Agent in Charge in his/her area; or

(2) If the person is not a registrant, he/she shall submit to the Special Agent in Charge a letter stating:

(i) The name and address of the person;

(ii) The name and quantity of each controlled substance to be disposed of;

(iii) How the applicant obtained the substance, if known; and

(iv) The name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.

* * * * *

10. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1307.11(a)(2)	1304.24(e) ...	1304.22(c).
1307.11(a)(2)	1304.24(c)	1304.22(c).
1307.11(a)(4)	1301.28	1301.25.
1307.11(b)	1301.28	1301.25.
1307.22	28083	20537.

PART 1308—[AMENDED]

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

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

2. Section 1308.02 is proposed to be revised to read as follows:

§ 1308.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

§ 1308.04 [Removed]

3. Section 1308.04 is proposed to be removed.

4. Section 1308.24 is proposed to be amended by removing the Exempt Chemical Preparations Table and revising paragraphs (a) and (i) to read as follows:

§ 1308.24 Exempt chemical preparations.

(a) The chemical preparations and mixtures approved pursuant to § 1308.23 are exempt from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 822–823, 825–829, 952–954) and § 1301.74 of this chapter, to the extent described in paragraphs (b) to (h) of this section. Substances set forth in paragraph (j) shall be exempt from the application of Sections 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 825–829, 952–954) and §§ 1301.71–1301.73 and 1301.74 (a), (b), (d), (e) and (f) of this chapter to the extent as hereinafter may be provided.

* * * * *

(i) A listing of exempt chemical preparations may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug

Enforcement Administration, Washington, DC 20537.

* * * * *

5. In Section 1308.26(a) the Table of Excluded Veterinary Anabolic Steroid Implant Products is proposed to be removed. As revised, § 1308.26(a) is proposed to read as follows:

§ 1308.26 Excluded veterinary anabolic steroid implant products.

(a) The anabolic steroid-containing products, which are expressly intended for administration through implants to cattle or other nonhuman species and which have been approved by the Secretary of Health and Human Services for such administration are excluded from all schedules pursuant to Section 102(41)(B)(I) of the Act (21 U.S.C. 802(41)(B)(I)). A listing of the excluded products may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington DC 20537.

* * * * *

6. In § 1308.32, the Table of Exempted Prescription Products is proposed to be removed. As revised § 1308.32 is proposed to read as follows:

§ 1308.32 Exempted prescription products.

The compounds, mixtures, or preparations which contain a nonnarcotic controlled substance listed in § 1308.12(e) or in § 1308.13 (b) or (c) or in § 1308.14 or in § 1308.15 listed in the Table of Exempted Prescription Products have been exempted by the Administrator from the application of sections 302 through 305, 307 through 309, 1002 through 1004 of the Act (21 U.S.C. 822–825, 827–829, and 952–954) and Sections 1301.13, 1301.22, and §§ 1301.71 through 1301.76 of this chapter for administrative purposes only. An exception to the above is that those products containing butalbital shall not be exempt from the requirement of 21 U.S.C. 952–954 concerning importation, exportation, transshipment and in-transit shipment of controlled substances. Any deviation from the quantitative composition of any of the listed drugs shall require a petition of exemption in order for the product to be exempted. A listing of the Exempted Prescription Products may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537.

7. In Section 1308.34, the Table of Exempt Anabolic Steroid Products is proposed to be removed. As revised, § 1308.34 is proposed to read as follows:

§ 1308.34 Exempt anabolic steroid products.

The anabolic steroid containing compounds, mixtures, or preparations which have been exempted by the Administrator from application of sections 302 through 309 and 1002 through 1004 of the Act (21 U.S.C. 822–829 and 952–954) and §§ 1301.13, 1301.22, and 1301.71 through 1301.76 of this chapter for administrative purposes only may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537.

8. Section 1308.42 is proposed to be revised to read as follows:

§ 1308.42 Purpose of hearing.

If requested by any interested person after proceedings are initiated pursuant to § 1308.43 of this chapter, the Administrator shall hold a hearing for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable pursuant to Section 201(a) of the Act (21 U.S.C. 811(a)). Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law. Additional information relating to hearings to include waivers or modification of rules, request for hearing, burden of proof, time and place, and final order are set forth in Part 1316 of this chapter.

§ 1308.43 [Removed]

9. Section 1308.43 is proposed to be removed.

§ 1308.44 [Redesignated as § 1308.43]

10. Sections 1308.44 is proposed to be redesignated as § 1308.43 and the citation ''1308.45'' in paragraph (f) is changed to read ''1308.44''.

§ 1308.45 [Redesignated as § 1308.44]

11. Section 1308.45 is proposed to be redesignated as 1308.44 and the citation ''1308.48'' in paragraph (e) changed to read ''1308.45''.

§ 1308.46 and 1308.47

[Removed]

12. Sections 1308.46 and 1308.47 are proposed to be removed.

§§ 1308.48—1308.50 [Redesignate as §§ 1308.45–1308.47]

13. Sections 1308.48 through 1308.50 are proposed to be redesignated as §§ 1308.45 through 1308.47.

§ 1308.5 [Removed]

14. Section 1308.51 is proposed to be removed.

§ 1308.52 [Redesignated as § 1308.49 and corrected]

15. Section 1308.52 is proposed to be redesignated as § 1308.49 and the typographical error ''withott'' in the introductory text is corrected to read ''without''.

16. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
Table of Contents for Part 1308.	1308.52 sheduling.	1308.52 scheduling.
1308.03(a)	1301.44 and 1311.43.	1301.35.
1308.12(g)	prectrsors	precursors.
1308.13(b)(1)	quantitive	quantitative.
1308.13(b)(1)	lirted	listed.
1308.13(b)(1)	308.32	1308.32.
1308.22	nonarcotic	nonnarcotic.
1308.23(c)(7)	1302.01	Part 1300 of this chapter.
1308.23(f)	revoje	revoke.
1308.24(d)	Drug Control	Drug and Chemical Evaluation.
1308.33(a)	1308.02	Part 1300 of this chapter.
1308.33(b)	1308.02	Part 1300 of this chapter.

PART 1309—[AMENDED]

1. The authority citation for part 1309 continues to read as follows:

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

2. Section 1309.02 is proposed to be revised to read as follows:

§ 1309.02 Definitions.

Any term used in this part shall have the definition set forth in Section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

§§ 1309.53 and 1309.57 [Removed] and §§ 1309.54–1309.56 [Redesignated as §§ 1309.53–1309.55]

3. Sections 1309.53 and 1309.57 are proposed to be removed and §§ 1309.54 through 1309.56 are proposed to be redesignated as §§ 1309.53 through 1309.55.

4. In addition to the proposed amendments set forth above, DEA is proposing to remove the words ''Section

1310.01(f)(1)(iv) and add in their place the words ''Section 1300.01(b)(28)(i)(D)'' in the following places:
(a) Section 1309.02(g)
(b) Section 1309.21 (a) and (b)
(c) Section 1309.25 (a) and (b); and
(d) Section 1309.71(a)(2).

PART 1310—[AMENDED]

1. The authority citation for part 1310 continues to read as follows:

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

2. Section 1310.01 is proposed to be revised to read as follows:

§ 1310.01 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

§ 1310.05 [Amended]

2. Section 1310.05(c) is proposed to be amended removing the words ''as defined in § 1310.01(i)'' and ''as defined in § 1310.01(j)''

§ 1310.08 [Amended]

3. Section 1310.08, introductory text, is proposed to be amended removing the words ''containted in 21 CFR 1310.01(f) and 1313.02(d)''

§ 1310.09 [Removed]

4. Section 1310.09 is proposed to be removed.

5. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1310.10(a)	1310.01(f)(1)(iv)	1300.01(b)(28)(i)(D).
1310.14(a)	1310.01(f)(1)(iv)(A)	1300.01(b)(28)(i)(D)(*1*).
1310.15(d)	1310.01(f)(1)(iv)(A)	1300.01(b)(28)(i)(D)(*1*).

PART 1311—[REMOVED AND RESERVED]

Part 1311 is proposed to be removed and reserved.

PART 1312—[AMENDED]

1. The authority citation for part 1312 continues to read as follows:

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

2. Section 1312.02 is proposed to be revised to read as follows:

§ 1312.02 Defintions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or Part 1300 of this chapter.

3. Part 1312 is proposed to be amended to remove the words, ''1405 EYE Street, NW.'', in the following sections:
(a) 1312.12(a);
(b) 1312.16(b);
(c) 1312.18(b);
(d) 1312.19(b);
(e) 1312.22(a);
(f) 1312.24(a);
(g) 1312.27(a);
(h) 1312.27(b)(5)(iv);
(i) 1312.28(d);
(j) 1312.31(b); and
(k) 1312.32(a).

4. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1312.12(a)	Drug Control Section	Drug Operations Section.
1312.14(a)	Drug Control Section	Drug Operations Section.
1312.16(b)	Drug Control Section	Drug Operations Section.
1312.17	304	1304.
1312.18(b)	Drug Control Section	Drug Operations Section.
1312.18(c)	(or BND)	
1312.19(a)	Drug Control Section	Drug Operations Section.
1312.19(b)	Drug Control Section	Drug Operations Section.
1312.22(a)	Drug Control Section	Drug Operations Section.
1312.24(a)	Bureau	Administration.
1312.24(a)	Drug Control Section	Drug Operations Section.
1312.25	Drug Control Section	Drug Operations Section.
1312.27(a)	regirtered	registered.
1312.27(a)	Drug Control Section	Drug Operations Section.
1312.27(b)(5)(iii)	inital	initial.
1312.27(b)(5)(iv)	Drug Control Section	Drug Operations Section.
1312.28(d)	Drug Control Section	Drug Operations Section.
1312.28(d)	1327.27(b)(4)	1312.27(b0(4).
1312.31(b)	Drug Control Section	Drug Operations Section.
1312.32(a)	Drug Control Section	Drug Operations Section.

PART 1313—[AMENDED]

1. The authority citation for part 1313 continues to read as follows:

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

2. Section 1313.02 is proposed to be revised to read as follows:

§ 1313.02 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

3. Section 1313.15(a) is proposed to be amended by removing the words ''§ 1313.02(i)'' and replace them with the words ''§ 1300.01(b)(13)''

4. Section 1313.21(c)(1) is proposed to be amended by removing the words ''as defined § 1313.02(j)''

5. Section 1313.24(a) is proposed to be amended by removing the words ''§ 1313.02(j)'' and replacing them with the words ''§ 1300.01(b)(12)''

PART 1316—[AMENDED]

1. The authority citation for part 1316 continues to read as follows:

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

2. Section 1316.02 is proposed to be amended by revising paragraph (g) to read as follows:

§ 1316.02 Definitions.

* * * * *

(g) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

3. Section 1316.13 is proposed to be amended by revising the text to read as follows:

§ 1316.13 Frequency of administrative inspections.

Except where circumstances otherwise dictate, it is the intent of the Administration to inspect all manufacturers of controlled substances listed in Schedules I and II and distributors of controlled substances listed in Schedule I once each year. Distributors of controlled substances listed in schedules II through V and manufacturers of controlled substances listed in Schedules III through V shall be inspected as circumstances may require, based in part on the registrant's history of compliance with the requirements of this chapter and maintenance of effective controls and procedures to guard against the diversion of controlled substances.

4. Section 1316.42 is proposed to be amended by revising paragraph (h) to read as follows:

§ 1316.42 Definitions.

* * * * *

(h) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

5. Section 1316.71 is proposed to be amended by revising paragraph (f) to read as follows:

§ 1316.71 Definitions.

* * * * *

(f) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

6. In addition to the proposed amendments set forth above, DEA is proposing to amend each section indicated in the left column by removing the words indicated in the middle column and adding the words in the right column:

Section	Remove	Add
1316.03, introductory text	Adminirtrator	Administrator.
1316.05	1314.06	1316.06.
1316.05	1316.09–1316.14	1316.09–1316.13.
1316.23(b)	1405 I Street	
1316.24(c)	1316.21(b)	1316.23(b).
1316.24(c)	1316.22(b)	1316.24(b).
1316.41	1303.41–1303.47	1303.31–1303.37.
		1313.51–1313.57.
1316.46(b)(1)	1301.32(a)(3)	1301.32(a)(6).
1316.52(a)	1301.60	1301.56.
1316.77(a)	Forward	Forward.
1316.81	proceeeding	proceeding.

Dated: February 26, 1996.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 96–4663 Filed 3–4–96; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 906

[SPATS No. CO–029–FOR]

Colorado Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; reopening and extension of public comment period on proposed amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of revisions pertaining to a previously proposed amendment to the Colorado regulatory program (hereinafter, the ''Colorado program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The revisions of Colorado's proposed rules pertain to the definitions of ''Permit area'' and ''Self-bonding;'' permit application information concerning the legal right to enter and proposed operations in which the affected area is within 100 feet of a public road; the content of public notices in which the affected areas would be within 100 feet of a public road or operations which propose to close or relocate a public road; decisions on requests to disclose confidential information; the area of the proposed surface coal mining operation which is subject to the requirements concerning valid existing rights; the right to comment on technical revisions; approval of and conditions for self bonds; the requirements for vegetative cover at the time of release of bond coverage for liability associated with temporary drainage and sediment control facilities; and the contents of a showing in lieu of the requirement for an engineer's certification of the construction or reconstruction of haul and access roads that were completed prior to August 1, 1995. The amendment is intended to revise the Colorado program to be consistent with the corresponding Federal regulations, incorporate the additional flexibility afforded by the revised Federal regulations, and improve operational efficiency.

DATES: Written comments must be received by 4:00 p.m., m.s.t. March 20, 1996.

ADDRESSES: Written comments should be mailed or hand delivered to James F. Fulton at the address listed below. Copies of the Colorado program, the proposed amendment, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free