Alternative Methods of Compliance (AMOCs)

(j)(1) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Marcia Smith, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 917–6484; fax (425) 917–6590. Or, e-mail information to *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

Material Incorporated by Reference

(k) You must use Boeing Service Bulletin 747–25A3368, Revision 2, dated June 12, 2008, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, Washington 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; e-mail *me.boecom@boeing.com;* Internet *https://www.myboeingfleet.com.*

(3) You may review copies of the service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221 or 425–227–1152.

(4) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on February 25, 2010.

Jeffrey E. Duven,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2010–4650 Filed 3–8–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301, 1303, 1304, 1307, 1308, 1309, 1310, 1312, 1313, 1314, 1315, 1316, 1321

[Docket No. DEA–312F]

RIN 1117–AB19

Changes to and Consolidation of DEA Mailing Addresses

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

ACTION: Final rule.

SUMMARY: DEA is amending Title 21 of the Code of Federal Regulations (CFR) to update and consolidate existing mailing addresses. Mailing addresses are being removed from the individual sections in which they currently appear and are being consolidated into one table in a new part 1321. DEA is making this change to the CFR to ensure registrants have the most current and accurate information, reduce administrative costs, and facilitate future address changes. A statement directing persons to the Table of DEA Mailing Addresses within the CFR is being provided in place of specific mailing addresses.

DATES: *Effective Date:* This rule is effective March 9, 2010.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), parts 1300 to end. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical purposes and to deter the diversion of controlled substances to illegal purposes.

Controlled substances are drugs and other substances that have a potential for abuse and psychological and physical dependence; these include substances classified as opioids, stimulants, depressants, hallucinogens, anabolic steroids, and drugs that are immediate precursors of these classes of substances. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity.

The CSA, as amended, also requires DEA to regulate the manufacture, distribution, importation, and exportation of chemicals that may be used to manufacture controlled substances. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances. Registrants are also required to provide other reports and information to DEA on an ongoing basis in compliance with a variety of statutory and regulatory obligations.

Background

Currently, 21 CFR parts 1300 to end contain numerous office names and mailing addresses to which specific forms and other information are to be sent. However, oftentimes these mailing addresses and office names are not consistent and many are no longer accurate. DEA became aware of this internal inconsistency when it determined that, to improve agency management and efficiency, its Washington, DC, addresses would be moved to other locations. As DEA reviewed the number of addresses contained in 21 CFR, it became clear that a significant administrative burden would be involved in updating these addresses. DEA recognized that this administrative burden could potentially not be a one-time occurrence; that is, it is quite possible that DEA might move some of its mailing addresses in the future, necessitating further revisions to the CFR.

For registrants to have the most current mailing addresses to which applications, forms, and other materials are to be sent, DEA believes directing registrants and other interested persons to a single location within the CFR is the most practical way to convey current mailing address information. To address this, DEA is establishing a new part 1321 in the CFR that will contain the Table of DEA Mailing Addresses. Providing this information in the table format in the CFR allows for easy retrieval of necessary information in

multiple formats. By consolidating this information into a table within the CFR, DEA will be able to rapidly respond should mailing addresses change due to facility relocation, special mail handling procedures, or other circumstances.

With publication of this Final Rule, all entries citing DEA mailing addresses will be removed and replaced with language directing interested persons to the Table of DEA Mailing Addresses found at 21 CFR 1321.01.

Information Affected by the Removal of Addresses

As noted previously, the current CFR contains numerous addresses specific to applications, forms, and other information to be physically mailed to DEA. Below are two tables. The first table lists the CFR section which previously contained a mailing address, the subject, and the corresponding DEA office that is responsible for that activity. The second table provides the mailing address information that will be provided in 21 CFR 1321.01.

TABLE 1—MAILING ADDRESSES REFERENCED IN THE CFR

CFR Section	Subject	DEA Office
1301.03	Procedures information request (controlled substances registration)	DEA Registration Section.
1301.13(e)(2)	Request DEA Forms 224, 225, and 363	DEA Registration Section.
1301.14(a)	Controlled substances registration application submission	DEA Registration Section.
1301.18(c)	Research project controlled substance increase request	DEA Registration Section.
1301.51	Controlled substances registration modification request	DEA Registration Section.
1301.52(b)	Controlled substances registration transfer request	DEA Registration Section.
1301.52(c)	Controlled substances registration return for cancellation	DEA Office of Diversion Control.
1301.71(d)	Controlled substances security system compliance review	DEA Regulatory Section.
1303.12(b)	Application for controlled substances procurement quota (DEA Form 250) filing and request.	DEA Drug & Chemical Evaluation Section.
1303.12(d)	Controlled substances quota adjustment request	DEA Drug & Chemical Evaluation Section.
1303.22	Application for individual manufacturing quota (DEA Form 189) filing and request for schedule I or II controlled substances.	DEA Drug & Chemical Evaluation Section.
1304.04(d)	ARCOS separate central reporting identifier request	DEA ARCOS Unit.
1304.31(a)	Manufacturers importing narcotic raw material report submission	DEA Drug & Chemical Evaluation Section.
1304.32(a)	Manufacturers importing coca leaves report submission	DEA Drug & Chemical Evaluation Section.
1304.33(a)	Reports to ARCOS	DEA ARCOS Unit.
1307.03	Exception request filing	DEA Office of Diversion Control.
1307.22	Disposal of controlled substances by the Administration delivery application	DEA Office of Diversion Control.
1308.21(a)	Exclusion of nonnarcotic substance	DEA Office of Diversion Control.
1308.23(b)	Exemption for chemical preparations	DEA Office of Diversion Control.
1308.24(d)	Exempt narcotic chemical preparations importer/exporter reporting	DEA Drug & Chemical Evaluation Section.
1308.24(i)	Exempted chemical preparations listing	DEA Drug & Chemical Evaluation Section.
1308.25(a)	Exclusion of veterinary anabolic steroid implant product application	DEA Office of Diversion Control.
1308.26(a)	Excluded veterinary anabolic steroid implant products listing	DEA Drug & Chemical Evaluation Section.
1308.31(a)	Exemption of a nonnarcotic prescription product application	DEA Office of Diversion Control.
1308.32	Exempted prescription products listing	DEA Drug & Chemical Evaluation Section.
1308.33(b)	Exemption of certain anabolic steroid products application	DEA Office of Diversion Control.
1308.34	Exempted anabolic steroid products listing	DEA Drug & Chemical Evaluation Section.
1308.43(b)	Petition to initiate proceedings for rulemaking	DEA Administrator.
1309.03	List I chemicals registration procedures information request	DEA Registration Section.
1309.32(c)	Request DEA Form 510	DEA Registration Section.
1309.33(a)	List I chemicals registration application submission	DEA Registration Section.
1309.61	List I chemicals registration modification request	DEA Registration Section.
1309.71(c)	List I chemicals security system compliance review	DEA Regulatory Section.
1310.05(c)	Importer/exporter of tableting or encapsulation machines reporting	DEA Import/Export Unit.
1310.05(d)	Bulk manufacturer of listed chemicals reporting	DEA Drug & Chemical Evaluation Section.
1310.05(e)(1)	Reporting by persons required to keep records and file reports regarding List I chemicals.	DEA Import/Export Unit.
1310.05(e)(2)	Request to submit List I chemicals reports in electronic form	DEA Import/Export Unit.
1310.06(g)	Report of declared exports of machines refused, rejected, or returned	DEA Import/Export Unit.
1310.13(b)	Exemption for chemical preparations	DEA Office of Diversion Control.
1310.21(b)	Sale by Federal departments or agencies of chemicals which could be used to manufacture controlled substances certification request.	DEA Office of Diversion Control.
1312.12(a)	Application for import permit (DEA Form 357)	DEA Import/Export Unit.
1312.16(b)	Return unused import permits	DEA Import/Export Unit.
1312.18(b)	Import declaration (DEA Form 236) submission	DEA Import/Export Unit.
1312.19(b)	DEA Form 236 copy 4	DEA Import/Export Unit.
1312.22(a)	Application for export permit (DEA Form 161)	DEA Import/Export Unit.
1312.22(d)(8)	Request for return of unacceptable or undeliverable exported controlled substances..	DEA Import/Export Unit
1312.24(a)	DEA Form 161 copy 2	DEA Import/Export Unit.

TABLE 1—MAILING ADDRESSES REFERENCED IN THE CFR—Continued

CFR Section	Subject	DEA Office
1312.27(a)	Special controlled substances export invoice (DEA Form 236) filing	DEA Import/Export Unit.
1312.27(b)(5)(iv)	Request for reexport	DEA Import/Export Unit.
1312.28(d)	Distribution of special controlled substances invoice (DEA Form 236) copy 4	DEA Import/Export Unit.
1312.31(b)	Controlled substances transshipment permit application	DEA Import/Export Unit.
1312.32(a)	Advanced notice of importation for transshipment or transfer of controlled substances.	DEA Import/Export Unit.
1313.12(b)	Authorization to import listed chemicals (DEA Form 486)	DEA Import/Export Unit.
1313.12(e)	Quarterly reports for listed chemicals importation	DEA Import/Export Unit.
1313.21(b)	Authorization to export listed chemicals (DEA Form 486)	DEA Import/Export Unit.
1313.21(e)	Quarterly reports for listed chemicals exportation	DEA Import/Export Unit.
1313.22(e)	Written notice of declared exports of listed chemicals refused, rejected or undeliverable.	DEA Import/Export Unit.
1313.31(b)	Advanced notice of importation for transshipment or transfer of listed chemicals.	DEA Import/Export Unit.
1313.32(b)(1)	International transaction authorization (DEA Form 486)	DEA Import/Export Unit.
1314.110(a)(1)	Reports for mail-order sales	DEA Import/Export Unit.
1314.110(a)(2)	Request to submit mail-order sales reports in electronic form	DEA Import/Export Unit.
1315.22	Application for individual manufacturing quota for ephedrine, pseudoephedrine, phenylpropanolamine (DEA Form 189) filing and request.	DEA Drug & Chemical Evaluation Section.
1315.32(e)	Application for procurement quota for ephedrine, pseudoephedrine, phenylpropanolamine (DEA Form 250) filing and request.	DEA Drug & Chemical Evaluation Section.
1315.32(g)	Procurement quota adjustment request for ephedrine, pseudoephedrine, phenylpropanolamine.	DEA Drug & Chemical Evaluation Section.
1315.34(d)	Application for import quota for ephedrine, pseudoephedrine, phenylpropanolamine (DEA Form 488) request and filing.	DEA Drug & Chemical Evaluation Section.
1315.36(b)	Request import quota increase for ephedrine, pseudoephedrine, or phenylpropanolamine.	DEA Drug & Chemical Evaluation Section.
1316.23(b)	Petition for grant of confidentiality for research subjects	DEA Administrator.
1316.24(b)	Petition for exemption from prosecution for researchers	DEA Administrator.
1316.45	Hearings documentation filing	DEA Hearing Clerk.
1316.46(a)	Inspection of record	DEA Hearing Clerk.
1316.47(a)	Request for hearing	DEA Federal Register Representative.
1316.48	Notice of appearance	DEA Administrator.

TABLE 2—TABLE OF DEA MAILING ADDRESSES

Code of Federal Regulations Section—Topic	DEA Mailing address
DEA Administrator	
1308.43(b)—Petition to initiate proceedings for rulemaking 1316.23(b)—Petition for grant of confidentiality for research subjects. 1316.24(b)—Petition for exemption from prosecution for researchers. 1316.48—Notice of appearance.	Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, VA 22152.
DEA Office of Diversion Control	
1301.52(c)—Controlled substances registration return for cancellation 1307.03—Exception request filing. 1307.22—Disposal of controlled substances by the Administration delivery application. 1308.21(a)—Exclusion of nonnarcotic substance. 1308.23(b)—Exemption for chemical preparations. 1308.25(a)—Exclusion of veterinary anabolic steroid implant product application. 1308.31(a)—Exemption of a nonnarcotic prescription product application. 1308.33(b)—Exemption of certain anabolic steroid products application. 1310.13(b)—Exemption for chemical preparations. 1310.21(b)—Sale by Federal departments or agencies of chemicals which could be used to manufacture controlled substances certification request.	Drug Enforcement Administration, Attn: Office of Diversion Control/OD, 8701 Morrissette Drive, Springfield, VA 22152.
DEA Regulatory Section	
1301.71(d)—Security system compliance review for controlled substances 1309.71(c)—Security system compliance review for List I chemicals.	Drug Enforcement Administration, Attn: Regulatory Section/ODG, 8701 Morrissette Drive, Springfield, VA 22152.
DEA Import/Export Unit	
1310.05(c)—Importer/exporter of tableting or encapsulation machines reporting 1310.05(e)(1)—Reporting by persons required to keep records and file reports regarding List I chemicals. 1310.05(e)(2)—Request to submit List I chemicals reports in electronic form.	Drug Enforcement Administration, Attn: Import/Export Unit/ODGI, 8701 Morrissette Drive, Springfield, VA 22152.

TABLE 2—TABLE OF DEA MAILING ADDRESSES—Continued

Code of Federal Regulations Section—Topic	DEA Mailing address
1310.06(g)—Report of declared exports of machines refused, rejected, or returned. 1312.12(a)—Application for import permit (DEA Form 357). 1312.16(b)—Return unused import permits. 1312.18(b)—Import declaration (DEA Form 236) submission. 1312.19(b)—DEA Form 236 copy 4 filing. 1312.22(a)—Application for export permit (DEA Form 161). 1312.22(d)(8)—Request for return of unacceptable or undeliverable exported controlled substances. 1312.24(a)—DEA Form 161 copy 2 filing. 1312.27(a)—Special controlled substances export invoice (DEA Form 236) filing. 1312.27(b)(5)(iv)—Request for reexport. 1312.28(d)—Distribution of special controlled substances invoice (DEA Form 236) copy 4. 1312.31(b)—Controlled substances transshipment permit application. 1312.32(a)—Advanced notice of importation for transshipment or transfer of controlled substances. 1313.12(b)—Authorization to import listed chemicals (DEA Form 486). 1313.12(e)—Quarterly reports of listed chemicals importation. 1313.21(b)—Authorization to export listed chemicals (DEA Form 486). 1313.21(e)—Quarterly reports of listed chemicals exportation. 1313.22(e)—Written notice of declared exports of listed chemicals refused, rejected or undeliverable. 1313.31(b)—Advanced notice of importation for transshipment or transfer of listed chemicals. 1313.32(b)(1)—International transaction authorization (DEA Form 486). 1314.110(a)(1)—Reports for mail-order sales. 1314.110(a)(2)—Request to submit mail-order sales reports in electronic form.	
DEA Drug & Chemical Evaluation Section	
1303.12(b)—Application for controlled substances procurement quota (DEA Form 250) filing and request. 1303.12(d)—Controlled substances quota adjustment request. 1303.22—Application for individual manufacturing quota (DEA Form 189) filing and request for schedule I or II controlled substances. 1304.31(a)—Manufacturers importing narcotic raw material report submission. 1304.32(a)—Manufacturers importing coca leaves report submission. 1308.24(d)—Exempt narcotic chemical preparations importer/exporter reporting. 1308.24(i)—Exempted chemical preparations listing. 1308.26(a)—Excluded veterinary anabolic steroid implant products listing. 1308.32—Exempted prescription products listing. 1308.34—Exempted anabolic steroid products listing. 1310.05(d)—Bulk manufacturer of listed chemicals reporting. 1315.22—Application for individual manufacturing quota for ephedrine, pseudoephedrine, phenylpropanolamine (DEA Form 189) filing and request. 1315.32(e)—Application for procurement quota for ephedrine, pseudoephedrine, phenylpropanolamine (DEA Form 250) filing and request. 1315.32(g)—Procurement quota adjustment request for ephedrine, pseudoephedrine, phenylpropanolamine. 1315.34(d)—Application for import quota for ephedrine, pseudoephedrine, phenylpropanolamine (DEA Form 488) request and filing. 1315.36(b)—Request import quota increase for ephedrine, pseudoephedrine, or phenylpropanolamine.	Drug Enforcement Administration, Attn: Drug & Chemical Evaluation Section/ODE, 8701 Morrissette Drive, Springfield, VA 22152.
DEA ARCOS Unit	
1304.04(d)—ARCOS separate central reporting identifier request ..... 1304.33(a)—Reports to ARCOS.	Drug Enforcement Administration, Attn: ARCOS Unit/ODPT, P.O. Box 2520, Springfield, VA 22152–2520, OR Drug Enforcement Administration, Attn: ARCOS Unit/ODPT, 8701 Morrissette Drive, Springfield, VA 22152.
DEA Registration Section	
1301.03—Procedures information request (controlled substances registration) ..... 1301.13(e)(2)—Request DEA Forms 224, 225, and 363. 1301.14(a)—Controlled substances registration application submission. 1301.18(c)—Research project controlled substance increase request. 1301.51—Controlled substances registration modification request. 1301.52(b)—Controlled substances registration transfer request. 1309.03—List I chemicals registration procedures information request. 1309.32(c)—Request DEA Form 510. 1309.33(a)—List I chemicals registration application submission.	Drug Enforcement Administration, Attn: Registration Section/ODR P.O. Box 2639, Springfield, VA 22152–2639.

TABLE 2—TABLE OF DEA MAILING ADDRESSES—Continued

Code of Federal Regulations Section—Topic	DEA Mailing address
1309.61—List I chemicals registration modification request.	
DEA Hearing Clerk	
1316.45—Hearings documentation filing 1316.46(a)—Inspection of record.	Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, VA 22152.
DEA Federal Register Representative	
1316.47(a)—Request for hearing	Drug Enforcement Administration, Attn: Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

DEA is removing address references for the two information collections specifically listed in the regulations (21 CFR 1310.06(d) and 1313.24(e)), as the information was provided inconsistently. Persons are encouraged to submit comments regarding information collections as each specific collection is renewed. Notices regarding such renewal are published in the **Federal Register,** seek public comment, and provide the address to be used when submitting those comments.

Technical Corrections

While preparing this rule, DEA became aware of inaccurate section citations in 21 CFR 1310.05(d) and 21 CFR 1310.06(h)(5). Those paragraphs referenced 21 CFR 1310.01(f)(1)(iv) and 21 CFR 1310.01(f)(1)(v) which had previously been redesignated as 21 CFR 1300.02(b)(28)(i)(D) and 21 CFR 1300.02(b)(28)(i)(E), respectively. DEA is correcting these inaccurate citations in this rule.

Regulatory Certifications

Administrative Procedure Act (5 U.S.C. 553)

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (5 U.S.C. 553), including notice of proposed rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. This rule updates existing mailing addresses and consolidates those addresses into a new part in 21 CFR. By consolidating this information, DEA will be able to rapidly respond should mailing addresses change due to facility relocation, special mail handling procedures, or other circumstances. As this Final Rule only updates existing mailing addresses and consolidates those addresses (some of which were outdated), DEA finds it unnecessary and impracticable to permit public notice and comment. Therefore, DEA is publishing this document as a final rule. Further, as the changes of address have occurred and it is administratively burdensome for DEA to continue to support previous mailing addresses, and since a delay in the effective date of this regulation could impede the timely receipt of required reports by DEA from the regulated industry and cause further confusion, DEA finds there is good cause to make this final rule effective immediately upon publication.

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This final rule merely changes DEA mailing addresses, permitting industry to report to DEA in a timely manner.

Executive Order 12866

The Deputy Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant regulatory action. Therefore, this action has not been reviewed by the Office of Management and Budget.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

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

List of Subjects

21 CFR Part 1301

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

21 CFR Part 1303

Administrative practice and procedure, Drug traffic control.

21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1307

Drug traffic control.

21 CFR Part 1308

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

21 CFR Part 1309

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

21 CFR Part 1310

Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

21 CFR Part 1312

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

21 CFR Part 1313

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

21 CFR Part 1314

Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1315

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

21 CFR Part 1316

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

21 CFR Part 1321

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

■ For the reasons set out above, 21 CFR Chapter II is amended as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

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

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957, 958.

■ 2. Section 1301.03 is revised to read as follows:

§ 1301.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Registration Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

■ 3. Section 1301.13 is amended by revising paragraph (e)(2) to read as follows:

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

* * * * *

(e) * * *

(2) DEA Forms 224, 225, and 363 may be obtained at any area office of the Administration or by writing to the Registration Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 4. Section 1301.14 is amended by revising paragraph (a) to read as follows:

§ 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. The appropriate registration fee and any required attachments must accompany the application. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 5. Section 1301.18 is amended by revising paragraph (c) to read as follows:

§ 1301.18 Research protocols.

* * * * *

(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, by registered mail, return receipt requested. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. 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.

* * * * *

■ 6. Section 1301.51 is revised to read as follows:

§ 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. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. 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.

■ 7. Section 1301.52 is amended by revising paragraphs (b) and (c) to read as follows:

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

* * * * *

(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. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(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. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Any controlled substances in his/her possession may be disposed of in accordance with § 1307.21 of this chapter.

* * * * *

■ 8. Section 1301.71 is amended by revising paragraph (d) to read as follows:

§ 1301.71 Security requirements generally.

* * * * *

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in §§ 1301.72–1301.76 may submit any plans, blueprints, sketches or other materials regarding the proposed security system either to the Special Agent in Charge in the region in which the system will be used, or to the Regulatory Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

PART 1303—QUOTAS

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

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

■ 10. Section 1303.12 is amended by revising paragraphs (b) and (d) to read as follows:

§ 1303.12 Procurement quotas.

* * * * *

(b) Any person who is registered to manufacture controlled substances listed in any schedule and who desires to use during the next calendar year any basic class of controlled substances listed in Schedule I or II (except raw opium being imported by the registrant pursuant to an import permit) for purposes of manufacturing, shall apply on DEA Form 250 for a procurement quota for such basic class. A separate application must be made for each basic class desired to be procured or used. The applicant shall state whether he intends to manufacture the basic class himself or purchase it from another manufacturer. The applicant shall state separately each purpose for which the basic class is desired, the quantity desired for that purpose during the next calendar year, and the quantities used and estimated to be used, if any, for that purpose during the current and preceding 2 calendar years. If the purpose is to manufacture the basic class into dosage form, the applicant shall state the official name, common or usual name, chemical name, or brand name of that form. If the purpose is to manufacture another substance, the applicant shall state the official name, common or usual name, chemical name, or brand name of the substance, and, if a controlled substance listed in any schedule, the schedule number and Administration Controlled Substances Code Number, as set forth in part 1308 of this chapter, of the substance. If the purpose is to manufacture another basic class of controlled substance listed in Schedule I or II, the applicant shall also state the quantity of the other basic class which the applicant has applied to manufacture pursuant to § 1303.22 and the quantity of the first basic class necessary to manufacture a specified unit of the second basic class. DEA Form 250 shall be filed on or before April 1 of the year preceding the calendar year for which the procurement quota is being applied. Copies of DEA Form 250 may be obtained from, and shall be filed with, the Drug and Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

(d) Any person to whom a procurement quota has been issued may at any time request an adjustment in the quota by applying to the Administrator with a statement showing the need for the adjustment. Such application shall be filed with the Drug & Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The Administrator shall increase or decrease the procurement quota of such person if and to the extent that he finds, after considering the factors enumerated in paragraph (c) of this section and any occurrences since the issuance of the procurement quota, that the need justifies an adjustment.

* * * * *

■ 11. Section 1303.22 is amended by revising the introductory text to read as follows:

§ 1303.22 Procedure for applying for individual manufacturing quotas.

Any person who is registered to manufacture any basic class of controlled substance listed in Schedule I or II and who desires to manufacture a quantity of such class shall apply on DEA Form 189 for a manufacturing quota for such quantity of such class. Copies of DEA Form 189 may be obtained from, and shall be filed (on or before May 1 of the year preceding the calendar year for which the manufacturing quota is being applied) with, the Drug & Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A separate application must be made for each basic class desired to be manufactured. The applicant shall state:

* * * * *

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

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

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

■ 13. Section 1304.04 is amended by revising paragraph (d) to read as follows:

§ 1304.04 Maintenance of records and inventories.

* * * * *

(d) ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Request for central reporting identifiers will be submitted to the ARCOS Unit. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 14. Section 1304.31 is amended by revising paragraph (a) 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 and Chemical Evaluation Section, Drug Enforcement Administration, on or before the 15th day of the month immediately following the period for which it is submitted. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 15. Section 1304.32 is amended by revising paragraph (a) 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 and Chemical Evaluation Section, Drug Enforcement Administration, on or before the 15th day of the month immediately following the period for which it is submitted. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 16. Section 1304.33 is amended by revising paragraph (a) 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 on DEA Form 333, or on media which contains the data required by DEA Form 333 and which is acceptable to the ARCOS Unit. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

PART 1307—MISCELLANEOUS

■ 17. The authority citation for Part 1307 continues to read as follows:

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

■ 18. Section 1307.03 is 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 with the Office of Diversion Control, Drug Enforcement Administration, stating the reasons for such exception. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. 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.

■ 19. Section 1307.22 is revised to read as follows:

§ 1307.22 Disposal of controlled substances by the Administration.

Any controlled substance delivered to the Administration under § 1307.21 or forfeited pursuant to section 511 of the Act (21 U.S.C. 881) may be delivered to any department, bureau, or other agency of the United States or of any State upon proper application addressed to the Office of Diversion Control, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The application shall show the name, address, and official title of the person or agency to whom the controlled drugs are to be delivered, including the name and quantity of the substances desired and the purpose for which intended. The delivery of such controlled drugs shall be ordered by the Administrator, if, in his opinion, there exists a medical or scientific need therefor.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

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

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

■ 21. Section 1308.21 is amended by revising paragraph (a) to read as follows:

§ 1308.21 Application for exclusion of a nonnarcotic substance.

(a) Any person seeking to have any nonnarcotic drug that may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, excluded from any schedule, pursuant to section 201(g)(1) of the Act (21 U.S.C. 811(g)(1)), may apply to the Office of Diversion Control, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 22. Section 1308.23 is amended by revising paragraph (b) to read as follows:

§ 1308.23 Exemption of certain chemical preparations; application.

* * * * *

(b) Any person seeking to have any preparation or mixture containing a controlled substance and one or more noncontrolled substances exempted from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Office of Diversion Control, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 23. Section 1308.24 is amended by revising paragraphs (d) and (i) to read as follows:

§ 1308.24 Exempt chemical preparations.

* * * * *

(d) *Records and reports:* Any person who manufactures an exempt chemical preparation or mixture must keep complete and accurate records and file all reports required under part 1304 of this chapter regarding all controlled substances being used in the manufacturing process until the preparation or mixture is in the form described in paragraph (i) of this section. In lieu of records and reports required under part 1304 of this chapter regarding exempt chemical preparations, the manufacturer need only record the name, address, and registration number, if any, of each person to whom the manufacturer distributes any exempt chemical preparation. Each importer or exporter of an exempt narcotic chemical preparation must submit a semiannual report of the total quantity of each substance imported or exported in each calendar half-year within 30 days of the close of the period to the Drug and Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Any other person who handles an exempt chemical preparation after it is in the form described in paragraph (i) of this section is not required to maintain records or file reports.

* * * * *

(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. See the Table of DEA Mailing Addresses in

§ 1321.01 of this chapter for the current mailing address.

* * * * *

■ 24. Section 1308.25 is amended by revising paragraph (a) to read as follows:

§ 1308.25 Exclusion of a veterinary anabolic steroid implant product; application.

(a) Any person seeking to have any anabolic steroid product, 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, identified as being excluded from any schedule, pursuant to section 102(41)(B)(i) of the Act (21 U.S.C. 802(41)(B)(i)), may apply to the Office of Diversion Control, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 25. Section 1308.26 is amended by revising paragraph (a) to read as follows:

§ 1308.26 Excluded veterinary anabolic steroid implant products.

(a) Products containing an anabolic steroid, that 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. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 26. Section 1308.31 is amended by revising paragraph (a) to read as follows:

§ 1308.31 Application for exemption of a nonnarcotic prescription product.

(a) Any person seeking to have any compound, mixture, or preparation containing any nonnarcotic controlled substance listed in § 1308.12(e), or in § 1308.13(b) or (c), or in § 1308.14, or in § 1308.15, exempted from application of all or any part of the Act pursuant to section 201(g)(3)(A), of the Act (21 U.S.C. 811(g)(3)(A)) may apply to the Office of Diversion Control, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 27. Section 1308.32 is revised to read as follows:

§ 1308.32 Exempted prescription products.

The compounds, mixtures, or preparations that 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, and 1002 through 1004 of the Act (21 U.S.C. 822–825, 827–829, and 952–954) and §§ 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. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

■ 28. Section 1308.33 is amended by revising paragraph (b) to read as follows:

§ 1308.33 Exemption of certain anabolic steroid products; application.

* * * * *

(b) Any person seeking to have any compound, mixture, or preparation containing an anabolic steroid as defined in part 1300 of this chapter exempted from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Office of Diversion Control, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 29. Section 1308.34 is revised to read as follows:

§ 1308.34 Exempt anabolic steroid products.

The list of compounds, mixtures, or preparations that contain an anabolic steroid that 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. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

■ 30. Section 1308.43 is amended by revising paragraph (b) to read as follows:

§ 1308.43 Initiation of proceedings for rulemaking.

* * * * *

(b) Petitions shall be submitted in quintuplicate to the Administrator. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Petitions shall be in the following form:

_____ (Date)

Administrator, Drug Enforcement Administration _____ (Mailing Address)

Dear Sir: The undersigned _____ hereby petitions the Administrator to initiate proceedings for the issuance (amendment or repeal) of a rule or regulation pursuant to section 201 of the Controlled Substances Act.

Attached hereto and constituting a part of this petition are the following:

(A) The proposed rule in the form proposed by the petitioner. (If the petitioner seeks the amendment or repeal of an existing rule, the existing rule, together with a reference to the section in the Code of Federal Regulations where it appears, should be included.)

(B) A statement of the grounds which the petitioner relies for the issuance (amendment or repeal) of the rule. (Such grounds shall include a reasonably concise statement of the facts relied upon by the petitioner, including a summary of any relevant medical or scientific evidence known to the petitioner.)

All notices to be sent regarding this petition should be addressed to:

_____ (Name)

_____ (Street Address)

_____ (City and State)

Respectfully yours,

_____ (Signature of petitioner)

* * * * *

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

■ 31. 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, 886a, 958.

■ 32. Section 1309.03 is revised to read as follows:

§ 1309.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Registration Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

■ 33. Section 1309.32 is amended by revising paragraph (c) to read as follows:

§ 1309.32 Application forms; contents; signature.

* * * * *

(c) DEA Form 510 may be obtained at any divisional office of the Administration or by writing to the Registration Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. DEA Form 510a will be mailed to each List I chemical registrant approximately 60 days before the expiration date of his or her registration; if any registered person does not receive such forms within 45 days before the expiration date of the registration, notice must be promptly given of such fact and DEA Form 510a must be requested by writing to the Registration Section of the Administration at the foregoing address.

* * * * *

■ 34. Section 1309.33 is amended by revising paragraph (a) to read as follows:

§ 1309.33 Filing of application; joint filings.

(a) All applications for registration shall be submitted for filing to the Registration Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The appropriate registration fee and any required attachments must accompany the application.

* * * * *

■ 35. Section 1309.61 is revised to read as follows:

§ 1309.61 Modification in registration.

Any registrant may apply to modify his or her registration to authorize the handling of additional List I chemicals or to change his or her name or address, by submitting a letter of request to the Registration Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The letter shall contain the registrant's name, address, and registration number as printed on the certificate of registration, and the List I chemicals to be added to his registration or the new name or address and shall be signed in accordance with § 1309.32(g). 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 511) to the registrant, who shall maintain it with the old certificate of registration until expiration.

■ 36. Section 1309.71 is amended by revising paragraph (c) as follows:

§ 1309.71 General security requirements.

* * * * *

(c) Any registrant or applicant desiring to determine whether a proposed system of security controls and procedures is adequate may submit materials and plans regarding the proposed security controls and procedures either to the Special Agent in Charge in the region in which the security controls and procedures will be used, or to the Regulatory Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

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

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

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

■ 38. Section 1310.05 is amended by revising paragraphs (c), (d), (e)(1), and (e)(2) to read as follows:

§ 1310.05 Reports.

* * * * *

(c) Each regulated person who imports or exports a tableting machine, or encapsulation machine, shall file a report (not a 486) of such importation or exportation with the Import/Export Unit, Drug Enforcement Administration, on or before the date of importation or exportation. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. In order to facilitate the importation or exportation of any tableting machine or encapsulating machine and implement the purpose of the Act, regulated persons may wish to report to the Administration as far in advance as possible. A copy of the report may be transmitted directly to the Drug Enforcement Administration through electronic facsimile media. Any tableting machine or encapsulating machine may be imported or exported if that machine is needed for medical, commercial, scientific, or other legitimate uses. However, an importation or exportation of a tableting machine or encapsulating machine may not be completed with a person whose description or identifying characteristic has previously been furnished to the regulated person by the Administration unless the transaction is approved by the Administration.

(d) Each regulated bulk manufacturer of a listed chemical shall submit manufacturing, inventory and use data on an annual basis as set forth in § 1310.06(h). This data shall be submitted annually to the Drug and Chemical Evaluation Section, Drug Enforcement Administration, on or before the 15th day of March of the year immediately following the calendar year for which submitted. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A business entity which manufactures a listed chemical may elect to report separately by individual location or report as an aggregate amount for the entire business entity provided that they inform the DEA of which method they will use. This reporting requirement does not apply to drug or other products which are exempted under §§ 1300.02(b)(28)(i)(D) or 1300.02(b)(28)(i)(E) except as set forth in § 1310.06(h)(5). Bulk manufacturers that produce a listed chemical solely for internal consumption shall not be required to report for that listed chemical. For purposes of these reporting requirements, internal consumption shall consist of any quantity of a listed chemical otherwise not available for further resale or distribution. Internal consumption shall include (but not be limited to) quantities used for quality control testing, quantities consumed in-house or production losses. Internal consumption does not include the quantities of a listed chemical consumed in the production of exempted products. If an existing standard industry report contains the information required in § 1310.06(h) and such information is

separate or readily retrievable from the report, that report may be submitted in satisfaction of this requirement. Each report shall be submitted to the DEA under company letterhead and signed by an appropriate, responsible official. For purposes of this paragraph only, the term regulated bulk manufacturer of a listed chemical means a person who manufactures a listed chemical by means of chemical synthesis or by extraction from other substances. The term bulk manufacturer does not include persons whose sole activity consists of the repackaging or relabeling of listed chemical products or the manufacture of drug dosage form products which contain a listed chemical.

(e) * * *

(1) Submit a written report, containing the information set forth in § 1310.06(i) of this part, on or before the 15th day of each month following the month in which the distributions took place. The report shall be submitted under company letterhead, signed by the person authorized to sign the registration application forms on behalf of the registrant, to the Import/Export Unit, Drug Enforcement Administration (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address); or

(2) Upon request to and approval by the Administration, submit the report in electronic form, either via computer disk or direct electronic data transmission, in such form as the Administration shall direct. Requests to submit reports in electronic form should be submitted to the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 39. Section 1310.06 is amended by revising paragraphs (d), (g), and (h)(5) to read as follows:

§ 1310.06 Content of records and reports.

* * * * *

(d) A suggested format for the reports is provided below:

Supplier:
Registration Number _____
Name _____
Business Address _____
City _____
State _____
Zip _____
Business Phone _____
Purchaser:
Registration Number _____
Name _____
Business Address _____
City _____
State _____
Zip _____
Business Phone _____
Identification _____
Shipping Address (if different than purchaser Address):
Street _____
City _____
State _____
Zip _____
Date of Shipment _____
Name of Listed Chemical(s) _____
Quantity and Form of Packaging _____
Description of Machine:
Make _____
Model _____
Serial # _____
Method of Transfer _____
If Loss or Disappearance:
Date of Loss _____
Type of Loss _____
Description of Circumstances _____

* * * * *

(g) Declared exports of machines which are refused, rejected, or otherwise deemed undeliverable may be returned to the U.S. exporter of record. A brief written report outlining the circumstances must be sent to the Import/Export Unit, Drug Enforcement Administration, following the return within a reasonable time. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. This provision does not apply to shipments that have cleared foreign customs, been delivered, and accepted by the foreign consignee. Returns to third parties in the United States will be regarded as imports.

(h) * * *

(5) The aggregate quantity of each listed chemical manufactured which becomes a component of a product exempted from §§ 1300.02(b)(28)(i)(D) or 1300.02(b)(28)(i)(E) during the preceding calendar year.

* * * * *

■ 40. Section 1310.13 is amended by revising paragraph (b) to read as follows:

§ 1310.13 Exemption of chemical mixtures; application.

* * * * *

(b) Any manufacturer seeking an exemption for a chemical mixture, not exempt under § 1310.12, from the application of all or any part of the Act, may apply to the Office of Diversion Control, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 41. Section 1310.21 is amended by revising the introductory text of paragraph (b) to read as follows:

§ 1310.21 Sale by Federal departments or agencies of chemicals which could be used to manufacture controlled substances.

* * * * *

(b) A Federal department or agency must request certification by submitting a written request to the Administrator, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A request for certification may be transmitted directly to the Office of Diversion Control, Drug Enforcement Administration, through electronic facsimile media. A request for certification must be submitted no later than fifteen calendar days before the proposed sale is to take place. In order to facilitate the sale of chemicals from Federal departments' or agencies' stocks, Federal departments or agencies may wish to submit requests as far in advance of the fifteen calendar days as possible. The written notification of the proposed sale must include:

* * * * *

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

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

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

■ 43. Section 1312.12 is amended by revising paragraph (a) to read as follows:

§ 1312.12 Application for import permit.

(a) An application for a permit to import controlled substances shall be made on DEA Form 357. DEA Form 357 may be obtained from, and shall be filed with, the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Each application shall show the date of execution; the registration number of the importer; a detailed description of each controlled substance to be imported including the drug name, dosage form, National Drug Code (NDC) number, the Administration Controlled Substance Code Number as set forth in part 1308 of this chapter, the number and size of packages or containers, the name and quantity of the controlled substance contained in any finished dosage units, and the net quantity of any controlled substance (expressed in anhydrous acid, base or alkaloid) given in kilograms or parts

thereof. The application shall also include the following:

* * * * *

■ 44. Section 1312.16 is amended by revising paragraph (b) to read as follows:

§ 1312.16 Cancellation of permit; expiration date.

* * * * *

(b) An import permit shall not be valid after the date specified therein, and in no event shall the date be subsequent to 6 months after the date the permit is issued. Any unused import permit shall be returned for cancellation by the registrant to the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

■ 45. Section 1312.18 is amended by revising paragraph (b) to read as follows:

§ 1312.18 Contents of import declaration.

* * * * *

(b) Any person registered or authorized to import and desiring to import any non-narcotic controlled substance in Schedules III, IV, or V which is not subject to the requirement of an import permit as described in paragraph (a) of this section, must furnish a controlled substances import declaration on DEA Form 236 to the Import/Export Unit, Drug Enforcement Administration, not later than 15 calendar days prior to the proposed date of importation and distribute four copies of same as hereinafter directed in § 1312.19. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 46. Section 1312.19 is amended by revising paragraph (b) to read as follows:

§ 1312.19 Distribution of import declaration.

* * * * *

(b) Copy 4 shall be forwarded, within the time limit required in § 1312.18, directly to the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 47. Section 1312.22 is amended by revising paragraphs (a) and (d)(8) to read as follows:

§ 1312.22 Application for export permit.

(a) An application for a permit to export controlled substances shall be made on DEA Form 161, and an application for a permit to reexport controlled substances shall be made on DEA Form 161R. Forms may be obtained from, and shall be filed with, the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Each application shall show the exporter's name, address, and registration number; a detailed description of each controlled substance desired to be exported including the drug name, dosage form, National Drug Code (NDC) number (in accordance with Food and Drug Administration regulations), the Administration Controlled Substance Code Number as set forth in Part 1308 of this chapter, the number and size of packages or containers, the name and quantity of the controlled substance contained in any finished dosage units, and the quantity of any controlled substance (expressed in anhydrous acid, base, or alkaloid) given in kilograms or parts thereof. The application shall include the name, address, and business of the consignee, foreign port of entry, the port of exportation, the approximate date of exportation, the name of the exporting carrier or vessel (if known, or if unknown it should be stated whether shipment will be made by express, freight, or otherwise, exports of controlled substances by mail being prohibited), the date and number, if any, of the supporting foreign import license or permit accompanying the application, and the authority by whom such foreign license or permit was issued. The application shall also contain an affidavit that the packages are labeled in conformance with obligations of the United States under international treaties, conventions, or protocols in effect on May 1, 1971. The affidavit shall further state that to the best of affiant's knowledge and belief, the controlled substances therein are to be applied exclusively to medical or scientific uses within the country to which exported, will not be reexported therefrom and that there is an actual need for the controlled substance for medical or scientific uses within such country, unless the application is submitted for reexport in accordance with paragraphs (c) and (d) of this section. In the case of exportation of crude cocaine, the affidavit may state that to the best of affiant's knowledge and belief, the controlled substances will be processed within the country to which exported, either for medical or scientific use within that country or for reexportation in accordance with the laws of that country to another for medical or scientific use within that country. The application shall be signed and dated by the exporter and shall contain the address from which the substances will be shipped for exportation.

* * * * *

(d) * * *

(8) Shipments that have been exported from the United States and are refused by the consignee in either the first or second country, or are otherwise unacceptable or undeliverable, may be returned to the registered exporter in the United States upon authorization of the Administration. In these circumstances, the exporter in the United States shall file a written request for the return of the controlled substances to the United States with a brief summary of the facts that warrant the return, along with a completed DEA Form 357, Application for Import Permit, with the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The Administration will evaluate the request after considering all the facts as well as the exporter's registration status with the Administration. If the exporter provides sufficient documentation, the Administration will issue an import permit for the return of these drugs, and the exporter can then obtain an export permit from the country of original importation. The substance may be returned to the United States only after affirmative authorization is issued in writing by the Administration.

* * * * *

■ 48. Section 1312.24 is amended by revising paragraph (a) to read as follows:

§ 1312.24 Distribution of copies of export permit.

* * * * *

(a) The original, duplicate, and triplicate copies (Copy 1, Copy 2, and Copy 3) shall be transmitted by the Administration to the exporter who will retain the triplicate copy (Copy 3) as his record of authority for the exportation. The exporter shall present to the District Director of the U.S. Customs Service at the port of export and at the time of shipment, the original and duplicate copies (Copy 1 and Copy 2). After endorsing the port of export on the reverse side of the original and duplicate copies (Copy 1 and Copy 2) the District Director shall forward the endorsed original copy (Copy 1) with the shipment, and return the endorsed duplicate copy (Copy 2) to the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 49. Section 1312.27 is amended by revising paragraphs (a) and (b)(5)(iv) to read as follows:

§ 1312.27 Contents of special controlled substances invoice.

(a) A person registered or authorized to export any non-narcotic controlled substance listed in Schedule III, IV, or V, which is not subject to the requirement of an export permit pursuant to § 1312.23 (b) or (c), or any person registered or authorized to export any controlled substance in Schedule V, must furnish a special controlled substances export invoice on DEA Form 236 to the Import/Export Unit, Drug Enforcement Administration, not less than 15 calendar days prior to the proposed date of exportation, and distribute four copies of same as hereinafter directed in § 1312.28 of this part. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(b) * * *

(5) * * *

(iv) Shipments which have been exported from the United States and are refused by the consignee in the country of destination, or are otherwise unacceptable or undeliverable, may be returned to the registered exporter in the United States upon authorization of the Drug Enforcement Administration. In this circumstance, the exporter in the United States shall file a written request for reexport, along with a completed DEA Form 236, Import Declaration with the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A brief summary of the facts that warrant the return of the substance to the United States along with an authorization from the country of export will be included with the request. DEA will evaluate the request after considering all the facts as well as the exporter's registration status with DEA. The substance may be returned to the United States only after affirmative authorization is issued in writing by DEA.

* * * * *

■ 50. Section 1312.28 is amended by revising paragraph (d) to read as follows:

§ 1312.28 Distribution of special controlled substances invoice.

* * * * *

(d) Copy 4 shall be forwarded, within the time limit required in § 1312.27 of this part, directly to the Import/Export Unit, Drug Enforcement Administration. The documentation required by § 1312.27(b)(4) of this part must be attached to this copy. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 51. Section 1312.31 is amended by revising the introductory text of paragraph (b) to read as follows:

§ 1312.31 Schedule I: Application for prior written approval.

* * * * *

(b) An application for a transshipment permit must be submitted to the Import/Export Unit, Drug Enforcement Administration, at least 30 days, or in the case of an emergency as soon as practicable, prior to the expected date of importation, transfer or transshipment. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. Each application shall contain the following:

* * * * *

■ 52. Section 1312.32 is amended by revising paragraph (a) to read as follows:

§ 1312.32 Schedules II, III, IV: Advance notice.

(a) A controlled substance listed in Schedules II, III, or IV may be imported into the United States for transshipment, or may be transferred or transshipped within the United States for immediate exportation, provided that written notice is submitted to the Import/Export Unit, Drug Enforcement Administration, at least 15 days prior to the expected date of importation, transfer or transshipment. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

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

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

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

■ 54. Section 1313.12 is amended by revising paragraph (b) and the introductory text of paragraph (e) to read as follows:

§ 1313.12 Requirement of authorization to import.

* * * * *

(b) A completed DEA Form 486 must be received by the Import/Export Unit, Drug Enforcement Administration, not later than 15 days prior to the importation. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A copy of the completed DEA Form 486 may be transmitted directly to the Drug Enforcement Administration through electronic facsimile media not later than 15 days prior to the importation.

* * * * *

(e) For importations where advance notification is waived pursuant to paragraph (c)(2) of this section no DEA Form 486 is required; however, the regulated person shall submit quarterly reports to the Import/Export Unit, Drug Enforcement Administration, no later than the 15th day of the month following the end of each quarter. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The report shall contain the following information regarding each individual importation:

* * * * *

■ 55. Section 1313.21 is amended by revising paragraph (b) and the introductory text of paragraph (e) to read as follows:

§ 1313.21 Requirement of authorization to export.

* * * * *

(b) A completed DEA Form 486 must be received by the Import/Export Unit, Drug Enforcement Administration, not later than 15 days prior to the exportation. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A copy of the completed DEA Form 486 may be transmitted directly to the Drug Enforcement Administration through electronic facsimile media not later than 15 days prior to the exportation.

* * * * *

(e) For exportations where advance notification is waived pursuant to paragraph (c)(2) of this section, no DEA Form 486 is required; however, the regulated person shall file quarterly reports with the Import/Export Unit, Drug Enforcement Administration, no later than the 15th day of the month following the end of each quarter. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The report shall contain the following information regarding each individual exportation:

* * * * *

■ 56. Section 1313.22 is amended by revising paragraph (e) to read as follows:

§ 1313.22 Contents of export declaration.

* * * * *

(e) Declared exports of listed chemicals which are refused, rejected, or otherwise deemed undeliverable may be returned to the U.S. chemical exporter of record. A brief written notification (this does not require a DEA Form 486) outlining the circumstances

must be sent to the Import/Export Unit, Drug Enforcement Administration, following the return within a reasonable time. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. This provision does not apply to shipments that have cleared foreign customs, been delivered, and accepted by the foreign consignee. Returns to third parties in the United States will be regarded as imports.

■ 57. Section 1313.24 is amended by revising paragraph (e) to read as follows:

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

* * * * *

(e) The Administrator may notify any chemical exporter that a regular customer has been disqualified or that a new customer for whom a notification has been submitted is not to be accorded the status of a regular customer. In the event of a disqualification of an established regular customer, the chemical exporter will be notified in writing of the reasons for such action.

■ 58. Section 1313.31 is amended by revising the introductory text of paragraph (b) to read as follows:

§ 1313.31 Advance notice of importation for transshipment or transfer.

* * * * *

(b) Advance notification must be provided to the Import/Export Unit, Drug Enforcement Administration, not later than 15 days prior to the proposed date the listed chemical will transship or transfer through the United States. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The written notification (not a DEA Form 486) shall contain the following information:

* * * * *

■ 59. Section 1313.32 is amended by revising paragraph (b)(1) to read as follows:

§ 1313.32 Requirement of authorization for international transactions

* * * * *

(b)(1) A completed DEA Form 486 must be received by the Import/Export Unit, Drug Enforcement Administration, not later than 15 days prior to the international transaction. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

PART 1314—RETAIL SALE OF SCHEDULED LISTED CHEMICAL PRODUCTS

■ 60. The authority citation for part 1314 continues to read as follows:

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

■ 61. Section 1314.110 is amended by revising paragraphs (a)(1) and (a)(2) to read as follows:

§ 1314.110 Reports for mail-order sales.

(a) * * *

(1) Submit a written report, containing the information set forth in paragraph (b) of this section, on or before the 15th day of each month following the month in which the distributions took place. The report must be submitted under company letterhead, signed by the person authorized to sign on behalf of the regulated seller, to the Import/Export Unit, Drug Enforcement Administration (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address); or

(2) Upon request to and approval by the Administration, submit the report in electronic form, either via computer disk or direct electronic data transmission, in such form as the Administration shall direct. Requests to submit reports in electronic form should be submitted to the Import/Export Unit, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

PART 1315—IMPORTATION AND PRODUCTION QUOTAS FOR EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPANOLAMINE

■ 62. The authority citation for part 1315 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 826, 871(b), 952.

■ 63. Section 1315.22 is amended by revising the introductory text to read as follows:

§ 1315.22 Procedure for applying for individual manufacturing quotas.

Any person who is registered to manufacture ephedrine, pseudoephedrine, or phenylpropanolamine and who desires to manufacture a quantity of the chemical must apply on DEA Form 189 for a manufacturing quota for the quantity of the chemical. Copies of DEA Form 189 may be obtained from the Office of Diversion Control Web site, and must be filed (on or before April 1 of the year preceding the calendar year for which the manufacturing quota is being applied) with the Drug & Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A separate application must be made for each chemical desired to be manufactured. The applicant must state the following:

* * * * *

■ 64. Section 1315.32 is amended by revising paragraphs (e) and (g) to read as follows:

§ 1315.32 Obtaining a procurement quota.

* * * * *

(e) DEA Form 250 must be filed on or before April 1 of the year preceding the calendar year for which the procurement quota is being applied. Copies of DEA Form 250 may be obtained from the Office of Diversion Control Web site, and must be filed with the Drug & Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

(g) Any person to whom a procurement quota has been issued may at any time request an adjustment in the quota by applying to the Administrator with a statement showing the need for the adjustment. The application must be filed with the Drug & Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The Administrator shall increase or decrease the procurement quota of the person if and to the extent that he finds, after considering the factors enumerated in paragraph (f) of this section and any occurrences since the issuance of the procurement quota, that the need justifies an adjustment.

* * * * *

■ 65. Section 1315.34 is amended by revising paragraph (d) to read as follows:

§ 1315.34 Obtaining an import quota.

* * * * *

(d) DEA Form 488 must be filed on or before April 1 of the year preceding the calendar year for which the import quota is being applied. Copies of DEA Form 488 may be obtained from the Office of Diversion Control Web site, and must be filed with the Drug & Chemical Evaluation Section. See the Table of DEA Mailing Addresses in

§ 1321.01 of this chapter for the current mailing address.

* * * * *

■ 66. Section 1315.36 is amended by revising paragraph (b) to read as follows:

§ 1315.36 Amending an import quota.

* * * * *

(b) Any person to whom an import quota has been issued may at any time request an increase in the quota quantity by applying to the Administrator with a statement showing the need for the adjustment. The application must be filed with the Drug & Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The Administrator may increase the import quota of the person if and to the extent that he determines that the approval is necessary to provide for medical, scientific, or other legitimate purposes regarding the chemical. The Administrator shall specify a period of time for which the approval is in effect or shall provide that the approval is in effect until the Administrator notifies the applicant in writing that the approval is terminated.

* * * * *

PART 1316—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

■ 67. The authority citation for Subpart B of part 1316 continues to read as follows:

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

■ 68. Section 1316.23 is amended by revising the introductory text of paragraph (b) to read as follows:

§ 1316.23 Confidentiality of identity of research subjects.

* * * * *

(b) All petitions for Grants of Confidentiality shall be addressed to the Administrator, Drug Enforcement Administration (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address):

* * * * *

■ 69. Section 1316.24 is amended by revising the introductory text of paragraph (b) to read as follows:

§ 1316.24 Exemption from prosecution for researchers.

* * * * *

(b) All petitions for Grants of Exemption from Prosecution for the Researcher shall be addressed to the Administrator, Drug Enforcement Administration, (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address) and shall contain the following:

* * * * *

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

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

■ 71. Section 1316.45 is revised to read as follows:

§ 1316.45 Filings; address; hours.

Documents required or permitted to be filed in, and correspondence relating to, hearings governed by the regulations in this chapter shall be filed with the Hearing Clerk, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. This office is open Monday through Friday from 8:30 a.m. to 5 p.m. eastern standard or daylight saving time, whichever is effective in the District of Columbia at the time, except on national legal holidays. Documents shall be dated and deemed filed upon receipt by the Hearing Clerk.

■ 72. Section 1316.46 is amended by revising paragraph (a) to read as follows:

§ 1316.46 Inspection of record.

(a) The record bearing on any proceeding, except for material described in subsection (b) of this section, shall be available for inspection and copying by any person entitled to participate in such proceeding, during office hours in the office of the Hearing Clerk, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

* * * * *

■ 73. Section 1316.47 is amended by revising paragraph (a) to read as follows:

§ 1316.47 Request for hearing.

(a) Any person entitled to a hearing and desiring a hearing shall, within the period permitted for filing, file a request for a hearing in the following form (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address):

_____ (Date)

Administrator, Drug Enforcement Administration, Attention: DEA Federal Register Representative.

Dear Sir: The undersigned _____ (Name of person) hereby requests a hearing in the matter of: _____ (Identification of the proceeding).

(A) (State with particularity the interest of the person in the proceeding.)

(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.)

(C) (State briefly the position of the person with regard to the particular objections or issues.)

All notices to be sent pursuant to the proceeding should be addressed to:

_____ (Name)

_____ (Street address)

_____ (City and State)

Respectfully yours,

_____ (Signature of person)

* * * * *

■ 74. Section 1316.48 is revised to read as follows:

§ 1316.48 Notice of appearance.

Any person entitled to a hearing and desiring to appear in any hearing, shall, if he has not filed a request for hearing, file within the time specified in the notice of proposed rulemaking, a written notice of appearance in the following form (see the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address):

_____ (Date)

Administrator, Drug Enforcement Administration

_____ (Mailing Address), Attention: Federal Register Representative

Dear Sir: Please take notice that _____ (Name of person) will appear in the matter of: _____ (Identification of the proceeding).

(A) (State with particularity the interest of the person in the proceeding.)

(B) (State with particularity the objections or issues, if any, concerning which the person desires to be heard.)

(C) (State briefly the position of the person with regard to the particular objections or issues.)

All notices to be sent pursuant to this appearance should be addressed to:

_____ (Name)

_____ (Street address)

_____ (City and State)

Respectfully yours,

_____ (Signature of person)

■ 75. Part 1321 is added to 21 CFR Chapter II to read as follows:

PART 1321—DEA MAILING ADDRESSES

Sec.

1321.01 DEA mailing addresses.

Authority: 21 U.S.C. 871(b).

§ 1321.01 DEA mailing addresses.

The following table provides information regarding mailing addresses to be used when sending specified correspondence to the Drug Enforcement Administration.

TABLE OF DEA MAILING ADDRESSES

Code of Federal Regulations Section—Topic	DEA Mailing address
DEA Administrator	
1308.43(b)—Petition to initiate proceedings for rulemaking 316.23(b)—Petition for grant of confidentiality for research subjects. 1316.24(b)—Petition for exemption from prosecution for researchers. 1316.48—Notice of appearance.	Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, VA 22152.
DEA Office of Diversion Control	
1301.52(c)—Controlled substances registration return for cancellation 1307.03—Exception request filing. 1307.22—Disposal of controlled substances by the Administration delivery application. 1308.21(a)—Exclusion of nonnarcotic substance. 1308.23(b)—Exemption for chemical preparations. 1308.25(a)—Exclusion of veterinary anabolic steroid implant product application. 1308.31(a)—Exemption of a nonnarcotic prescription product application. 1308.33(b)—Exemption of certain anabolic steroid products application. 1310.13(b)—Exemption for chemical preparations. 1310.21(b)—Sale by Federal departments or agencies of chemicals which could be used to manufacture controlled substances certification request.	Drug Enforcement Administration, Attn: Office of Diversion Control/OD, 8701 Morrissette Drive, Springfield, VA 22152.
DEA Regulatory Section	
1301.71(d)—Security system compliance review for controlled substances 1309.71(c)—Security system compliance review for List I chemicals.	Drug Enforcement Administration, Attn: Regulatory Section/ODG, 8701 Morrissette Drive, Springfield, VA 22152
DEA Import/Export Unit	
1310.05(c)—Importer/exporter of tableting or encapsulation machines reporting 1310.05(e)(1)—Reporting by persons required to keep records and file reports regarding List I chemicals. 1310.05(e)(2)—Request to submit List I chemicals reports in electronic form. 1310.06(g)—Report of declared exports of machines refused, rejected, or returned. 1312.12(a)—Application for import permit (DEA Form 357). 1312.16(b)—Return unused import permits. 1312.18(b)—Import declaration (DEA Form 236) submission. 1312.19(b)—DEA Form 236 copy 4 filing. 1312.22(a)—Application for export permit (DEA Form 161). 1312.22(d)(8)—Request for return of unacceptable or undeliverable exported controlled substances. 1312.24(a)—DEA Form 161 copy 2 filing. 1312.27(a)—Special controlled substances export invoice (DEA Form 236) filing. 1312.27(b)(5)(iv)—Request for reexport. 1312.28(d)—Distribution of special controlled substances invoice (DEA Form 236) copy 4. 1312.31(b)—Controlled substances transshipment permit application. 1312.32(a)—Advanced notice of importation for transshipment or transfer of controlled substances. 1313.12(b)—Authorization to import listed chemicals (DEA Form 486). 1313.12(e)—Quarterly reports of listed chemicals importation. 1313.21(b)—Authorization to export listed chemicals (DEA Form 486). 1313.21(e)—Quarterly reports of listed chemicals exportation. 1313.22(e)—Written notice of declared exports of listed chemicals refused, rejected or undeliverable. 1313.31(b)—Advanced notice of importation for transshipment or transfer of listed chemicals. 1313.32(b)(1)—International transaction authorization (DEA Form 486). 1314.110(a)(1)—Reports for mail-order sales. 1314.110(a)(2)—Request to submit mail-order sales reports in electronic form.	Drug Enforcement Administration, Attn: Import/Export Unit/ODGI, 8701 Morrissette Drive, Springfield, VA 22152.
DEA Drug & Chemical Evaluation Section	
1303.12(b)—Application for controlled substances procurement quota (DEA Form 250) filing and request. 1303.12(d)—Controlled substances quota adjustment request. 1303.22—Application for individual manufacturing quota (DEA Form 189) filing and request for schedule I or II controlled substances. 1304.31(a)—Manufacturers importing narcotic raw material report submission. 1304.32(a)—Manufacturers importing coca leaves report submission.	Drug Enforcement Administration, Attn: Drug & Chemical Evaluation Section/ODE, 8701 Morrissette Drive, Springfield, VA 22152.

TABLE OF DEA MAILING ADDRESSES—Continued

Code of Federal Regulations Section—Topic	DEA Mailing address
1308.24(d)—Exempt narcotic chemical preparations importer/exporter reporting. 1308.24(i)—Exempted chemical preparations listing. 1308.26(a)—Excluded veterinary anabolic steroid implant products listing. 1308.32—Exempted prescription products listing. 1308.34—Exempted anabolic steroid products listing. 1310.05(d)—Bulk manufacturer of listed chemicals reporting. 1315.22—Application for individual manufacturing quota for ephedrine, pseudoephedrine, phenylpropanolamine (DEA Form 189) filing and request. 1315.32(e)—Application for procurement quota for ephedrine, pseudoephedrine, phenylpropanolamine (DEA Form 250) filing and request. 1315.32(g)—Procurement quota adjustment request for ephedrine, pseudoephedrine, phenylpropanolamine. 1315.34(d)—Application for import quota for ephedrine, pseudoephedrine, phenylpropanolamine (DEA Form 488) request and filing. 1315.36(b)—Request import quota increase for ephedrine, pseudoephedrine, or phenylpropanolamine.	
DEA ARCOS Unit	
1304.04(d)—ARCOS separate central reporting identifier request 1304.33(a)—Reports to ARCOS.	Drug Enforcement Administration, Attn: ARCOS Unit/ODPT, P.O. Box 2520, Springfield, VA 22152–2520, OR Drug Enforcement Administration, Attn: ARCOS Unit, 8701 Morrissette Drive, Springfield, VA 22152.
DEA Registration Section	
1301.03—Procedures information request (controlled substances registration) 1301.13(e)(2)—Request DEA Forms 224, 225, and 363. 1301.14(a)—Controlled substances registration application submission. 1301.18(c)—Research project controlled substance increase request. 1301.51—Controlled substances registration modification request. 1301.52(b)—Controlled substances registration transfer request. 1309.03—List I chemicals registration procedures information request. 1309.32(c)—Request DEA Form 510. 1309.33(a)—List I chemicals registration application submission. 1309.61—List I chemicals registration modification request.	Drug Enforcement Administration, Attn: Registration Section/ODR P.O. Box 2639, Springfield, VA 22152–2639.
DEA Hearing Clerk	
1316.45—Hearings documentation filing 1316.46(a)—Inspection of record.	Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, VA 22152.
DEA Federal Register Representative	
1316.47(a)—Request for hearing	Drug Enforcement Administration, Attn: Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152.

Dated: February 25, 2010.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010–4714 Filed 3–8–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2008–1017]

RIN 1625–AA11

Regulated Navigation Areas; Bars Along the Coasts of Oregon and Washington; Correction

AGENCY: Coast Guard, DHS.

ACTION: Correcting amendment.

SUMMARY: The Coast Guard published a document in the **Federal Register** on November 17, 2009, adding a section and establishing regulated navigation areas for bars along the coasts of Oregon and Washington. That document inadvertently failed to include an option for mariners to use VHF–FM Channel 16 for notifying the Coast Guard, and also contained typographical errors improperly describing VHF–FM Channel 16 and a position of latitude. This document corrects the final regulations.

DATES: Effective March 9, 2010.

FOR FURTHER INFORMATION CONTACT: If you have questions about this