

phone number). You may also submit comments through the Internet at <http://www.regulations.gov>.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2010-0028 and Airspace Docket No. 10-AWP-1." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

#### Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at <http://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at [http://www.faa.gov/air\\_traffic/publications/airspace\\_amendments/](http://www.faa.gov/air_traffic/publications/airspace_amendments/).

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Western Service Center, Operations Support Group, Federal Aviation Administration, 1601 Lind Avenue, SW., Renton, WA 98055.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267-9677, for a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

#### The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to replace the DOBNE waypoint with the KENNO waypoint to provide additional lateral separation from the boundary of R-2508 and Q-15. The FAA has determined that this segment of Q-15 does not provide adequate separation from R-2508. The

operational benefits of this change will positively impact the day-to-day traffic flow on Q-15 within the NAS.

Area Navigation Routes are published in paragraph 2006 of FAA Order 7400.9T, dated August 27, 2009 and effective September 15, 2009, which is incorporated by reference in 14 CFR 71.1. The Area Navigation Route listed in this document would be subsequently published in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies an RNAV route in California.

#### Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures," prior to any FAA final regulatory action.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration

proposes to amend 14 CFR part 71 as follows:

#### **PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS**

1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

#### **§ 71.1 [Amended]**

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9T, Airspace Designations and Reporting Points, dated August 27, 2009 and effective September 15, 2009, is amended as follows:

*Paragraph 2006 Area Navigation Routes*  
\* \* \* \* \*

#### **Q-15 LOMIA to CHILY**

LOMIA WP  
(Lat. 39°13'12" N., long. 119°06'23" W.)  
RUSME WP  
(Lat. 37°29'39" N., long. 117°31'12" W.)  
KENNO WP  
(Lat. 37°17'53" N., long. 117°18'37" W.)  
BIKKR WP  
(Lat. 36°34'00" N., long. 116°45'00" W.)  
DOVEE Fix  
(Lat. 35°26'51" N., long. 114°48'01" W.)  
CHILY Fix  
(Lat. 34°42'49" N., long. 112°45'42" W.)

Issued in Washington, DC, February 17, 2010.

**Paul Gallant,**

*Acting Manager, Airspace and Rules Group.*

[FR Doc. 2010-3747 Filed 2-23-10; 8:45 am]

**BILLING CODE 4910-13-P**

#### **DEPARTMENT OF JUSTICE**

#### **Drug Enforcement Administration**

#### **21 CFR Part 1310**

[Docket No. DEA-320P]

**RIN 1117-AB24**

#### **Control of Ergocristine, a Chemical Precursor Used in the Illicit Manufacture of Lysergic Acid Diethylamide, as a List I Chemical**

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

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration (DEA) is proposing to control the chemical precursor ergocristine as a List I chemical under the Controlled Substances Act (CSA). Clandestine laboratories are using this

chemical as a substitute for the List I chemicals ergotamine and ergonovine to illicitly manufacture the schedule I controlled substance lysergic acid diethylamide (LSD).

If finalized as proposed, handlers of ergocristine would be subject to the chemical regulatory provisions of the CSA and its implementing regulations, including 21 CFR parts 1309, 1310, 1313, and 1316. This rulemaking does not propose the establishment of a threshold for domestic and international transactions of ergocristine. As such, all transactions involving ergocristine, regardless of size, would be regulated. This rulemaking also proposes to specify that chemical mixtures containing ergocristine will not be exempt from regulatory requirements at any concentration. Therefore, all transactions of chemical mixtures containing any quantity of ergocristine would be regulated and subject to control under the CSA if this rule is finalized as proposed.

**DATES:** Written comments must be postmarked and electronic comments must be submitted on or before April 26, 2010. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

**ADDRESSES:** To ensure proper handling of comments, please reference "Docket No. DEA-320P" on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152. Comments may be sent to DEA by sending an electronic message to [dea.diversion@usdoj.gov](mailto:dea.diversion@usdoj.gov). Comments may also be sent electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document is also available at the <http://www.regulations.gov> Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern Time on the day the comment period closes because <http://www.regulations.gov> terminates the public's ability to submit comments at midnight Eastern time on the day the comment period closes. Commenters in

time zones other than Eastern Time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

**FOR FURTHER INFORMATION CONTACT:**

Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152; telephone: (202) 307-7183.

**SUPPLEMENTARY INFORMATION:**

*Posting of Public Comments:* Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by

appointment, please see the "For Further Information" paragraph.

**Background**

Lysergic acid diethylamide (LSD) is a synthetic schedule I hallucinogen. It is the most potent hallucinogen known and only microgram amounts are required to produce overt hallucinations. LSD has been abused for its hallucinogenic properties since the 1960s. It induces a heightened awareness of sensory input that is accompanied by an enhanced sense of clarity, but reduced ability to control what is experienced. The LSD "trip" is composed of perceptual and psychic effects. A user may experience the following perceptual effects: Visual distortion in the size and shape of objects, movements, color, sound, touch, and the user's own body image. The user may report "hearing colors" or "seeing sounds." The psychic effects experienced by the user may include feelings of obtaining true insight, intensified emotions, sudden and dramatic mood swings, impairment of attention, concentration and motivation, distortion of time, and depersonalization.

High doses of LSD can induce a "bad trip" characterized by intense anxiety or panic, confusion, and combative behaviors. After a LSD trip, a user may also experience fatigue, acute anxiety, or depression for 12 to 24 hours. LSD is commonly abused by teenagers and young adults in connection with "raves," nightclubs, and concert settings.

LSD is most commonly found in the form of small squares of paper, called blotter, that are generally decorated with artwork or designs, perforated, soaked in liquid LSD solution, and dried. Each square represents one dose of LSD. There have been some instances of blotter paper being found impregnated with hallucinogens other than LSD. For example, the hallucinogens 2,5-dimethoxyamphetamine (DMA) and 4-bromo-2,5-dimethoxyamphetamine (DOB) have been found on blotter paper passed off as LSD.

Other forms of LSD include tablets (known as microdots), gelatin squares (known as window pane), and impregnated sugar cubes. LSD has also been available in gel wraps which look like "bubble-wrap" packing material, and are blue in color. LSD is also distributed in liquid form which often is packaged in small bottles typically sold as breath drops. Additionally, LSD has been embedded in candy such as "Gummy Worms," "Sweet Tarts," "Smarties," and "Pez." The most common venues for retail LSD

distribution are “raves,” dance clubs, and concerts.

According to the National Forensic Laboratory Information System (NFLIS), Federal, State, and local forensic laboratories analyzed 1,785 and 1,368 exhibits of LSD in 2000 and 2001, respectively. In 2002, the number of LSD exhibits dropped dramatically to 198 due to the seizure of a large clandestine LSD laboratory in Kansas. The number of LSD samples analyzed by Federal, State, and local forensic laboratories remained low for 2003 and 2004 with 362 and 338 LSD exhibits, respectively. However, there appears to be a slight increasing trend seen in 2005, 2006 and 2007, with 521, 590, and 844 exhibits reported, respectively. This trend appears to carry over into 2008 since NFLIS data, entered as of December 29, 2008 already documents 839 LSD exhibits.

#### **Control Status**

Lysergic acid diethylamide is in schedule I of the CSA (21 U.S.C. 812). LSD precursors, lysergic acid and lysergic acid amide, are both schedule III controlled substances (21 U.S.C. 812(b)). The LSD precursors ergotamine and ergonovine are regulated as List I chemicals under the CSA.

#### **Illicit Production of LSD**

LSD has been manufactured illegally since the 1960s. A limited number of chemists, probably less than a dozen, are believed to be manufacturing nearly all of the LSD available in the United States. Clandestine laboratory operators must adhere to precise and complex production procedures, and production of LSD is relatively difficult.

LSD has historically been produced from lysergic acid, which is made from ergotamine or ergonovine, substances derived from an ergot fungus on rye, or from lysergic acid amide, a chemical found in morning glory seeds. Although theoretically possible, manufacture of LSD from morning glory seeds is not economically feasible and these seeds never have been found to be a successful starting material for LSD production. The List I chemicals ergotamine and ergonovine are not widely available in the United States, and their purchase by other than established pharmaceutical firms is suspect. Therefore, ergotamine and/or ergonovine used in clandestine LSD laboratories are believed to have been acquired from sources located abroad. Only a small amount of ergotamine or ergonovine is required to produce LSD in large batches. For example, 25 kilograms of ergotamine tartrate can produce five or six kilograms of pure

LSD crystal that, under ideal circumstances, could be processed into 100 million dosage units. Thus, clandestine LSD manufacturers need import only a small quantity of precursor material.

#### **Movement to Ergocristine as LSD Precursor and Largest LSD Laboratory Ever Seized by DEA**

Because of the existing CSA regulatory controls on the LSD precursors lysergic acid, lysergic acid amide, ergotamine, and ergonovine, clandestine laboratory operators have sought uncontrolled sources of precursor material for the production of LSD. This has led to the illicit utilization of the precursor chemical ergocristine as a direct substitute for ergotamine and ergonovine for the illicit production of LSD. In fact, the largest clandestine LSD laboratory ever seized by DEA utilized ergocristine as the LSD precursor. Recipes documenting procedures for utilizing ergocristine in LSD synthesis are easily found on the Internet.

In late 2000, in the largest clandestine LSD laboratory seizure ever made by the DEA, agents seized approximately 41.3 kilograms (90.86 pounds) of LSD, manufactured in a clandestine laboratory set up in a missile silo near Wamego, Kansas. On November 6, 2000, two clandestine laboratory operators were moving the illegal laboratory when they were arrested. The clandestine laboratory operators utilized the chemical ergocristine as the unregulated source of precursor material for the production of the LSD. A total of 19 kilograms of ergocristine was seized. According to court testimony, the two defendants previously clandestinely manufactured LSD in Santa Fe, New Mexico, where every five weeks the clandestine laboratory produced about 2.2 pounds of LSD, approximately 10 million doses that cost less than one cent a dose to produce and would sell for as much as \$10 a dose. According to court testimony, the LSD was shipped to California and later to Europe for distribution.

The El Paso Intelligence Center's National Seizure System data show that five clandestine LSD laboratories have been seized since 2001. According to law enforcement reporting, the seized laboratories were operated by a small number of experienced chemists and were of limited capacity: three of which produced less than two ounces, and two of which produced between two and eight ounces per batch.

#### **Availability of the Precursor Chemical**

DEA has determined that ergocristine is readily available from commercial chemical suppliers. DEA has identified at least three suppliers of ergocristine, of which one distributor is located domestically; the other two are based in Germany and the Czech Republic. The ergocristine used by the clandestine laboratory operator arrested in conjunction with the November 2000, clandestine LSD laboratory in Wamego, Kansas, was obtained through a chemical supplier in Germany who obtained the ergocristine from a chemical source firm operating out of the Czech Republic.

In the 2005 International Narcotics Control Board (INCB) report titled “Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances,” the INCB reported that in response to Czech authorities expression of concern over orders for ergocristine, INCB scrutiny over such shipments led to the one kilogram seizure of ergocristine by Panamanian authorities in early 2005. The INCB further reported that following the seizure, a further order was received from the Netherlands Antilles. The shipment of ergocristine was followed and a clandestine LSD laboratory identified. In that report, the INCB urged governments to exercise vigilance in regard to shipments of ergot alkaloids (such as ergocristine) and related substitutes not under international control.

This rule proposes the addition of both domestic and import/export controls on ergocristine (and its salts). Such controls are deemed necessary for law enforcement to identify domestic and international transactions in ergocristine, due to growing concerns regarding its use for the illicit manufacture of LSD.

#### **Regulation of Ergocristine as a List I Chemical**

The CSA, specifically 21 U.S.C. 802(34) and 21 U.S.C. 802(35), and its implementing regulations at 21 CFR 1310.02(c), provide the Attorney General with the authority to specify, by regulation, additional chemicals as “listed chemicals” if they are used in the manufacture of a controlled substance in violation of the CSA, and are important to the manufacture of the controlled substance. Ergocristine is being used in clandestine laboratories as the precursor material for the illicit manufacture of the schedule I controlled substance LSD. This rule proposes the regulation of ergocristine as a List I

chemical because DEA finds that it is used in the illicit manufacture of the controlled substance LSD and is important to the illicit manufacture of the controlled substance LSD.

If finalized as proposed, handlers of ergocristine will become subject to the chemical regulatory provisions of the CSA, including 21 CFR parts 1309, 1310, 1313, and 1316. This rulemaking does not propose the establishment of a threshold for domestic and import transactions of ergocristine pursuant to the provisions of 21 CFR 1310.04(g). Due to the high potency of LSD, even a single gram (*i.e.*, 1/28th of an ounce) of ergocristine can be used illicitly to make thousands of dosage units of LSD. Therefore, DEA is proposing that all ergocristine transactions, regardless of size, shall be regulated transactions as defined in 21 CFR 1300.02(b)(28). As such, if finalized as proposed, all ergocristine transactions will be subject to recordkeeping, annual manufacturer reporting of inventory and use data, import/export controls, and other CSA chemical regulatory requirements.

#### **Chemical Mixtures Containing Ergocristine**

This rulemaking also proposes that chemical mixtures containing ergocristine not be exempt from regulatory requirements at any concentration, unless an application for exemption of a chemical mixture is submitted by an ergocristine manufacturer and the application is reviewed and accepted by DEA under 21 CFR 1310.13 (Exemption by Application Process). Since even a small amount of ergocristine is able to make a significant amount of LSD, the control of chemical mixtures containing any amount of ergocristine is necessary to prevent the illicit extraction, isolation, and use of the ergocristine. Therefore, all chemical mixtures containing any quantity of ergocristine will be subject to CSA control, if this rule is finalized as proposed, unless the ergocristine manufacturer is granted an exemption by the application process discussed below. If finalized, this proposed rule will modify the Table of Concentration Limits in 21 CFR 1310.12(c) to reflect the fact that chemical mixtures containing any amount of ergocristine are subject to CSA chemical control provisions.

#### **Exemption by Application Process**

DEA has implemented an application process to exempt chemical mixtures from the requirements of the CSA and its implementing regulations (21 CFR 1310.13). Under the application process, manufacturers may submit an

application for exemption for those mixtures that do not qualify for automatic exemption. Exemption status can be granted if DEA determines that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical cannot be readily recovered (*i.e.*, it meets the conditions in 21 U.S.C. 802(39)(A)(vi)).

#### **Requirements for Handling List I Chemicals**

If finalized as proposed, the designation of ergocristine as a List I chemical will subject ergocristine handlers to all of the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importing, and exporting of a List I chemical. Upon publication of a final rule, persons potentially handling ergocristine, including regulated chemical mixtures containing ergocristine, will be required to comply with the following List I chemical regulations:

*Registration.* Any person who manufactures, distributes, imports, or exports a List I chemical, or proposes to engage in the manufacture, distribution, importation, or exportation of a List I chemical, must obtain a registration pursuant to the CSA (21 U.S.C. 822, 957). Regulations describing registration for List I chemical handlers are set forth in 21 CFR part 1309. Consistent with 21 CFR parts 1309 and 1310, separate registrations will be required for manufacturing, distribution, importing, and exporting of ergocristine. Different locations operated by a single entity require separate registration if any location is involved with the manufacture, distribution, importation, or exportation of ergocristine. Further, a separate registration is required for each principal place of business at one general physical location where List I chemicals are manufactured, distributed, imported, or exported by a person (21 CFR 1309.23). Any person manufacturing, distributing, importing, or exporting an ergocristine chemical mixture will be subject to the registration requirement under the CSA as well.

DEA notes that warehouses are exempt from the requirement of registration and may lawfully possess List I chemicals, if the possession of those chemicals is in the usual course of business (21 U.S.C. 822(c)(2), 21 U.S.C. 957(b)(1)(B)). For purposes of this exemption, the warehouse must receive the List I chemical from a DEA registrant and shall only distribute the List I chemical back to the DEA registrant and registered location from

which it was received. All other activities conducted by a warehouse do not fall under this exemption; a warehouse that distributes List I chemicals to persons other than the registrant and registered location from which they were obtained is conducting distribution activities and is required to register as such (21 CFR 1309.23(b)(1)).

Upon publication of a final rule, any person manufacturing, distributing, importing, or exporting ergocristine or a chemical mixture containing ergocristine will become subject to the registration requirement under the CSA. DEA recognizes, however, that it is not possible for persons who are subject to the registration requirement to immediately complete and submit an application for registration and for DEA to immediately issue registrations for those activities. Therefore, to allow continued legitimate commerce in ergocristine, DEA is proposing to establish in 21 CFR 1310.09 a temporary exemption from the registration requirement for persons desiring to engage in activities with ergocristine, provided that DEA receives a properly completed application for registration on or before 30 days after publication of a Final Rule implementing regulations regarding ergocristine. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration or application for exemption of a chemical mixture.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, would become effective on the effective date of the Final Rule. Therefore, all transactions of ergocristine and chemical mixtures containing ergocristine will be regulated while an application for registration or exemption is pending. This is necessary because not regulating these transactions could result in increased diversion of chemicals desirable to drug traffickers.

Additionally, the temporary exemption does not suspend applicable federal criminal laws relating to ergocristine, nor does it supersede State or local laws or regulations. All handlers of ergocristine must comply with applicable State and local requirements in addition to the CSA regulatory controls.

*Records and Reports.* The CSA (21 U.S.C. 830) requires that certain records be kept and reports be made with respect to listed chemicals. Regulations describing recordkeeping and reporting requirements are set forth in 21 CFR part 1310. Pursuant to 21 CFR 1310.04, a record must be made and maintained

for two years after the date of a transaction involving a listed chemical, provided the transaction is a regulated transaction.

Each regulated bulk manufacturer of a listed chemical will be required to submit manufacturing, inventory, and use data on an annual basis (21 CFR 1310.05(d)). Existing standard industry reports containing the required information will be acceptable, provided the information is readily retrievable from the report.

Title 21 CFR 1310.05(a) requires that each regulated person shall report to DEA any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the CSA and its corresponding regulations. Persons are also required to report any proposed regulated transaction with a person whose description or other identifying characteristics the Administration has previously furnished to the regulated person; any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person; any in-transit loss in which the regulated person is the supplier; and any domestic regulated transaction in a tableting or encapsulating machine.

**Import/Export.** All imports, exports, and international transactions of a listed chemical shall comply with the CSA import and export provisions including 21 U.S.C. 957 and 971. Regulations for importation and exportation of List I chemicals are described in 21 CFR part 1313.

**Security.** All applicants and registrants shall provide effective controls against theft and diversion of chemicals as described in 21 CFR 1309.71.

**Administrative Inspection.** Places, including factories, warehouses, or other establishments and conveyances, where registrants or other regulated persons may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of a regulated chemical/chemical mixture or where records relating to those activities are kept or required to be kept, are controlled premises as defined in 21 CFR 1316.02(c). The CSA (21 U.S.C. 880) allows for administrative inspections of these controlled premises as provided in 21 CFR 1316 Subpart A.

### Regulatory Certifications

#### *Regulatory Flexibility Act and Small Business Concerns*

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612). DEA has been able to identify only one U.S. distributor that lists ergocristine among its products. Because most of the firm's product source appears to be located outside the U.S. and because DEA has not been able to identify any U.S. manufacturer that produces a product containing ergocristine, DEA does not consider it likely that this domestic distributor would be subject to the rule, unless they imported ergocristine. The only probable legitimate commerce in this chemical appears to be the use of ergocristine as precursor material for the synthesis of a research compound. If used for this purpose, then there would be a registration and recordkeeping requirement for this distributor to import the ergocristine. Such use would likely be extremely limited. Therefore, the Deputy Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities.

#### *Executive Order 12866*

The Deputy Administrator certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). It has been determined that this is "a significant regulatory action." Therefore, this action has been reviewed by the Office of Management and Budget. DEA has not conducted an economic analysis of the proposed rule because DEA has been able to identify only one company with a U.S. address that lists ergocristine among its products. DEA was able to identify only two foreign firms that list ergocristine as a product. These firms appear to sell ergocristine as an active pharmaceutical ingredient, but a search of the Food and Drug Administration's database of approved drugs did not identify any drug with ergocristine as an active ingredient. Consequently, DEA does not believe that at this time any firm conducting legitimate business is likely to have to comply with the rule.

#### *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 Congressional Review Act/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 cost 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 in 21 CFR Part 1310

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

For the reasons set out above, 21 CFR part 1310 is proposed to be amended as follows:

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

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

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

2. Section 1310.02 is amended by adding a new paragraph (a)(30) to read as follows:

#### § 1310.02 Substances covered.

\* \* \* \* \*

(a) \* \* \*

(30) Ergocristine and its salts 8612

\* \* \* \* \*

3. Section 1310.04 is amended by redesignating paragraphs (g)(1)(ii) through (g)(1)(vii) as paragraphs (g)(1)(iii) through (g)(1)(viii), and adding

a new paragraph (g)(1)(ii) to read as follows:

**§ 1310.04 Maintenance of records.**

- \* \* \* \* \*
- (g) \* \* \*
- (1) \* \* \*
- (ii) Ergocristine and its salts
- \* \* \* \* \*

4. Section 1310.09 is amended by adding new paragraph (k) to read as follows:

**§ 1310.09 Temporary exemption from registration.**

(k)(1) Each person required under Sections 302 and 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated ergocristine and its salts, including regulated chemical mixtures pursuant to Section 1310.12 of this part, is temporarily exempted from

the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing ergocristine and its salts pursuant to Section 1310.13 of this part on or before (30 days after publication of a Final Rule implementing regulations regarding ergocristine). The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports or exports a chemical mixture containing ergocristine and its salts whose application for exemption is

subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications for exemption are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

5. Section 1310.12(c) is amended by adding in alphabetical order an entry "Ergocristine and its salts" in the table "Table of Concentration Limits" to read as follows:

**§ 1310.12 Exempt chemical mixtures.**

- \* \* \* \* \*
- (c) \* \* \*

TABLE OF CONCENTRATION LIMITS

	DEA chemical code number	Concentration	Special conditions
List I Chemicals			
Ergocristine and its salts .....	8612	Not exempt at any concentration.	Chemical mixtures containing any amount of ergocristine and its salts are not exempt.

\* \* \* \* \*

Dated: February 12, 2010.  
**Michele M. Leonhart,**  
*Deputy Administrator.*  
 [FR Doc. 2010-3701 Filed 2-23-10; 8:45 am]  
**BILLING CODE 4410-09-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA-R03-OAR-2010-0009; FRL-9115-8]

**Approval and Promulgation of Air Quality Implementation Plans; Virginia; Opacity Source Surveillance Methods**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the Commonwealth of Virginia for the purpose of updating methods for determining compliance with opacity

standards for existing, new and modified stationary sources in Virginia. In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

**DATES:** Comments must be received in writing by March 26, 2010.

**ADDRESSES:** Submit your comments, identified by Docket ID Number EPA-R03-OAR-2010-0009 by one of the following methods:

A. <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

B. *E-mail:* [fernandez.cristina@epa.gov](mailto:fernandez.cristina@epa.gov).

C. *Mail:* EPA-R03-OAR-2010-0009, Cristina Fernandez, Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. EPA-R03-OAR-2010-0009. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information