Abbreviation	Commenter
SCE	Southern California Edison.
SDG&E	San Diego Gas & Electric.
SIA	Security Industry Association.
Southern	Southern Company Services, Inc.
TAPS	Transmission Access Policy Study Group.
TVA	Tennessee Valley Authority.
Trade Associations	American Public Power Association, Large Public Power Council, National Rural Electric Cooperative Association.
Xcel	Xcel Energy Services Inc.
Reply Commenters	
Foundation	Foundation for Resilient Societies.
ITC	International Transmission Company.
NIPSCO	Northern Indiana Public Service Company.
SmartSenseCom	SmartSenseCom, Inc.
SWTDUG	Southwest Transmission Dependent Utility Group.
Tallahassee	City of Tallahassee.

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BILLING CODE 6717–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–394]

RIN 1117–AB38

Exemption From Registration for Persons Authorized Under U.S. Nuclear Regulatory Commission or Agreement State Medical Use Licenses or Permits and Administering the Drug Product DaTscan™

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule with request for comment.

SUMMARY: The Drug Enforcement Administration (DEA) is amending its regulations to waive the requirement of registration for persons who are authorized under United States Nuclear Regulatory Commission or Agreement State medical use licenses or permits and administer the drug product DaTscan™.

DATES: Effective November 25, 2014. Interested persons may file written comments on this interim final rule pursuant to 5 U.S.C. 553. Electronic comments must be submitted, and written comments must be postmarked, on or before January 26, 2015. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–394'' on all electronic and written correspondence. The DEA 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 attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Paper comments that duplicate electronic submissions are not necessary. Should you, however, wish to submit written comments in lieu of electronic comments, they must be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/ODXL, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, 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 in response to this docket are considered part of the public record and will be made available 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 the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

An electronic copy of this document and supplemental information to this interim final rule with request for comment are available at *http://www.regulations.gov* for easy reference. If you wish to personally inspect the comments and materials received or the supporting documentation the DEA used in preparing the interim final rule with request for comment, these materials will be available for public inspection by appointment. To arrange a viewing, please see the **FOR FURTHER INFORMATION CONTACT** paragraph above.

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 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 purpose 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), parts 1300 to 1321. 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, every controlled substance is classified into one of five schedules based upon its potential for abuse, currently accepted medical use, 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 all scheduled substances is published at 21 CFR part 1308. Pursuant to 21 U.S.C. 822(a)(1), ''every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.'' Further, pursuant to 21 U.S.C. 822(a)(2), ''every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.''

The Attorney General however may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety pursuant to 21 U.S.C. 822(d). The Attorney General delegated this authority to the Administrator of the DEA, 28 CFR 0.100(b), who in turn redelegated that authority to the Deputy Assistant Administrator of the DEA Office of Diversion Control (''Deputy Assistant Administrator''). Section 7 of 28 CFR part 0, subpart R, App.

Purpose and Background of the Regulatory Action

On May 10, 1994, the United States Patent and Trademark Office issued a patent to GE Healthcare, the sole manufacturer of the radioactive drug DaTscan™, for 20 years for the development of DaTscan™. On January 14, 2011, the U.S. Food and Drug Administration (FDA) approved DaTscan™ as a diagnostic tool containing a radioisotopic form of ioflupane, [^{123}I]ioflupane. This product is approved for medical use and was simultaneously granted exclusive marketing rights to GE Healthcare for five years in accordance with 21 CFR 314.108. Ioflupane is a schedule II controlled substance under the CSA.

The FDA approved labeling of DaTscan™ states that DaTscan™ is a radiopharmaceutical indicated for striatal dopamine transporter visualization using single photon emission computed tomography (SPECT) brain imaging to assist in the evaluation of adult patients with suspected Parkinsonian syndromes (PS). DaTscan™ is an adjunct to other diagnostic evaluations, and it may be used to help differentiate essential tremors from tremors due to PS, (idiopathic Parkinson's disease (PD), multiple system atrophy (MSA), and progressive supranuclear palsy (PSP)). According to GE Healthcare, DaTscan™ was not designed to distinguish among PD, MSA, and PSP. However, the results created by the contrast that occurs after the administration of DaTscan™ may also be used to help rule out other diseases that may have similar symptoms, like essential tremor, for individuals early in the course of their disease.

Because DaTscan™ contains [^{123}I]ioflupane, a schedule II controlled substance, it may only be handled by entities registered with the DEA to handle schedule II controlled substances.[1] However, due to its I–123 radioactive component, the handling of DaTscan™ in the United States is also strictly controlled by Federal and State laws limiting distribution to licensed radiopharmacies and certain licensed medical facilities. It is regulated by the United States Nuclear Regulatory Commission (NRC) under 10 CFR part 35 or by an Agreement State[2] under equivalent Agreement State requirements. NRC also authorizes certain Federal Agencies (*i.e.,* Master Materials licensees (MML)) to issue their medical facilities medical use permits that are equivalent to NRC medical use licenses. The NRC and Agreement States require those medical facilities administering radioactive medical byproduct material to obtain a medical use license or permit and comply with specific regulations pertaining to security, recordkeeping, and reporting. *Id.* In accordance with 10 CFR parts 20 and 35 and equivalent Agreement State requirements, applicants for NRC and Agreement State licensure must comply with and demonstrate radiation safety precautions and instructions, methodologies for measurement of dosages to be administered, physical security of medical byproduct material, and recordkeeping requirements.

As a result of these overlapping registration/licensing requirements, DaTscan™ is available only by authorization from a DEA-registered practitioner. Therefore, it may only be administered to a patient by physicians authorized under an NRC or an Agreement State license or NRC MML permit to perform imaging and localization studies under 10 CFR 35.200 or equivalent Agreement State requirements who are also registered with the DEA to administer schedule II controlled substances. Accordingly, only NRC- or Agreement State-licensed or NRC MML permitted radiology imaging centers that are also registered with the DEA to handle schedule II controlled substances, such as hospitals and private practice imaging centers, may conduct diagnostic analysis using DaTscan™.

Currently, GE Healthcare manufactures DaTscan™ and provides it directly to its DEA-registered radiopharmacies, who then transfer it to DEA-registered imaging centers for administration and scanning procedures. This process occurs in a closed system of distribution that is currently regulated by both the DEA and the NRC/Agreement State.

[1] The DEA continues to review the control status of [^{123}I] Ioflupane pursuant to 21 U.S.C. 811. While this interim final rule with request for comment is separate and apart from the control process, and does not resolve the control status of [^{123}I] Ioflupane, this waiver of registration is designed to encourage use of this drug product as a diagnostic tool until the control status of [^{123}I] Ioflupane is resolved.

[2] An Agreement State is defined as any State with which the Nuclear Regulatory Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended (the Act). Further, Section 274 of the Act provides a statutory basis under which the NRC discontinues its regulatory authority to regulate byproduct materials; source materials; and small quantities of special nuclear materials. The Agreement State assumes authority from the NRC with its own compatible legislation and regulations, including compatible requirements to 10 CFR part 35, once the Agreement is signed in accordance with Section 274b of the Act. Agreement States implement regulatory programs to regulate byproduct, source and certain special nuclear materials that are compatible with NRC requirements and adequate to protect public health and safety.

In addition to qualifying for registration with the DEA pursuant to 21 U.S.C. 823(f), practitioners must adhere to controls pertaining to physical security, reporting, and recordkeeping, in order to detect and prevent diversion of controlled substances. See, *e.g.,* 21 CFR 1301.75–1301.76, 1304.21–1304.22. For example, DEA-registered pharmacies and institutional practitioners may disperse controlled substances throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances; they must also report thefts or significant losses of controlled substances to the DEA within one business day of discovery; dispositions of schedule II controlled substances must be authorized by a DEA Form 222; and they must maintain specified records of each transaction involving a controlled substance for a period of two years.

The NRC and Agreement States require that any person who manufactures, produces, acquires, receives, possesses, prepares, uses, or transfers radioactive byproduct material for medical use do so only in accordance with a specific medical use license issued by the NRC or an Agreement State or permit issued by an NRC MML. *See* 10 CFR 35.11–12. Radioisotope I–123 meets the definition of byproduct material in paragraph 3B of Section 11e. of the Atomic Energy Act (AEA), as revised in 1978 and in 2005 by the Energy Policy Act (EPAct) (*i.e.,* any material that has been made radioactive by use of a particle accelerator; and is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity).

The NRC and Agreement States regulate licensed materials (*i.e.,* byproduct material) which must be tracked from initial production to final disposal in order to ensure accountability; to identify when licensed material could be lost, stolen, or misplaced; and to ensure that possession limits listed on the license are not exceeded.

In accordance with 10 CFR 20.1101, licensees are required to implement a radiation protection program that requires licensees to develop, document, and implement procedures to ensure the security and safe use of all the licensed material from the time it arrives at their facilities until it is used, transferred, or disposed of. The DEA regulations require practitioners to ''provide effective controls and procedures to guard against theft and diversion of controlled substances.'' 21 CFR 1301.71(a). In addition, in accordance with 21 CFR 1301.75(b), practitioners must store schedule II controlled substances in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners (*e.g.,* hospitals) may ''disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.'' *Id.*

The NRC and Agreement States also require distributor-licensees to verify the licensure status of each recipient prior to transferring radioactive byproduct material each time it is transferred. *See* 10 CFR 30.41. In contrast to the NRC/Agreement State regulations and licensure requirements, the DEA in accordance with 21 CFR 1301.74(a) has mandated that ''before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.''

The NRC and Agreement States also require licensees to comply with recordkeeping requirements for three years from the date of receipt and to provide the NRC with accurate records for the receipt, transfer, and disposal of the byproduct material in accordance with 10 CFR 30.51. This is more stringent than the DEA regulations, which require registrants to maintain records for a period of two years for inspection and copying by the DEA. *See* 21 CFR 1304.04(a).

With this interim final rule, the DEA is only waiving registration requirements specifically for persons administering DaTscan™ directly to patients for diagnostic purposes.[3] Persons administering the specific drug product DaTscan™ are exempt from requirements pertaining to registration, security, recordkeeping, and reporting. In addition, the drug product DaTscan™ is exempt from the labeling and packaging requirements of the CSA. Exempt persons must follow the applicable NRC or Agreement State regulations and requirements when handling DaTscan™.

Because persons who administer DaTscan are subject to strict NRC/Agreement State requirements, the DEA has determined that the waiver from registration of persons who administer DaTscan™ is consistent with the public health and safety. These exempt persons must be authorized by a valid NRC or Agreement State medical use license or NRC MML medical use permit for imaging or localization studies under 35.200 or equivalent Agreement State requirements and be subject to security, oversight, and monitoring that is as stringent as that provided by the CSA and its implementing regulations. Compliance with NRC or Agreement State requirements significantly reduces the risk of diversion, thereby ensuring that the public health and safety will not be compromised by this waiver.

Finally, in accordance with the AEA disposal requirements in 10 CFR 20.2002 through 20.2005, the licensee is required to dispose of the radioactive medical waste while complying with environmental and health protection regulations. Since DaTscan™ has a radiologic shelf life of less than 36 hours, it cannot be stored for any significant amount of time between the time it is manufactured and the time it is administered to a patient, thereby minimizing the risk of diversion during the transfer process and decreasing the time to detect theft or loss. Accordingly, those persons waived from registration and other requirements by this interim final rule (*i.e.,* those persons administering DaTscan™ directly to patients for diagnostic purposes) will be also exempted from the disposal requirements of 21 CFR part 1317, and the manufacturers and distributors of DaTscan™ will be required to comply with the DEA disposal regulations (21 CFR part 1317) in order to ensure that any drug product that is not administered or that remain after administration is not diverted to illicit use.

Under this interim final rule, a DEA-registered practitioner must prepare a record containing the practitioner's name and signature, DEA registration number, drug product name, date the record was signed, and patient name, and provide this record to the patient. The record must be transferred by the patient to the imaging center. The imaging center will then request the drug product DaTscan™ from the DEA-registered distributor by providing the written record as authorization to transfer the drug product. The DEA-registered distributor shall maintain this document as the record of the transaction. The DEA-registered distributor will verify that the imaging center has a current, valid NRC or Agreement State medical use license or

[3] Persons that handle other controlled substances in addition to DaTscan™ must be registered with the DEA to handle those other controlled substances.

NRC MML medical use permit that authorizes imaging and localization and if it does, the distributor will then request the drug product DaTscan™ from the manufacturer. After receipt of the drug product DaTscan™ from the manufacturer, the distributor will transfer the ordered amount of the drug product DaTscan™ to the imaging center for the test. The DaTscan™ will be administered to the patient, and the test will be performed. Any DaTscan™ that is not administered or that remains after the administration will then be returned to the distributor by the licensee and subsequently disposed of in accordance with the DEA disposal regulations. Both the DEA-registered distributor and the DEA-registered manufacturer must comply with all DEA regulations pertaining to schedule II controlled substances including security, registration, and recordkeeping.

Regulatory Analyses

Executive Orders 12866 and 13563

This interim final rule, which waives registration for persons authorized under United States Nuclear Regulatory Commission or Agreement State medical use licenses or NRC MML medical use permits, who administer the drug product DaTscan™ directly to patients for diagnostic purposes, has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review'' section 1(b), Principles of Regulation, and in accordance with Executive Order 13563 ''Improving Regulation and Regulatory Review'' section 1(b) General Principles of Regulation.

The Department of Justice has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget.

Further, both Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The DEA assessed the costs and benefits of this regulation and believes that the regulatory approach selected maximizes net benefits.

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 proposed rule does 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.

Executive Order 13175

This rule does not have tribal implications warranting the application of Executive Order 13175. It 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 Deputy Assistant Administrator, in accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The RFA applies ''[w]henever an agency is required by section 553 of [the APA], or any other law, to publish a general notice of proposed rulemaking for any proposed rule.'' 5 U.S.C. 603. Here, the DEA for good cause finds that notice and comment procedures are unnecessary and contrary to the public interest because without prompt waiver of registration, some members of the healthcare community may not be able to utilize the diagnostic tool. Accordingly, these rules are being adopted on an interim final basis. Additionally, this interim final rule is alleviating regulatory restrictions on those affected by its implementation.

Although, the DEA does not have a basis to estimate the number of affected entities and quantify the economic impact of this interim final rule, a qualitative analysis indicates that this interim final rule is likely to result in some cost savings for the healthcare industry. The affected entities will continue to meet NRC or Agreement State requirements for licensure, security, recordkeeping, and reporting, which in many cases are more stringent than the DEA's requirements. The DEA estimates cost savings will be realized from the removal of DEA requirements for those administering the drug product DaTscan™ that are duplicative of NRC or Agreement State requirements, such as: Registration fees, recordkeeping, and periodic reports. While the DEA does estimate that this interim final rule will provide some cost savings, it does not believe the savings will be significant since the affected entities are required to continue to meet NRC requirements for handling DaTscan™.

Paperwork Reduction Act of 1995

This rule does not involve a collection of information within the meaning of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*), the DEA has determined and certifies pursuant to UMRA 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 million or more (adjusted for inflation) in any one year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under the provisions of UMRA of 1995.

Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act (CRA) (5 U.S.C. 804). 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 have significant 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 export markets. However, pursuant to the CRA, the DEA has submitted a copy of this interim final rule with request for comment to both Houses of Congress and to the Comptroller General.

Administrative Procedure Act

An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA), including notice of proposed rulemaking and the pre-promulgation opportunity for public comment, if it is determined to be unnecessary,

impracticable, or contrary to the public interest (5 U.S.C. 553 (b)(B)). The DEA for good cause finds that it is unnecessary and contrary to the public interest to seek public comment prior to promulgating this interim final rule because, without prompt waiver of registration, some members of the healthcare community may not be able to utilize this diagnostic tool and patients in need may not receive it. DaTscan™ is an important tool in differentiating essential tremors from tremors due to Parkinsonian Syndrome (PS) and can help healthcare professionals provide more accurate diagnoses. These rules are therefore, being adopted on an interim final basis. Additionally, the DEA is alleviating the regulatory burdens on those administering the drug product DaTscan™. Furthermore, this alleviation will mean that patients have a greater chance of receiving important diagnostic testing.

In addition, the APA permits an agency to make effective upon date of publication ''a substantive rule which grants or recognizes an exemption or relieves a restriction.'' 5 U.S.C. 553 (d)(1). The DEA finds that this interim final rule with request for comments meets the criterion set forth in 5 U.S.C. 553 (d)(1) for an exception to the APA effective date requirement.

List of Subjects in 21 CFR Part 1301

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

For the reasons set out above, 21 CFR part 1301 is amended as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957, 958, unless otherwise noted.

■ 2. Add a new § 1301.29 to read as follows:

§ 1301.29 Registration waivers; exemption from practitioner registration for persons authorized by a United States Nuclear Regulatory Commission or agreement state medical use license or permit and administering the drug product DaTscan™

(a) The requirement of registration is waived for persons administering the drug product DaTscan™ to a patient for diagnostic purposes if the person is authorized by a valid medical use license or permit issued by the United States Nuclear Regulatory Commission (NRC) or NRC master materials licensee or an agreement state authorizing the person to receive, possess, use, or transfer byproduct material in accordance with NRC or agreement state rules and regulations.

(1) As used in this section, ''agreement state'' is any state with which the NRC or the Atomic Energy Commission has entered into an effective agreement under Section 274(b) of the Atomic Energy Act of 1954, as amended. As of October 2014, those states considered ''non-agreement states'' include: Alaska, Connecticut, Delaware, Hawaii, Idaho, Indiana, Michigan, Missouri, Montana, South Dakota, Vermont, Washington, DC, West Virginia, and Wyoming. All other states have entered into agreements with the NRC.

(2) This section does not exempt persons identified in this paragraph (a) from any statutory or regulatory requirements pertaining to any controlled substance other than the drug product DaTscan™.

(3) This section does not exempt from the requirement of registration persons who prescribe, or order the administration of, the drug product DaTscan™.

(b) Persons identified in paragraph (a) of this section are exempt from application of 21 U.S.C. 822(a)(2), 827, and 828 (registration, records, reports, and order forms) and sections 1301.71, 1301.75, and 1301.76 of this chapter (practitioner security), to the extent described in paragraphs (e) and (f) of this section, only with respect to administering the drug product DaTscan™.

(c) The drug product DaTscan™ is exempt from application of 21 U.S.C. 825 and § 1302.03 of this chapter to the extent described in paragraph (d) of this section.

(d) *Labeling and packaging.* In lieu of the requirements set forth in part 1302 of this chapter, the label and the packaging of the drug product DaTscan™ must be prominently marked with its full trade name or other description and the name of the manufacturer in such a way that the product can be readily identified as the drug product DaTscan™. The symbol designating the schedule of the drug product DaTscan™ is not required on either the label or the packaging of the drug product DaTscan™.

(e) *Registration and security.* Any person who manufactures or distributes the drug product DaTscan™ must be registered under the Act and comply with all relevant security requirements regarding the schedule II controlled substances being distributed or used in the manufacturing process. Any person identified in paragraph (a) of this section is not required to be registered under the Act to handle the drug product DaTscan™, and these persons are not required to store the drug product DaTscan™ in accordance with security requirements regarding controlled substances.

(f) *Records and reports.* Any person who manufactures or distributes the drug product DaTscan™ must keep complete and accurate records and file all reports required under part 1304 of this chapter regarding all controlled substances distributed or used in the manufacturing process for the drug product DaTscan™. In reports required by 21 CFR 1304.33 due to transactions with persons identified in paragraph (a) of this section, the DEA registration number of the person identified in paragraph (a) is not required to be reported. Any person identified in paragraph (a) who handles the drug product DaTscan™ is not required to maintain records or file reports required by the Act or its implementing regulations. The authorizing practitioner shall prepare a record containing the practitioner's name, signature, date of authorization, DEA registration number, drug product name, and patient name, and provide this record to the patient. This record prepared by the DEA registered practitioner shall be used as the distributor's record of the distribution.

(g) *Criminal penalties* No exemption granted pursuant to this section affects the criminal liability for illegal manufacture, distribution, or possession of controlled substances contained in the drug product DaTscan™. Use of the drug product DaTscan™ is lawful for registrants and nonregistrants only as long as such activity is intended for administration for diagnostic purposes.

(h) The persons identified in paragraph (a) of this section shall return all unused drug product DaTscan™ to the DEA-registered distributor from whom the person received it, for disposal in accordance with 10 CFR 20.2001–20.2008.

(i) Once the drug product DaTscan™ is returned to the appropriate DEA-registered distributor, it shall be disposed of in accordance with the following procedures:

(1) The DEA-registered distributor shall keep a record of the return;

(2) After receipt of the drug product DaTscan™, the DEA-registered distributor shall hold the drug product DaTscan™ until it is no longer considered low-level radioactive waste

in accordance with 10 CFR 20.2001(a)(2); and

(3) After the drug product DaTscan™ is no longer considered low-level radioactive waste, the DEA-registered distributor shall dispose of all unused DaTscan™ in accordance with 21 CFR part 1317.

(j) The exemptions specified in this section are not applicable to the drug product DaTscan™ if there are any changes in the quantitative or qualitative composition of the preparation or mixture after the date of this regulation, or change in the trade name or other designation of the drug product DaTscan™.

Dated: November 18, 2014.

Joseph T. Rannazzisi,

Deputy Assistant Administrator.

[FR Doc. 2014–27917 Filed 11–24–14; 8:45 am]

BILLING CODE 4410–09–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4001, 4022, and 4044

RIN 1212–AB23

Title IV Treatment of Rollovers From Defined Contribution Plans to Defined Benefit Plans

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: In April 2014, PBGC proposed to amend its regulations to clarify the treatment of benefits resulting from a rollover distribution from a defined contribution plan to a defined benefit plan, if the defined benefit plan was terminated and trusteed by PBGC. Under the proposal, a benefit resulting from rollover amounts generally would not be subject to PBGC's maximum guaranteeable benefit or phase-in limitations and would be in the second highest priority category of benefits in the allocation of assets. PBGC is now finalizing that proposal. Except for making minor clarifications suggested by commenters, the final regulation is the same as the proposed regulation. This rulemaking is part of PBGC's efforts to enhance retirement security by promoting lifetime income options.

DATES: Effective December 26, 2014. See Applicability in **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion (*klion.catherine@pbgc.gov*), Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005–4026; 202–326–4024. (TTY and TDD users may call the Federal relay service toll free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Regulatory Action

This regulatory action is needed to provide guidance on treatment of benefits resulting from a rollover distribution from a defined contribution plan to a defined benefit plan, where the defined benefit plan is terminated and trusteed by the Pension Benefit Guaranty Corporation (PBGC).

Legal authority for this action comes from section 4002(b)(3) of the Employee Retirement Income Security Act of 1974 (ERISA), which authorizes PBGC to issue regulations to carry out the purposes of Title IV of ERISA, section 4022 of ERISA (Single-Employer Plan Benefits Guaranteed), and section 4044 of ERISA (Allocation of Assets).

Major Provisions of the Regulatory Action

Under the final regulation, a benefit resulting from rollover amounts generally will be in the second highest priority category among various classes of benefits in the allocation of assets and generally will not be subject to PBGC's maximum guaranteeable benefit or phase-in limitations.

Background

PBGC administers the single-employer pension plan termination insurance program under Title IV of ERISA. The program covers private-sector, single-employer defined benefit plans, for which premiums are paid to PBGC each year. Covered plans that are underfunded may terminate either in a distress termination under section 4041(c) of ERISA or in an involuntary termination (one initiated by PBGC) under section 4042 of ERISA. When such a plan terminates, PBGC typically is appointed statutory trustee of the plan, and becomes responsible for paying benefits in accordance with the provisions of Title IV. At times, plans trusteed by PBGC include contributions made by employees that fund part of the benefit under the plan.

Mandatory Contributions

A plan may be funded in whole or in part by mandatory contributions. Under section 4044(b)(6) of ERISA, the term ''mandatory contributions'' means amounts contributed to the plan by a participant that are required as a condition of employment, as a condition of participation in such plan, or as a condition of obtaining benefits under the plan attributable to employer contributions.

Typically, mandatory employee contributions are required under the plan as a percentage of the employee's compensation. They are withheld from the salary of the employee by the employer and deposited to the employee's credit in the defined benefit plan on an after-tax basis.[1] Such mandatory employee contributions have generally been used to fund a portion of the participant's accrued benefit as determined under the plan's benefit formula and are required in order to receive the portion of the accrued benefit derived from employer contributions.

Section 411(c)(2)(B) of the Code[2] provides that, in the case of a defined benefit plan, the accrued benefit derived from mandatory employee contributions is equal to the employee's contributions accumulated to normal retirement age using specified rates under section 411(c)(2)(C), and converted to an actuarially equivalent annuity commencing at normal retirement age, using an interest rate under section 417(e)(3) of the Code as of the determination date. Section 411(c)(1) of the Code provides that an employee's accrued benefit derived from employer contributions as of any date is the excess, if any, of the accrued benefit for the employee as of that date over the accrued benefit derived from contributions made by the employee as of that date.

PBGC Treatment of Mandatory Employee Contributions in Terminated Plans

When a plan terminates in a distress termination or an involuntary termination, each participant's plan benefit is assigned to one or more of six ''priority categories'' that are described in paragraphs (1) through (6) of section 4044(a) of ERISA.[3] Participants' accrued

[1] Generally, contributions by employees to defined benefit plans (whether mandatory or voluntary) are not deductible for federal income tax purposes.

[2] See also ERISA section 204(c)(2)(B). References to the Code in this preamble should be read to include the parallel provision under ERISA.

[3] Plan assets must be allocated to each priority category in succession, beginning with priority category one (PC1). The benefits assigned to each priority category under section 4044 of ERISA in general are as follows:

- PC1: The portion of a participant's accrued benefit derived from the participant's voluntary contributions.
- PC2: The portion of a participant's accrued benefit derived from the participant's mandatory contributions.