

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 7. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1081 [Amended]

■ 8. In paragraph (b)(2) of § 522.1081, remove “Nos. 058639 and 063323” and in its place add “No. 058639”.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 9. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.520 [Removed]

■ 10. Remove § 524.520.

§ 524.1580c [Amended]

■ 11. In paragraph (b) of § 524.1580c, remove “Nos. 000010, 000069, and 050749” and in its place add “Nos. 000010 and 000069”.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: 21 U.S.C. 360b, 371.

§ 558.485 [Amended]

■ 13. In § 558.485, in paragraph (b)(3), remove “010439”.

§ 558.625 [Amended]

■ 14. In § 558.625, remove and reserve paragraphs (b)(42) and (b)(45).

§ 558.630 [Amended]

■ 15. In § 558.630, remove and reserve paragraph (b)(4); and in paragraph (b)(5), remove “010439,” and “016968,”.

Dated: March 25, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Part 1310**

[Docket No. DEA-320F]

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: Final rule.

SUMMARY: This rulemaking finalizes a February 24, 2010, Notice of Proposed Rulemaking in which DEA proposed 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).

This rule is being finalized as proposed. Therefore, handlers of ergocristine shall be subject to the chemical regulatory provisions of the CSA and its implementing regulations. This rulemaking does not establish a threshold for domestic and international transactions of ergocristine. As such, all transactions involving ergocristine, regardless of size, shall be regulated. This rulemaking also specifies 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 shall be regulated and subject to control under the CSA.

DATES: This rulemaking becomes effective May 2, 2011. Persons seeking registration must apply on or before May 2, 2011 to continue their business pending final action by DEA on their application.

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:**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. 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.

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.

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.

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.

This rule implements both domestic and import/export controls on ergocristine (and its salts). As noted in the February 24, 2010, Notice of Proposed Rulemaking (75 FR 8287), 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 its implementing regulations at 21 CFR 1310.02(c), provide the Attorney General with the authority to specify, by regulation, additional chemicals as List I 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 implements 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.

Handlers of ergocristine shall be subject to the chemical regulatory provisions of the CSA, including 21 CFR parts 1309, 1310, 1313, and 1316. This rulemaking does not establish 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, all ergocristine transactions, regardless of size, shall be regulated transactions as defined in 21 CFR 1300.02(b)(28). As such, 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.

Comments

DEA did not receive any comments in response to the February 24, 2010, Notice of Proposed Rulemaking (NPRM), which proposed the control of ergocristine. Therefore, this rule finalizes the NPRM, as proposed.

As such, effective May 2, 2011, handlers of ergocristine shall be subject to the chemical regulatory provisions of the CSA and its implementing regulations, including 21 CFR parts 1309, 1310, 1313, and 1316.

Chemical Mixtures Containing Ergocristine

Chemical mixtures containing ergocristine will 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 be used in the illicit manufacture of 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, unless the ergocristine manufacturer is granted an exemption by the application process discussed below. The Table of Concentration Limits in 21 CFR 1310.12(c) is hereby modified 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

The designation of ergocristine as a List I chemical subjects 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. 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)).

Any person manufacturing, distributing, importing, or exporting ergocristine or a chemical mixture containing ergocristine will be 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 establishing 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 May 2, 2011. 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 May 2, 2011. 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 part 1316, Subpart A.

Regulatory Certifications

Regulatory Flexibility Act and Small Business Concerns

The 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 Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12866

The 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 final 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 \$126,400,000 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 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

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■ 3. Section 1310.04 is amended by redesignating paragraphs (g)(1)(ii) through (g)(1)(ix) as paragraphs (g)(1)(iii) through (g)(1)(x), and adding a new paragraph (g)(1)(ii) to read as follows:

§ 1310.04 Maintenance of records.

* * * * *

(g) * * *

(1) * * *

(iii) Ergocristine and its salts

* * * * *

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

§ 1310.09 Temporary exemption from registration.

* * * * *

(l)(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 § 1310.12, 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 § 1310.13 on or before May 2, 2011. 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 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 No.	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: March 21, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011-7548 Filed 3-30-11; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9515]

RIN 1545-BH20

Guidance Under Section 1502; Amendment of Matching Rule for Certain Gains on Member Stock; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document describes correcting amends to final and temporary regulations concerning the treatment of certain intercompany gain with respect to stock owned by members of a consolidated group. These regulations provide for the redetermination of intercompany gain as excluded from gross income in certain transactions involving stock transfers between members of a consolidated group. These errors were made when the agency published final and temporary regulations (TD 9515) in the **Federal Register** on Friday, March 4, 2011 (76 FR 11956).

DATES: This correction is effective on March 31, 2011, and is applicable on March 4, 2011.

FOR FURTHER INFORMATION CONTACT: John F. Tarrant, (202) 622-7790 or Lawrence

M. Axelrod, (202) 622-7713 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations (TD 9515) that are the subject of this document are under section 1502 of the Internal Revenue Code.

Need for Correction

As published, the final and temporary regulations (TD 9515) contain errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments: