

will no longer meet or medically equal the criteria of a listing in this body system.

3. * * * If you have a recurrence or relapse of your malignancy, your impairment may meet or medically equal one of the listings in this body system again.

* * * * *

I. What do we mean by the following terms?

1. Metastases: The spread of tumor cells by blood, lymph, or other body fluid. This term does not include the spread of tumor cells by direct extension of the tumor to other tissue or organs.

2. Multimodal therapy: A combination of at least two types of treatment modalities given in close proximity as a unified whole and usually planned before any treatment has begun. There are three types of treatment modalities: Surgery, radiation, and systemic drug therapy (chemotherapy, hormonal therapy, and immunotherapy). Examples of multimodal therapy include:

- a. Surgery followed by chemotherapy or radiation.
b. Chemotherapy followed by surgery.
c. Chemotherapy and concurrent radiation.

3. Persistent: Failure to achieve a complete remission.

4. Progressive: The malignancy becomes more extensive despite treatment.

5. Recurrent, relapse: A malignancy that was in complete remission or entirely removed by surgery has returned.

* * * * *

K. How do we evaluate specific malignant neoplastic diseases?

1. Lymphoma.

a. We provide criteria for evaluating aggressive lymphomas that have not responded to antineoplastic therapy in 113.05. Indolent (non-aggressive) lymphomas are rare in children. We will evaluate indolent lymphomas in children under 13.05 in part A.

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2. Leukemia.

a. Acute leukemia. * * * Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination, or by testicular biopsy. * * *

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4. Brain tumors. We use the criteria in 113.13 to evaluate malignant brain tumors. We consider a brain tumor to be malignant if it is classified as grade II or higher under the World Health Organization (WHO) classification of tumors of the central nervous system (WHO Classification of Tumours of the Central Nervous System, 2007). We evaluate any complications of malignant brain tumors, such as resultant neurological or psychological impairments, under the criteria for the affected body system. We evaluate benign brain tumors under 111.05.

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113.09 Thyroid gland.

B. * * *

OR

C. Medullary carcinoma with metastases beyond the regional lymph nodes.

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113.13 Brain tumors. (See 113.00K4.) Highly malignant tumors, such as

medulloblastoma or other primitive neuroectodermal tumors (PNETs) with documented metastases, grades III and IV astrocytomas, glioblastoma multiforme, ependymoblastoma, diffuse intrinsic brain stem gliomas, or primary sarcomas.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-327F]

Schedules of Controlled Substances; Placement of Fospropofol Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance fospropofol, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule IV of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of schedule IV will be applicable to the manufacture, distribution, dispensing, importation, and exportation of fospropofol and products containing fospropofol.

DATES: Effective Date: November 5, 2009.

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, Virginia 22152, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION:

Background

On December 12, 2008, the Food and Drug Administration (FDA) approved fospropofol for marketing under the trade name Lusedra® in the United States as a drug product indicated for monitored anesthesia care (MAC) sedation in adult patients undergoing diagnostic or therapeutic procedures.

Fospropofol, 2,6-diisopropoylphenoxymethyl phosphate disodium, is a water soluble, phosphono-O-methyl prodrug of propofol. It is metabolized in the body to propofol, the active metabolite.

Propofol has been available for medical use in the United States since 1989 and is not currently a controlled substance. The pharmacological effects of fospropofol are attributed to the pharmacological actions of propofol. Propofol binds to gamma-aminobutyric acid (GABA_A) receptor and acts as a modulator by potentiating the activity of GABA at this receptor.

Since propofol is the active metabolite of fospropofol, the abuse potential of fospropofol is comparable to that of propofol. Animal self-administration studies demonstrated that the reinforcing effects of propofol are relatively low and comparable to midazolam and other schedule IV benzodiazepines. Fospropofol elicits behavioral effects similar to methohexital and midazolam, schedule IV sedative-hypnotics.

Since fospropofol is a new molecular entity, there has been no evidence of diversion, abuse, or law enforcement encounters involving the drug.

On February 27, 2009, the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a scientific and medical evaluation and a letter recommending that fospropofol be placed into schedule IV of the CSA. Enclosed with the February 27, 2009, letter was a document prepared by the FDA entitled, "Basis for the Recommendation for Control of Fospropofol and Its Salts in Schedule IV of the Controlled Substances Act (CSA)." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from DHHS, the Deputy Administrator of the DEA published a Notice of Proposed Rulemaking entitled "Schedules of Controlled Substances: Placement of Fospropofol into Schedule IV" on July 23, 2009 (74 FR 36424), which proposed placement of fospropofol into schedule IV of the CSA. The proposed rule provided an opportunity for all interested persons to submit their written comments on or before August 24, 2009.

Comments Received

The DEA received two comments in response to the Notice of Proposed Rulemaking. One comment received from a concerned citizen did not relate to fospropofol, the substance that is being controlled. Thus DEA did not consider this comment.

Another comment received from a professional organization of anesthesiologists is in agreement with the findings of scientific and medical evaluation that formed the basis for the present rule controlling fospropofol as a schedule IV substance and it fully supported this control action.

Scheduling of Fospropofol

Based on the recommendation of the Acting Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, the Deputy Administrator of DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Fospropofol has a low potential for abuse relative to the drugs or substances in schedule III. Although there is no direct comparison to a schedule III substance, this finding is based on the demonstration of the abuse potential of propofol, the active metabolite, relative to the schedule IV substances, methohexital and midazolam;

(2) Fospropofol has a currently accepted medical use in treatment in the United States; and

(3) Abuse of fospropofol may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III. This finding is based on the symptoms exhibited upon withdrawal from propofol.

Based on these findings, the Deputy Administrator of DEA concludes that fospropofol, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible warrants control in schedule IV of the CSA. (21 U.S.C. 812(b)(4))

Requirements for Handling Fospropofol

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with fospropofol, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with fospropofol, must be registered to conduct such activities in accordance with part 1301 of Title 21 of the Code of Federal Regulations. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before November 5, 2009 and may continue their activities until DEA has approved or denied that application.

Security. Fospropofol is subject to schedules III–V security requirements

and must be manufactured, distributed, and stored in accordance with §§ 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77 of Title 21 of the Code of Federal Regulations on or after November 5, 2009.

Labeling and Packaging. All labels and labeling for commercial containers of fospropofol must comply with requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations on or after November 5, 2009.

Inventory. Every registrant required to keep records and who possesses any quantity of fospropofol must keep an inventory of all stocks of fospropofol on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations on or after November 5, 2009. Every registrant who desires registration in schedule IV for fospropofol must conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants must keep records pursuant to §§ 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations on or after November 5, 2009.

Prescriptions. All prescriptions for fospropofol or prescriptions for products containing fospropofol must be issued pursuant to §§ 1306.03–1306.06 and 1306.21, 1306.22–1306.27 of Title 21 of the Code of Federal Regulations on or after November 5, 2009.

Importation and Exportation. All importation and exportation of fospropofol must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations on or after November 5, 2009.

Criminal Liability. Any activity with fospropofol not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act shall be unlawful on or after November 5, 2009.

Regulatory Certifications

Executive Order 12866

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking “on the record after opportunity for a hearing.” Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, section 3(d)(1).

Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has

reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Fospropofol products will be used for monitored anesthesia care (MAC) sedation in adult patients undergoing diagnostic or therapeutic procedures. Handlers of fospropofol also handle other controlled substances used for sedation which are already subject to the regulatory requirements of the CSA.

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 provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by § 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 in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

■ Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to 28

CFR 0.104, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

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

■ 2. Section 1308.14 is amended in paragraph (c), by redesignating paragraphs (c)(23) through (c)(51) as paragraphs (c)(24) through (c)(52) and adding a new paragraph (c)(23) as follows:

§ 1308.14 Schedule IV.

* * * * *
(c) * * *

(23) Fospropofol 2138
* * * * *

Dated: September 28, 2009.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. E9-23971 Filed 10-5-09; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Part 41

[Public Notice: 6779]

Visas: Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended; Requirements for Aliens in Religious Occupations

AGENCY: State Department.

ACTION: Final rule.

SUMMARY: To comply with the Department of Homeland Security regulation requiring sponsoring employers to file petitions for all aliens for whom R-1 nonimmigrant status is sought. This rule establishes the requirement that consular officers ensure that R-1 visa applicants have obtained an approved U.S. Citizenship and Immigration Services Form I-129 petition from the Department of Homeland Security before issuance of a visa.

DATES: This rule is effective October 6, 2009.

FOR FURTHER INFORMATION CONTACT: Lauren A. Prosnik, Legislation and Regulations Division, Visa Services, Department of State, 2401 E Street, NW., Room L-603D, Washington, DC 20520-0106, (202) 663-2951.

SUPPLEMENTARY INFORMATION:

Why is the Department promulgating this rule?

On November 26, 2008, the Department of Homeland Security (DHS) promulgated regulations requiring sponsoring employers to file petitions for all aliens for whom R-1 nonimmigrant status is sought. 73 FR 72276. As a result, the requirements for an R-1 nonimmigrant visa now include establishing that the applicant is the beneficiary of an approved petition. U.S. Citizenship and Immigration Services (USCIS) has implemented the petition requirement for nonimmigrant religious workers as a way to determine the bona fides of a petitioning religious organization located in the United States and to determine that a religious worker will be admitted to the United States to work for a specific religious organization at the request of that religious organization. This rule amends the Department regulations to ensure consistency with the regulations set forth by DHS.

Regulatory Findings

Administrative Procedure Act

This regulation involves a foreign affairs function of the United States and, therefore, in accordance with 5 U.S.C. 553(a)(1), is not subject to the rule making procedures set forth at 5 U.S.C. 553.

Regulatory Flexibility Act/Executive Order 13272: Small Business

Because this final rule is exempt from notice and comment rulemaking under 5 U.S.C. 553, it is exempt from the regulatory flexibility analysis requirements set forth at sections 603 and 604 of the Regulatory Flexibility Act (5 U.S.C. 603 and 604). Nonetheless, consistent with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Department certifies that this rule will not have a significant economic impact on a substantial number of small entities. This regulates individual aliens who seek consideration for R-1 nonimmigrant visas and does not affect any small entities, as defined in 5 U.S.C. 601(6).

The Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 (UFMA), Public Law 104-4, 109 Stat. 48, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of \$100 million or more by State, local, or tribal governments, or by the private sector. This rule will not result in any such expenditure, nor will

it significantly or uniquely affect small governments.

The Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking under the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104-121. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign based companies in domestic and import markets.

Executive Order 12866

The Department of State has reviewed this proposed rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866 and has determined that the benefits of this final regulation justify its costs. The Department does not consider this final rule to be an economically significant action within the scope of section 3(f)(1) of the Executive Order since it is not likely to have an annual effect on the economy of \$100 million or more or to adversely affect in a material way the economy, a sector of the economy, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities.

Executive Orders 12372 and 13132: Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Nor will the rule have federalism implications warranting the application of Executive Orders No. 12372 and No. 13132.

Executive Order 12988: Civil Justice Reform

The Department has reviewed the regulations in light of sections 3(a) and 3(b)(2) of Executive Order No. 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Paperwork Reduction Act

This rule does not impose information collection requirements under the provisions of the Paperwork Reduction Act, 44 U.S.C., Chapter 35.