

## I. Background

FDA is announcing the availability of a draft revised GFI #120 entitled “Veterinary Feed Directive Regulation Questions and Answers.” The audience for this draft guidance is comprised of veterinarians issuing VFD orders, feed mills manufacturing VFD feeds and other distributors, animal producers who obtain VFD feeds for use in treating their animals, and others. This draft revised guidance reflects changes to the VFD requirements under the VFD final rule published elsewhere in this edition of the **Federal Register**.

In 1996, Congress enacted the Animal Drug Availability Act (ADAA) to facilitate the approval and marketing of new animal drugs and medicated feeds. In passing the ADAA, Congress created a new regulatory category for certain animal drugs used in animal feed called veterinary feed directive (VFD) drugs. VFD drugs are new animal drugs intended for use in or on animal feed which are limited to use under the professional supervision of a licensed veterinarian. FDA published final regulations implementing the VFD-related provisions of the ADAA in 2000.

Elsewhere in this edition of the **Federal Register**, FDA is publishing a VFD final rule that revises those VFD regulations and introduces clarifying changes to specified definitions. This draft revised guidance includes revisions that are consistent with the requirements in that final rule.

## II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on this topic. It does not establish any rights for or on any person and does not bind on FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 558.6 have been approved under OMB control number 0910–0363.

## IV. Comments

Interested persons may submit either electronic comments regarding this

document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: May 28, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1308

[Docket No. DEA–415]

#### Schedules of Controlled Substances: Removal of [123]ioflupane From Schedule II of the Controlled Substances Act

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Drug Enforcement Administration proposes to remove [123]ioflupane from the schedules of the Controlled Substances Act. This action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after an opportunity for a hearing through formal rulemaking. [123]ioflupane is, by definition, a schedule II controlled substance because it is derived from cocaine via ecgonine, both of which are schedule II controlled substances. This action would remove the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, conduct research, import, export, or conduct chemical analysis) or propose to handle [123]ioflupane.

**DATES:** Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before July 6, 2015. 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.

Interested persons, defined at 21 CFR 1300.01 as those “adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)”, may file a request for hearing or waiver of participation pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45, 1316.47, 1316.48, or 1316.49, as applicable. Requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before July 6, 2015.

**ADDRESSES:** To ensure proper handling of comments, please reference “Docket No. DEA–415” on all correspondence, including any attachments.

- *Electronic comments:* The DEA encourages that all comments be submitted 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:* Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a comment *in lieu of* submitting a comment online, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODXL, 8701 Morrisette Drive, Springfield, Virginia 22152.

- *Hearing requests:* All requests for hearing must be sent to: DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, Virginia 22152.

**FOR FURTHER INFORMATION CONTACT:** John R. Scherbenske, Office of Diversion

Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

**SUPPLEMENTARY INFORMATION:**

**Posting of Public Comments**

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the 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 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 online submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at <http://www.regulations.gov> for easy reference.

**Request for Hearing, Notice of Appearance at or Waiver of Participation in Hearing**

Pursuant to 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 the Administrative Procedure Act (APA) (5 U.S.C. 551-559). 21 CFR 1308.41-1308.45, and 21 CFR part 1316 subpart D. In accordance with 21 CFR 1308.44 (a)-(c), requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)." 21 CFR 1300.01. Such requests or notices must conform to the requirements of 21 CFR 1308.44 (a) or (b), and 1316.47 or 1316.48, as applicable, and include a statement of the interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and 1316.49, including a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

**Legal Authority**

The Drug Enforcement Administration (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, but they are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purposes of this action. 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 ensuring an adequate supply is available 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 drug or other 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.

Pursuant to 21 U.S.C. 811(a)(2), the Attorney General may, by rule, "remove any drug or other substance from the schedules if he [or she] finds that the drug or other substance does not meet the requirements for inclusion in any schedule." 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 his or her own motion, (2) at the request of the Secretary of the Department of Health and Human Services,<sup>1</sup> or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action was initiated at the request of the Assistant Secretary for Health of the HHS, and is supported by an evaluation of all relevant data by the HHS and the DEA. This action would remove the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle or propose to handle [<sup>123</sup>I]ioflupane.

**Background**

DaTscan is a single-dose, injectable diagnostic radiopharmaceutical for use in hospital settings with specialized gamma cameras. It was developed as a diagnostic tool for visualization of dopamine transporters (DAT) by using single photon emission computed tomography (SPECT) brain imaging. The Food and Drug Administration (FDA) approved the New Drug Application (NDA) for DaTscan on January 14, 2011, for the indication of visualizing striatal DATs in the brains of adult patients with suspected Parkinsonian syndromes (PS). [<sup>123</sup>I]ioflupane is the active pharmaceutical ingredient (API) in DaTscan and it is a new molecular entity. However, [<sup>123</sup>I]ioflupane is, by definition, a schedule II controlled substance because it is derived from cocaine, a schedule II substance, via ecgonine (a schedule II substance). See 21 U.S.C. 812(c), Schedule II, (a)(4).

<sup>1</sup> 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.

Each vial of DaTscan contains 0.325 micrograms ( $\mu\text{g}$ ) of [ $^{123}\text{I}$ ]ioflupane per 2.5 milliliters (ml). The average and maximum amounts of non-radioactive ioflupane in each DaTscan vial are estimated to be between 0.21  $\mu\text{g}$  and 0.31  $\mu\text{g}$ . Although ioflupane, the non-radiolabeled API of the drug product DaTscan, binds to DAT and elicits behavioral effects similar to that of cocaine, based upon the available information and DaTscan's unique formulation-specific properties, DaTscan itself presents no practical possibility of abuse, misuse, diversion or clandestine production.

### Proposed Determination To Decontrol [ $^{123}\text{I}$ ]ioflupane

Pursuant to 21 U.S.C. 811(b), (c), and (f), the HHS recommended to the DEA on November 2, 2010, that FDA-approved products containing [ $^{123}\text{I}$ ]ioflupane be removed from schedule II of the CSA. HHS provided to DEA a scientific and medical evaluation document entitled "Basis for the Recommendation to Remove FDA Approved Products Containing [ $^{123}\text{I}$ ]ioflupane from Schedule II of the Controlled Substances Act (CSA)." Pursuant to 21 U.S.C. 811(b), this document contained an eight-factor analysis of FDA-approved products containing [ $^{123}\text{I}$ ]ioflupane, along with the HHS's recommendation to remove FDA-approved products containing [ $^{123}\text{I}$ ]ioflupane from the schedules of the CSA.

In response, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS, and all other relevant data. The DEA and HHS collaborated further regarding the available information. By letter dated February 2, 2015, the HHS provided detailed responses to specific inquiries from the DEA (submitted by letter dated September 16, 2014). Upon further review of all of the available information, the DEA completed its own eight-factor review document on FDA-approved diagnostic products containing [ $^{123}\text{I}$ ]ioflupane (currently, only DaTscan) pursuant to 21 U.S.C. 811(c). The FDA-approved diagnostic product, DaTscan, was used as the basis for the scientific and medical evaluation of FDA-approved diagnostic products containing [ $^{123}\text{I}$ ]ioflupane for both the HHS and DEA eight-factor analysis. Included below is a brief summary of each factor as analyzed by the HHS and the DEA, and as considered by the DEA in this proposed rule to remove [ $^{123}\text{I}$ ]ioflupane from the schedules of the CSA. Please note that both the DEA and HHS analyses and other relevant documents are available in their entirety

under "Supporting and Related Material" of the public docket for this rule at <http://www.regulations.gov> under docket number DEA-415.

#### 1. The Drug's Actual or Relative Potential for Abuse

According to HHS and the DEA, there are no data demonstrating that individuals are administering quantities of DaTscan sufficient to create a hazard to their health or to the safety of other individuals or to the community. In clinical studies, DaTscan, due to its low concentrations of [ $^{123}\text{I}$ ]ioflupane lacked, central nervous activity (CNS) in humans.

According to HHS review of Sponsor's calculation regarding psychoactive doses of DaTscan, approximately 6,000 vials of DaTscan would be required to produce a subjective "high" in humans from exposure to [ $^{123}\text{I}$ ]ioflupane in this product. The volume of 6,000 vials is about 15 liters (L) of fluid, an amount that would be lethal if administered intravenously (i.v.). The short half-life of DaTscan (due to its radioactive decay) will prevent its extended storage for future use at the manufacturing, distributing, or radiopharmacy site; thereby limiting the amount available for diversion. It is highly unlikely that individuals will administer DaTscan on their own initiative since DaTscan has a very dilute and small dose of [ $^{123}\text{I}$ ]ioflupane, and possesses radioactivity. As a result, DaTscan will not have significant capability of creating hazards to the health of the user or to the safety of the community.

#### 2. Scientific Evidence of the Drug's Pharmacological Effects, If Known

DaTscan blocks monoamine transporters, such as DAT and other monoamine transporters such as serotonin transporters. Ioflupane, the active pharmaceutical ingredient in DaTscan, was demonstrated to have an affinity to DAT that was approximately 10- and 100-fold greater than cocaine in rodent brain homogenates or in cells transfected with rat DAT (Neumeyer et al., 1996; Okada et al., 1998; Scheffel et al., 1997). As reported by HHS, non-radiolabeled ioflupane at doses  $>0.1$  mg/kg, i.v. was able to substitute for cocaine in cocaine-trained rats (10 mg/kg, intraperitoneal administration) using a drug discrimination protocol which is predictive of subjective behavioral effects in humans.

HHS reviewed data from eight human clinical trials involving 942 subjects and nine years of post-approval use in Europe and found that there was not any clinical evidence of

pharmacological effects resulting from DaTscan administration. The maximum dose of [ $^{123}\text{I}$ ]ioflupane in DaTscan that is administered to the patient prior to undergoing an imaging procedure is 0.325  $\mu\text{g}$  (0.13  $\mu\text{g}/\text{ml}$ ). HHS extrapolated from the locomotor study and drug discrimination study on non-radiolabeled ioflupane and estimated that the lowest active dose of DaTscan for a 60 kg (132.2 lb) human to achieve a pharmacologic effect would be 288  $\mu\text{g}$  or 886 vials of DaTscan. In addition, the recreational dose of DaTscan is estimated as 1921  $\mu\text{g}$  or 5,910 vials.

Although [ $^{123}\text{I}$ ]ioflupane would be expected to have a pharmacological profile nearly identical to its non-radioactive form, its unique properties (i.e., manufacturing limits and radioactive properties) pose practical barriers to its abuse. Furthermore, according to HHS, the amount of [ $^{123}\text{I}$ ]ioflupane in DaTscan is significantly less than the amounts of ioflupane used to elicit the pharmacological response in preclinical studies with this compound.

#### 3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

The international non-proprietary name of [ $^{123}\text{I}$ ]ioflupane is methyl(1R, 2S, 3S, 5S)-8-(3-fluoropropyl)-3-(4-[ $^{123}\text{I}$ ]iodophenyl)-8-azabicyclo[3,2,1]octane-2-carboxylate. The molecular formula of [ $^{123}\text{I}$ ]ioflupane is  $\text{C}_{18}\text{H}_{23}\text{F}^{123}\text{I}\text{NO}_2$  and the molecular weight is 427.28 g/mol. [ $^{123}\text{I}$ ]ioflupane is a clear, colorless solution and is only present in a solution of ethanol and sodium acetate buffer. Non-radioactive ioflupane is a white solid with a melting point of 83 °C to 87 °C and soluble in water (less than 0.1 mg/ml), sodium acetate buffer (pH 7.4; 16 mg/ml), and ethanol (27 mg/ml).

HHS states that meaningful extraction of [ $^{123}\text{I}$ ]ioflupane from DaTscan would be impossible due to its limited production and availability and because extraction is technically complex and would require advanced equipment not available to the general public. Importantly, if extraction of ioflupane from [ $^{123}\text{I}$ ]ioflupane is accomplished, the ioflupane would be subject to schedule II controls under the CSA. According to HHS, the retrosynthesis of DaTscan to cocaine and ecgonine would be difficult. Production of DaTscan is technically complex as it requires specialized equipment, facilities, scientific training and expertise, making clandestine manufacturing particularly difficult. HHS indicated that the non-radiolabeled precursors needed for the synthesis of [ $^{123}\text{I}$ ]ioflupane (and

DaTscan) are abusable. In addition, the non-radiolabeled precursors derived from cocaine or ecgonine are also schedule II controlled substances. However, even if an individual obtained the precursors, it is impractical and highly unlikely that they would synthesize the abusable compound into a radiolabeled formulation with a limited storage life that is not desired by drug users.

On January 14, 2011, FDA approved the NDA for DaTscan with the indication of visualizing striatal dopamine transporters in the brains of adult patients with suspected Parkinsonian syndromes using SPECT imaging. As such, any FDA-approved diagnostic product containing [<sup>123</sup>I]ioflupane has a currently accepted medical use in the United States.

#### 4. Its History and Current Pattern of Abuse

According to HHS, there have been no reports of abuse of [<sup>123</sup>I]ioflupane. Over 168,000 doses of DaTscan have been administered to patients worldwide, and no pharmacological effects have been noted. Further, according to HHS, no single user has received more than 10 vials of DaTscan in a single day.

#### 5. The Scope, Duration, and Significance of Abuse

There have been no reports of abuse of [<sup>123</sup>I]ioflupane. According to the National Forensic Laboratory Information System (NFLIS)<sup>2</sup> and the System to Retrieve Information from Drug Evidence (STRIDE)<sup>3</sup>, there have been no reports of [<sup>123</sup>I]ioflupane seizures during the time period January 2010 to February 2015.

#### 6. What, If Any, Risk There Is to the Public Health

According to the HHS, because of the limited amounts of manufactured DaTscan, the low concentration of [<sup>123</sup>I]ioflupane per vial, and the existence of stringent regulatory controls (controls other than those imposed by the CSA and its implementing regulations, including regulation by the United States Nuclear Regulatory Commission under 10 CFR

part 35 and/or by states)<sup>4</sup> on the manufacturing and handling of DaTscan, abuse of DaTscan is not possible as a practical matter. Thus, there is little to no practical risk to public health from DaTscan abuse.

#### 7. Its Psychic or Physiological Dependence Liability

As reviewed by HHS, non-radiolabeled ioflupane has cocaine-like properties. In a drug discrimination study in cocaine-trained rats, non-radiolabeled ioflupane produced cocaine-appropriate responding, which suggests that non-radiolabeled ioflupane may produce cocaine-like subjective effects in humans (HHS, 2010).

However, the available evidence suggests that there is no psychic or physiological dependence potential of FDA-approved diagnostic products containing [<sup>123</sup>I]ioflupane. The psychic or physiological dependence potential of FDA-approved diagnostic products is currently expected to be very limited due to the low exposure concentration of [<sup>123</sup>I]ioflupane, the aforementioned low potential for abuse (see Factor 1) and the extremely high and lethal quantities needed to achieve a subjective “high.”

#### 8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA

[<sup>123</sup>I]ioflupane is not an immediate precursor of a substance already controlled under the CSA.

#### Conclusion

Based on consideration of the scientific and medical evaluation and accompanying recommendation of the HHS and based on the DEA’s consideration of its own eight-factor analysis, the DEA finds that the facts and all available and relevant data demonstrate that [<sup>123</sup>I]ioflupane does not possess abuse or dependence potential. Accordingly, the DEA finds that [<sup>123</sup>I]ioflupane does not meet the requirements for inclusion in any schedule and should be removed from control under the CSA.

#### Findings for Schedule Placement Pursuant to 21 U.S.C. 812(b)

The CSA outlines the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). The Assistant Secretary for Health of the HHS recommended removal of “FDA approved products containing

[<sup>123</sup>I]ioflupane from schedule II of the” CSA. However, because the DEA finds no basis to remove only FDA approved products containing [<sup>123</sup>I]ioflupane from the schedules, this action proposes to remove the substance [<sup>123</sup>I]ioflupane from the CSA schedules. Historically, when new molecular entities are removed from control, the substance itself is removed from control rather than the specific FDA-approved drug product (e.g., naloxegol, 80 FR 3468; naloxone, 39 FR 44392). As summarized above, the data currently support removal of substances that contain [<sup>123</sup>I]ioflupane, primarily because [<sup>123</sup>I]ioflupane itself has a lethal radioactive barrier, and its manufacturing process is highly regulated and technically complex, thus making abuse highly unlikely.

After consideration of the analyses and recommendation of the Assistant Secretary for Health of the HHS and review of all relevant and available data, the Administrator of the DEA, pursuant to 21 U.S.C. 812(b)(5), finds that:

(1) [<sup>123</sup>I]ioflupane has no comparable potential for abuse relative to substances in Schedule V.

(2) [<sup>123</sup>I]ioflupane has a currently accepted medical use in treatment in the United States. FDA approved the New Drug Application for DaTscan on January 14, 2011, with the indication of visualizing striatal dopamine transporters in the brains of adult patients with suspected Parkinsonian syndromes using SPECT imaging.

(3) [<sup>123</sup>I]ioflupane is not abusable, therefore, its use is not likely to lead to physical or psychological dependence.

Based on these findings, the Administrator of the DEA concludes that [<sup>123</sup>I]ioflupane does not warrant control under the CSA.

#### Effect on Other Rulemakings

On November 25, 2014, DEA published an interim final rule waiving the requirement of DEA registration for certain entities that are authorized under other federal or state authorities to administer DaTscan. 79 FR 70085. If finalized, this proposal to remove [<sup>123</sup>I]ioflupane from the schedules of controlled substances would make such waivers unnecessary. Therefore, if this action is finalized, DEA intends to withdraw the regulations established through that interim final rule.

#### Regulatory Analyses

##### Executive Orders 12866 and 15363

In accordance with 21 U.S.C. 811(a), this scheduling action is subject to formal rulemaking procedures done “on the record after opportunity for a

<sup>2</sup> NFLIS is a program of the DEA that collects drug identification results from drug cases analyzed by other Federal, State, and local forensic laboratories. NFLIS was queried on April 16, 2015.

<sup>3</sup> STRIDE collected the results of drug evidence analyzed at DEA laboratories and reflects evidence submitted by the DEA, other Federal law enforcement agencies, and some local law enforcement agencies. STRIDE data was queried by date submitted to Federal forensic laboratories. On October 1, 2014, STARLiMS replaced STRIDE as the DEA laboratory drug evidence data system of record.

<sup>4</sup> There are Federal and state laws and regulations which limit the public’s exposure to radioactivity in radiopharmaceuticals, thus limiting the potential for toxicity imposed on the public.

hearing,” which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the criteria for scheduling a drug or other substance and for removing a drug or substance from the schedules of controlled substances. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

#### *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 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

#### *Executive Order 13132*

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The rule does not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or the distribution of power and responsibilities among the various levels of government.

#### *Executive Order 13175*

This rule does not have tribal implications warranting the application of Executive Order 13175. This rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

#### *Regulatory Flexibility Act*

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this proposed rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this rule is to remove [123I]ioflupane from the list of schedules of the CSA. This action will remove regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances for handlers and proposed handlers of [123I]ioflupane. Accordingly, it has the potential for some economic impact in the form of cost savings.

If finalized, the proposed rule will affect all persons who would handle, or propose to handle, [123I]ioflupane. Due to the wide variety of unidentifiable and

unquantifiable variables that potentially could influence the distribution and administration rates of new molecular entities, the DEA is unable to determine the number of entities and small entities which might handle [123I]ioflupane.

Although the DEA does not have a reliable basis to estimate the number of affected entities and quantify the economic impact of this proposed rule, a qualitative analysis indicates that, if finalized, this rule is likely to result in some cost savings for the healthcare industry. The affected entities will continue to meet existing Federal and/or state requirements applicable to those who handle radiopharmaceutical substances, including licensure, security, recordkeeping, and reporting requirements, which in many cases are more stringent than the DEA's requirements. However, the DEA estimates cost savings will be realized from the removal of the administrative, civil, and criminal sanctions for those entities handling or proposing to handle [123I]ioflupane, in the form of saved registration fees, and the elimination of additional physical security, recordkeeping, and reporting requirements.

Because of these facts, this rule will not result in a significant economic impact on a substantial number of small entities.

#### *Unfunded Mandates Reform Act of 1995*

On the basis of information contained in the “Regulatory Flexibility Act” section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1501 *et seq.*, that this action would not result in any federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year \* \* \*.” Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of UMRA.

#### *Paperwork Reduction Act*

This action does not impose a new collection of information requirement under the Paperwork Reduction Act, 44 U.S.C. 3501–3521. This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

#### **List of Subjects in 21 CFR part 1308**

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

For the reasons set out above, 21 CFR part 1308 is proposed to be amended to read 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. In § 1308.12, revise paragraph (b)(4) to read as follows:

#### **§ 1308.12 Schedule II.**

\* \* \* \* \*

(b) \* \* \*

(4) Coca leaves (9040) and any salt, compound, derivative or preparation of coca leaves (including cocaine (9041) and ecgonine (9180) and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include:

- (i) Decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine; or
- (ii) [123I]ioflupane.

\* \* \* \* \*

Dated: May 6, 2015.

**Michele M. Leonhart,**  
*Administrator.*

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#### **DEPARTMENT OF STATE**

#### **22 CFR Parts 120, 123, 125, and 127**

[Public Notice 9149]

RIN 1400–AD70

#### **International Traffic in Arms: Revisions to Definitions of Defense Services, Technical Data, and Public Domain; Definition of Product of Fundamental Research; Electronic Transmission and Storage of Technical Data; and Related Definitions**

**AGENCY:** Department of State.

**ACTION:** Proposed rule.

**SUMMARY:** As part of the President's Export Control Reform (ECR) initiative, the Department of State proposes to amend the International Traffic in Arms