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List of Subjects

21 CFR Parts 878 and 880

Medical devices.

21 CFR Part 895

Administrative practice and procedure, Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 878, 880, and 895 be amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Amend § 878.4460 by revising the heading and paragraph (a) to read as follows:

§ 878.4460 Non-powdered surgeon's glove.

(a) *Identification.* A non-powdered surgeon's glove is a device made of natural rubber latex or synthetic latex, intended to be worn by operating room personnel to protect a surgical wound from contamination. A non-powdered surgeon's glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

* * * * *

§ 878.4480 [Removed]

■ 3. Remove § 878.4480.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 4. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 5. Amend § 880.6250 by revising the heading and paragraph (a) to read as follows:

§ 880.6250 Non-powdered patient examination glove.

(a) *Identification.* A non-powdered patient examination glove is a disposable device made of either natural rubber latex or synthetic latex, intended for medical purposes, that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A non-powdered patient examination glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

* * * * *

PART 895—BANNED DEVICES

■ 6. The authority citation for 21 CFR part 895 continues to read as follows:

Authority: 21 U.S.C. 352, 360f, 360h, 360i, 371.

■ 7. Add § 895.102 to subpart B to read as follows:

§ 895.102 Powdered surgeon's glove.

A powdered surgeon's glove is a device made of natural rubber latex or synthetic latex, intended to be worn by operating room personnel to protect a surgical wound from contamination. A powdered surgeon's glove incorporates powder for purposes other than manufacturing.

■ 8. Add § 895.103 to subpart B to read as follows:

§ 895.103 Powdered patient examination glove.

A powdered patient examination glove is a disposable device made of natural rubber latex or synthetic latex, intended for medical purposes, that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A powdered patient examination glove incorporates powder for purposes other than manufacturing.

■ 9. Add § 895.104 to subpart B to read as follows:

§ 895.104 Absorbable powder for lubricating a surgeon's glove.

Absorbable powder for lubricating a surgeon's glove is a powder made from cornstarch that meets the specifications for absorbable powder in the United States Pharmacopeia (U.S.P.) and that is intended to be used to lubricate the surgeon's hand before putting on a surgeon's glove. The device is absorbable through biological degradation.

Dated: March 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–06360 Filed 3–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–417C]

Schedules of Controlled Substances: Placement of UR–144, XLR11, and AKB48 Into Schedule I; Correction

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: The Drug Enforcement Administration published a document in the **Federal Register** of May 14, 2015, concerning the proposal to place (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11), and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48) including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule I of the Controlled Substances Act (CSA), specifically under cannabimimetic agents. This corrected notice of proposed rulemaking proposes to place such substances into schedule I of the CSA under hallucinogenic substances.

DATES: Interested persons may file written comments on this correction to the initial proposal in accordance with 21 CFR 1308.43(g). The DEA is requesting comments on this change only and is not soliciting comments on other aspects of the May 14, 2015, notice of proposed rulemaking published at 80 FR 27611. Electronic comments must be submitted, and written comments must be postmarked, on or before April 21, 2016. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–417C'' on all correspondence, including any attachments. The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Barbara J. Boockholdt, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. 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 made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available 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 made publicly available, 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.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Legal Authority

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, and are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for the purposes of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, each controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308. 21 U.S.C. 812(a).

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, ''add to such a schedule or transfer between such schedules any drug or other substance if he * * * finds that such drug or other substance has a potential for abuse, and * * * makes with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of this title for the schedule in which such drug is to be placed * * *.'' The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General (1) on her own motion; (2) at the request of the Secretary of the Department of Health

and Human Services (HHS),[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action (80 FR 27611, May 14, 2015) is supported by a recommendation from the Assistant Secretary of the HHS and an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions of schedule I controlled substances on any person who handles, or proposes to handle, UR-144, XLR11, or AKB48.

Background

UR-144, XLR11, and AKB48 are currently subject to schedule I controls on a temporary basis, pursuant to 21 U.S.C. 811(h). 80 FR 27854, May 15, 2015. On May 14, 2015, the Administrator of the DEA published a notice of proposed rulemaking (NPRM) to permanently schedule (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11), and *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48) into schedule I pursuant to the CSA. 80 FR 27611.

In the NPRM, the DEA inadvertently proposed the addition of these substances in schedule I under 21 CFR 1308.11(g), cannabimimetic agents, by adding paragraphs (g)(16) through (18). These substances should have been proposed to be added in schedule I under 21 CFR 1308.11(d), hallucinogenic substances. This rulemaking therefore corrects the NPRM by proposing the placement of these substances in 21 CFR 1308.11(d) by adding paragraphs (d)(48) through (50). Because the DEA is proposing to classify these substances as schedule I hallucinogenic substances, then by operation of 21 U.S.C. 802(14), this classification will include any optical, positional, or geometric isomers. Interested persons may file written comments on this change in accordance with 21 CFR 1308.43(g). The DEA is requesting comments on this change only and is not soliciting comments on other aspects of the May 14, 2015, NPRM. The DEA previously had provided an opportunity for comments on other aspects of the NPRM on May 14, 2015, through June 15, 2015.

Regulatory Analyses

This correction has no effect on the regulatory analyses statements that were published with the notice of proposed rulemaking published in the **Federal Register** on May 14, 2015, at 80 FR 27611.

Correction

In proposed rule FR Doc. 2015–11762, beginning on page 27611 in the issue of May 14, 2015, make the following corrections.

■ 1. On page 27616 in the 3rd column, correct amendatory instruction 2.a. to read as follows: ''Adding paragraphs (d)(65) through (67); and''.

■ 2. On page 27616 in the 3rd column, correct § 1308.11 Schedule I regulatory text to read as follows:

§ 1308.11 Schedule I.

* * * * *

(d) * * *

(65) (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144)	(7144)
(66) [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl) methanone (5-fluoro-UR-144, XLR11)	(7011)
(67) *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48)	(7048)

* * * * *

Dated: March 16, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–06474 Filed 3–21–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

30 CFR Part 583

RIN 1010–AD90

[Docket ID: BOEM–2010–0041]

Negotiated Noncompetitive Leasing for the Use of Sand, Gravel, and Shell Resources on the Outer Continental Shelf

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Proposed rule.

SUMMARY: This rule proposes regulations to address the use of Outer Continental Shelf (OCS) sand, gravel and shell resources for shore protection, beach restoration, or coastal wetlands restoration projects by Federal, State, or local government agencies, or use in construction projects authorized by or funded in whole or in part by the Federal Government. The proposed rule describes the negotiated noncompetitive agreement process for qualifying projects and codifies new and existing procedures.

DATES: Submit comments by May 23, 2016. The Bureau of Ocean Energy Management (BOEM) may not fully consider comments received after this date. Submit comments to the Office of Management and Budget (OMB) on the information collection (IC) burden in this proposed rule by April 21, 2016. This does not affect the deadline for the public to comment to BOEM on the proposed regulation.

ADDRESSES: You may submit comments on the rulemaking by any of the following methods. Please use the Regulation Identifier Number (RIN) 1010–AD90 as an identifier in your comment. Please reference ''Outer Continental Shelf Marine Sand, Gravel and Shell Resources, 1010–AD90'' in your comments and include your name and return address.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Under the tab ''More Search Options,'' click ''Advanced Docket Search,'' then select ''Bureau of Ocean Energy Management'' from the agency drop-down menu, then click the submit button. In the Docket ID column, select BOEM–2010–0041 to submit public comments and to view supporting and related materials available for this rulemaking. Information on using *Regulations.gov,* including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's ''User Tips'' link. BOEM will post comments on *www.regulations.gov.*
- Mail or hand-carry comments to the U.S. Department of the Interior; Bureau of Ocean Energy Management; Attn: Office of Policy, Regulation and Analysis, 45600 Woodland Road, VAM–BOEM DIR, Sterling, Virginia 20166.
- Send comments on the IC in this proposed rule to: Interior Desk Officer 1010–AD90, Office of Management and Budget; 202–395–5806 (fax); email:

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.