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

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays, at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to establish Class E airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Dewitt Municipal Airport/Whitcomb Field, Dewitt, AR. This proposed amendment provides the controlled airspace required to support RNAV (GPS) standard instrument approach procedures for IFR operations at this airport.

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the FAA Order JO 7400.11.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW AR E5 Dewitt, AR [Established]

Dewitt Municipal Airport/Whitcomb Field, AR

(Lat. 34°15′44″ W″ N, long. 91°18′27″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Dewitt Municipal Airport/Whitcomb Field.

Issued in College Park, Georgia, on October 27, 2021.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2021–23966 Filed 11–3–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–837]

Schedules of Controlled Substances: Removal of [18F]FP-CIT From Control

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration proposes to remove [18F]FP-CIT (chemical names: [18F]N-ω-fluoropropyl-β-CIT; fluorine-18-N-3-fluoropropyl-2-beta-carbomethoxy-3-beta-(4-iodophenyl)tropane; [18F]fluoropropylcarbomethoxy nortropane) from the schedules of the Controlled Substances Act (CSA). This scheduling action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. [18F]FP-CIT is currently a schedule II controlled substance because it can be derived from cocaine, a schedule II substance, via ecgonine, also a schedule II substance. 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 [18F]FP-CIT.

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 December 6, 2021. 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 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 December 6, 2021.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–837'' on all correspondence, including any attachments.

- *Electronic comments:* 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 electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic format, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.
- *Hearing requests:* All requests for a hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 362–3261.

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 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 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 the 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 and supplemental information to this proposed rule are available at *http://www.regulations.gov* for easy reference. DEA specifically solicits written comments regarding DEA's economic analysis of the impact of these proposed changes. DEA requests that commenters provide detailed descriptions in their comments of any expected economic impacts, especially to small entities. Commenters should provide empirical data to illustrate the nature and scope of such impact.

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 (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 by interested persons. 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.

Please note that, pursuant to 21 U.S.C. 811(a)(2), the purpose of a hearing would be to determine whether [18F]FP-CIT should be removed from the list of controlled substances based on a finding that the drug does not meet the requirements for inclusion in any schedule. All requests for hearing and waivers of participation must be sent to DEA using the address information above, on or before the date specified above.

Legal Authority

The Controlled Substances Act (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 own motion, (2) at the request of the Secretary of the Department of Health and Human Services (HHS),[1] or (3) on the petition

[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), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, March 8, 1985. The Secretary of HHS has delegated to the Assistant Secretary for Health of HHS the authority to make

of any interested party. 21 U.S.C. 811(a). This action was initiated by a petition to remove [18F]FP-CIT from the list of scheduled controlled substances of the CSA, and is supported by, *inter alia,* a recommendation from the Assistant Secretary for Health of HHS and an evaluation of all relevant data by DEA. If finalized, 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 [18F]FP-CIT.

Background

[18F]FP-CIT (chemical names: [18F]N-ω-fluoropropyl-β-CIT; fluorine-18-N-3-fluoropropyl-2-beta-carbomethoxy-3-beta-(4-iodophenyl)tropane; [18F]fluoropropylcarbomethoxy nortropane) is described as a diagnostic substance that is used in assisting the evaluation of adult patients with suspected Parkinsonian syndromes. It is an entity used in the visualization of striatal dopamine transporters (DAT) using positron emission tomography (PET) imaging. [18F]FP-CIT is not yet approved by the United States Food and Drug Administration (FDA) and no New Drug Application (NDA) for [18F]FP-CIT or any [18F]FP-CIT-containing drug has been submitted to FDA.

[18F]FP-CIT is structurally similar to [123I]ioflupane, known as DaTscan or [123I]FP-CIT. Both [18F]FP-CIT and [123I]ioflupane were developed as clinical diagnostic substances to visualize DAT and contain the same tracer amount of the precursor, ecgonine. The only difference between these two compounds is the radiotracer (^{123}I versus ^{18}F). On January 14, 2011, FDA approved the NDA for [123I]ioflupane-containing drug product, DaTscan, for use to visualize striatal DAT in the brains of adult patients with suspected Parkinsonian syndromes using single photon emission computed tomography (SPECT) imaging. DEA removed [123I]ioflupane from schedule II of the CSA on September 11, 2015 (80 FR 54715).

The starting material for the synthesis of [18F]FP-CIT and [123I]ioflupane is *N*-nor-β-CIT (2β-carbomethoxy-3β -(4-iodophenyl) nortropane), which is derived from cocaine, a schedule II substance, via ecgonine (a schedule II substance). Thus, by definition [18F]FP-CIT is a schedule II controlled substance under the CSA. On June 28, 2018, DEA received a petition from Advanced Imaging Projects to initiate proceedings to amend 21 CFR 1308.12(b)(4) so as to decontrol [18F]FP-CIT (proposed tradename Fluoroseek) from schedule II of the CSA. On October 6, 2018 and November 6, 2018, DEA received supplemental information from the Petitioner; DEA accepted the petition on November 28, 2018.

Proposed Determination To Decontrol [18F]FP-CIT

Pursuant to 21 U.S.C. 811(b), on May 2, 2019, DEA, having gathered the necessary data on [18F]FP-CIT, forwarded that data and the petition to HHS with a request for scientific and medical evaluation and scheduling recommendation for [18F]FP-CIT. On April 16, 2021, DEA received from HHS a scientific and medical evaluation conducted by FDA entitled ''Basis for the recommendation to remove [18F]FP-CIT from schedule II of the Controlled Substances Act'' and a scheduling recommendation. The National Institute on Drug Abuse (NIDA) concurred with the scientific and medical evaluation conducted by FDA. Based on the totality of the available scientific data, [18F]FP-CIT does not conform with the findings for schedule II in 21 U.S.C. 812(b)(2) or in any other schedule as set forth in 21 U.S.C. 812(b). Based on FDA's scientific and medical review of the eight factors and findings related to the substance's abuse potential, legitimate medical use, and dependence liability, HHS recommended that [18F]FP-CIT be removed from all schedules of the CSA.

The CSA requires DEA, as delegated by the Attorney General,[2] to determine whether HHS's scientific and medical evaluation, scheduling recommendation, and all other relevant data constitute substantial evidence that a substance should be scheduled. 21 U.S.C. 811(b). DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, and all other relevant data, and completed its own eight-factor review document on [18F]FP-CIT pursuant to 21 U.S.C. 811(c). Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in this proposal to remove [18F]FP-CIT from the schedules of the CSA. Both DEA and HHS analyses 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–837.

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

The first factor that must be considered is the actual or relative potential for abuse of [18F]FP-CIT. The term ''abuse'' is not defined in the CSA. However, the legislative history of the CSA suggests the following points in determining whether a particular drug or substance has a potential for abuse:[3]

a. Whether there is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community.

According to HHS's scientific and medical evaluation, there are no data demonstrating that individuals are taking either [18F]FP-CIT or [123I]ioflupane in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community. Additionally, as reported in the [123I]ioflupane HHS review, no case reports or clinical trials were published in scientific or medical literature that describe any incidents of drug abuse, misuse, or diversion of [123I]ioflupane.

HHS notes that in their assessment of the abuse potential of [123I]ioflupane from studies conducted in animals, it was estimated that doses of the radiolabeled FP-CIT in the milligram range would be needed to elicit stimulant effects. Since the active pharmaceutical ingredient (API) is the same, the same calculations apply to [18F]FP-CIT. HHS further states that upon receiving prescriptions from physicians [18F]FP-CIT will be manufactured immediately prior to its shipment and its limited availability will make its abuse logistically not possible.

b. Whether there is significant diversion of the drug or drugs containing such a substance from legitimate drug channels.

There has been no demonstrated diversion of [123I]ioflupane or [18F]FP-CIT. According to DEA's forensic laboratory databases, the National Forensic Laboratory Information System (NFLIS),[4] there are no cases of [123I]ioflupane or [18F]FP-CIT (queried May 27, 2021). Further, according to data assessed for [123I]ioflupane, it is highly unlikely that [18F]FP-CIT or [18F]FP-CIT-containing products will be diverted in the United States. In the

domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

[2] 28 CFR 0.100(b).

[3] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No. 91–1444, 91st Cong., Sess. 1 (1970); 1970 U.S.C.C.A.N. 4566, 4603.

[4] NFLIS is a national forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by State and local forensic laboratories in the United States.

United States, the Nuclear Regulatory Commission (NRC), the Occupational Safety and Health Administration, the Environmental Protection Agency, the Department of Transportation, and state legislation regulate the production, handling, transportation, and disposal of radiopharmaceuticals, all of which limit the trade to licensed radiopharmacies with a valid prescription.[5] [18F]FP-CIT and any [18F]FP-CIT-containing products will be subject to oversight by such agencies.

HHS notes that with the manufacturing limits and current restrictions regarding distribution, handling and disposal will limit the potential for diversion of [18F]FP-CIT from legitimate drug channels.

c. Whether individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice.

There has been no demonstrated diversion of [18F]FP-CIT nor published case reports or epidemiological data indicating that individuals are using [18F]FP-CIT-containing products on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such substances. Due to the radioactive properties, [18F]FP-CIT will not be administered by the patient or be available for self-administration by patients.

d. Whether the drug or drugs containing such a substance are new drugs so related in their action to a substance already listed as having a potential for abuse to make it likely that it will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that they have a substantial capability of creating hazards to the health of the user or to the safety of the community.

As noted above, [18F]FP-CIT is chemically and pharmacologically similar to [123I]ioflupane. A formulation containing [18F]FP-CIT, similar to [123I]ioflupane, that is intended for diagnostic purposes, would contain the API in amounts too low than what is feasible for eliciting a central nervous system (CNS) stimulant pharmacological effect. It is estimated that milligram quantities would have to be administered to elicit a stimulant effect. Due to the manufacturing limitations and expected low concentrations of [18F]FP-CIT in an approved product, the volume of [18F]FP-CIT-containing product that would need to be administered to achieve a psychoactive effect for abuse is not logistically possible.

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

Preclinical Studies

According to HHS scientific review of [123I]ioflupane, non-radiolabeled FP-CIT acts on the CNS by blocking monoamine transporters, including DAT and other monoamine transporters (*e.g.,* serotonin) and is mechanistically similar to cocaine (a schedule II substance). FP-CIT's affinity for DAT is between 10- and 100-fold greater than cocaine's affinity for DAT and appears to be more potent than cocaine in some behavioral assessments. HHS states that this mechanism of action suggests, like [123I]ioflupane, [18F]FP-CIT may potentially have abuse potential if the dose taken is high enough and if the deterrent effect of the extremely low concentration of the available radioligand is not considered.

Drug discrimination assays in animals can be used to predict if a test drug will have abuse potential in humans. According to HHS, in a drug discrimination study, administration of non-radiolabeled FP-CIT at doses >0.1 mg/kg (i.v.) resulted in cocaine-appropriate responses in rats trained to discriminate cocaine (10 mg/kg, i.p.) from saline. Thus, non-radiolabeled FP-CIT may produce cocaine-like subjective effects.

HHS's review also noted that the administration of non-radiolabeled FP-CIT resulted in an increase of locomotor activity in rodents relative to vehicle, but produced a lower maximum level and was less potent compared to cocaine (schedule II substance), however the locomotor effects induced by FP-CIT lasted longer than cocaine.

Human Studies

HHS notes that when [18F]FP-CIT was administered at doses used in diagnostic tests there was no clinical evidence of stimulant effects.

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

The international non-proprietary name of [18F]FP-CIT is methyl (1*R,2S,*3*S,*5*S*)-8-[3-(fluoro-18F)propyl]-3-(4-iodophenyl)-8-azabicyclo[3.2.1]octane-2-carboxylate. The molecular formula of [18F]FP-CIT is C18H23[18F]INO2 and the molecular weight is 431.28 g/mol.

The petitioner states that their expected [18F]FP-CIT-containing product (Fluoroseek) exists only as a clear, colorless to slightly yellow liquid solution in ethanol and saline solution (sodium chloride 0.9% in water) and contains antioxidants such as gentisic acid and sodium ascorbate, with sodium carbonate as a pH modifier. The general chemical properties of [18F]FP-CIT are inferred from the chemical properties of the non-radioactive FP-CIT substance. FP-CIT 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).

As noted by HHS, there are no currently marketed [18F]FP-CIT-containing products available. However, in a letter dated January 8, 2020, the Petitioner sent a response to DEA on a request for information regarding the composition of the product and the expected doses patients will receive. In this communication, the Petitioner states that the synthesized product ''. . . contains 40 micrograms (µg) of [18F] Fluoroseek per 29 milliliters (mL). Each patient will receive 0.3–3.0 mL of the solution.'' Thus, based on the concentration (40 µg/29 mL) of the product, as indicated by the Petitioner, and the amount of the [18F]FP-CIT solution that the Petitioner estimates patients will receive (0.3–3.0 mL), the doses a patient may receive will be in the range of 0.41 µg to 4.13 µg.

For [123I]ioflupane, HHS mentions that the meaningful extraction of [123I]ioflupane from the marketed drug product, DaTscan, would be impossible due to its limited production and availability and it is technically complex and would require advanced equipment not available to the general public.

Medical Use

According to HHS, as of April 2021, the petitioner has yet to submit an NDA for the [18F]FP-CIT-containing drug product (Fluoroseek). It is expected that, similar to [123I]ioflupane, [18F]FP-CIT will be used as a diagnostic agent, potentially in conjunction with PET imaging, whereas [123I]ioflupane is used in SPECT imaging.

4. Its History and Current Pattern of Abuse

There have been no reports of abuse of [18F]FP-CIT or [123I]ioflupane at the doses used for diagnostic purposes.

[5] For radioactive substances there are controls other than those imposed by the CSA and its implementing regulations, including regulations by the NRC under 10 CFR part 35 and/or by states, which limit the public's exposure to radioactivity in radiopharmaceuticals, thus limiting the potential for toxicity imposed on the public.

Similar to [123I]ioflupane, [18F]FP-CIT was developed for diagnostic purposes and contains a small amount of the API. The amount of [18F]FP-CIT in each vial of [18F]FP-CIT would be limited and it is produced based on demand. Additional regulations and control mechanisms by the NRC and other federal agencies exist for the production, handling and use of [18F]FP-CIT due to its radioactivity.

5. The Scope, Duration, and Significance of Abuse

DEA has searched the scientific literature and the Federal, State, and local forensic laboratory databases such as NFLIS to assess the scope of [18F]FP-CIT abuse in the United States. There were no reports of [18F]FP-CIT seizures during the period of January 2010–April 2021.

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

The risk to public health is unknown for [18F]FP-CIT. However, as stated by HHS the radioactive nature of the substance, limited amounts of substance needed for imaging purposes, and the existence of stringent regulatory controls on the manufacturing and handling, [18F]FP-CIT poses little or no practical risk to public health. Because the API for [18F]FP-CIT is the same as [123I]ioflupane, [18F]FP-CIT is expected to have the same product characteristics.

7. Its Psychic or Physiological Dependence Liability

HHS reports that no systemic evaluation has been conducted to determine whether [123I]ioflupane or [18F]FP-CIT produces psychic or physiological dependence in animals or humans. It is expected that the use of the radiolabeled agents (*i.e.,* [123I]ioflupane and [18F]FP-CIT) will not produce psychic or physiological dependence due to the low dose and short-term exposure.

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

Similar to [123I]ioflupane, [18F]FP-CIT 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 HHS, and based on DEA's consideration of its own eight-factor analysis, DEA finds that these facts and all relevant data demonstrate that [18F]FP-CIT does not possess abuse or dependence potential. According to HHS, no NDA containing [18F]FP-CIT has been submitted. However, the finding that [18F]FP-CIT lacks abuse potential would, irrespective of other findings, permit decontrol of [18F]FP-CIT prior to or in the absence of an FDA action under 21 U.S.C. 355(c). Accordingly, DEA finds that [18F]FP-CIT does not meet the requirements for inclusion in any schedule, and should be removed from control under the CSA.

Regulatory Analyses

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

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

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 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, Federalism

This rulemaking does not have federalism implications warranting the application of E.O. 13132. The proposed 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, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of E.O. 13175. This proposed 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), 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 proposed rule is to remove [18F]FP-CIT 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 [18F]FP-CIT. 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 [18F]FP-CIT. [18F]FP-CIT is not currently available or marketed in any country. Due to the wide variety of unidentifiable and unquantifiable variables that potentially could influence the distribution and dispensing rates, if any, of [18F]FP-CIT, DEA is unable to determine the number of entities and small entities which might handle [18F]FP-CIT. In some instances where a controlled pharmaceutical drug is removed from the schedules of the CSA, DEA is able to quantify the estimated number of affected entities and small entities because the handling of the drug is expected to be limited to DEA registrants even after removal from the schedules. In such instances, DEA's knowledge of its registrant population forms the basis for estimating the number of affected entities and small entities. However, DEA does not have a basis to estimate whether [18F]FP-CIT is expected to be handled by persons who hold DEA registrations, by persons who are not currently registered with DEA to handle controlled substances, or both. Therefore, DEA is unable to estimate the number of entities and small entities who plan to handle [18F]FP-CIT.

Although 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 this rule is likely to result in some cost savings. As noted above, DEA is specifically soliciting comments on the economic impact of this proposed rule. DEA will revise this section if warranted after consideration of any comments received. Any person planning to handle [18F]FP-CIT will realize cost savings in the form of saved DEA registration fees, and the elimination of physical security, recordkeeping, and reporting requirements.

Because of these factors, DEA projects that this proposed rule will not result in a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined 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 annually for inflation) in any 1 year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521

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), 956(b), unless otherwise noted.

■ 2. In § 1308.12, revise paragraphs (b)(4)(i) through (iii) to read as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(4)(i) Decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine;

(ii) [^{123}I]ioflupane; or

(iii) [^{18}F]FP-CIT.

* * * * *

Anne Milgram,

Administrator.

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