regulatory flexibility analysis is required and none has been prepared.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—CONTROL POLICY: END-USE AND END-USER BASED

■ 1. The authority citation for part 744 is revised to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of September 19, 2019, 84 FR 49633 (September 20, 2019); Notice of November 12, 2019, 84 FR 61817 (November 13, 2019).

■ 2. Section 744.11 is amended by revising paragraph (a) to read as follows:

§ 744.11 License requirements that apply to entities acting contrary to the national security or foreign policy interests of the United States.

* * * * *

(a) *License requirement, availability of license exceptions, and license application review policy.* A license is required, to the extent specified on the Entity List, to export, reexport, or transfer (in-country) any item subject to the EAR when an entity that is listed on the Entity List is a party to the transaction as described in § 748.5(c) through (f). License exceptions may not be used unless authorized in the Entity List entry for the entity that is party to the transaction. Applications for licenses required by this section will be evaluated as stated in the Entity List entry for the entity that is party to the transaction, in addition to any other applicable review policy stated elsewhere in the EAR.

* * * * *

■ 3. Section 744.16 is amended by revising paragraph (a) to read as follows:

§ 744.16 Entity List.

* * * * *

(a) *License requirements.* In addition to the license requirements for items specified on the Commerce Control List (CCL), you may not, without a license from BIS, export, reexport, or transfer (in-country) any items included in the License Requirement column of an entity's entry on the Entity List (supplement No. 4 to this part) when that entity is a party to a transaction as described in § 748.5(c) through (f) of the EAR. The specific license requirement for each listed entity is identified in the license requirement column on the Entity List in Supplement No. 4 to this part.

* * * * *

■ 4. Supplement No. 4 to part 744 is amended by revising the introductory text of the supplement to read as follows:

Supplement No. 4 to Part 744—Entity List

This Supplement lists certain entities subject to license requirements for specified items under this part 744 and part 746 of the EAR. License requirements for these entities include exports, reexports, and transfers (in-country) unless otherwise stated. A license is required, to the extent specified on the Entity List, to export, reexport, or transfer (in-country) any item subject to the EAR when an entity that is listed on the Entity List is a party to the transaction as described in § 748.5(c) through (f). This list of entities is revised and updated on a periodic basis in this Supplement by adding new or amended notifications and deleting notifications no longer in effect.

* * * * *

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2020–17908 Filed 8–17–20; 2:30 pm]

BILLING CODE 3510–33–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 426

[Docket No. SSA–2020–0002]

RIN 0960–AI47

Improved Agency Guidance Documents

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: This final rule explains our process for issuing guidance documents under Executive Order (E.O.) 13891, ''Promoting the Rule of Law Through Improved Agency Guidance Documents.'' We will follow this process when we issue future guidance documents that meet the criteria set forth in the E.O. and the Office of Management and Budget's (OMB) guidance on the E.O.

DATES: This final rule will be effective September 21, 2020.

FOR FURTHER INFORMATION CONTACT: Jennifer Dulski, Office of Regulations and Reports Clearance, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 966–2341. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION: On October 9, 2019, President Trump issued E.O. 13891.[1] E.O. 13891 mandates that agencies, consistent with applicable law, finalize regulations, or amend existing regulations as necessary, to explain the process for issuing guidance documents as defined by the E.O. We are publishing this final rule to fulfill E.O. 13891's requirements.

As defined in E.O. 13891, guidance documents are agency statements of general applicability, intended to have future effect on the behavior of regulated parties, that set forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation. Unless the document falls within an enumerated exclusion to this definition,[2] any document that satisfies this definition would qualify as a guidance document, regardless of name or format.

The documents that we issue include Program Operations Manual System (POMS) instructions; the Hearings, Appeals and Litigation Law (HALLEX) manual; Social Security Rulings (SSR); and Acquiescence Rulings.[3] Most of the documents that we issue do not qualify as guidance documents under E.O. 13891; however, some may. We will use

[1] 84 FR 55235, available at: *https://www.federalregister.gov/documents/2019/10/15/2019-22623/promoting-the-rule-of-law-through-improved-agency-guidance-documents.*

[2] E.O. 13891 section 2 (b) lists the following as exclusions to the definition of guidance document: (i) Rules promulgated pursuant to notice and comment under section 553 of title 5, United States Code, or similar statutory provisions; (ii) rules exempt from rulemaking requirements under section 553(a) of title 5, United States Code; (iii) rules of agency organization, procedure, or practice; (iv) decisions of agency adjudications under section 554 of title 5, United States Code, or similar statutory provisions; (v) internal guidance directed to the issuing agency or other agencies that is not intended to have substantial future effect on the behavior of regulated parties; and (vi) internal executive branch legal advice or legal opinions addressed to executive branch officials. See 84 FR at 55235–36.

[3] See *other written guidelines* in 20 CFR 404.1602 and 416.1002 for more information about POMS and SSRs. See 20 CFR 402.35 for information about where we publish SSRs and ARs. See 20 CFR 404.985 and 416.1485 for more information about ARs. Additionally, our POMS instructions are publicly available at *https://secure.ssa.gov/poms.nsf/Home?readform,* our HALLEX manual is publicly available at *https://www.ssa.gov/OP_Home/hallex/hallex.html,* and our SSRs and ARs are publicly available at *https://www.ssa.gov/OP_Home/rulings/rulings.html.*

the process in this final rule for the documents we issue, as appropriate.

As required by E.O. 13891, this final rule includes:

- A requirement that each guidance document clearly state that it does not bind the public, except as authorized by law or as incorporated into a contract.
- Procedures for the public to petition for withdrawal or modification of a particular guidance document, including a designation of the official to whom the public should direct petitions.
- Specific requirements for a guidance document that qualifies as ''significant,'' unless an exemption applies.[4]

For significant guidance documents, absent an exemption from some or all requirements, this final rule sets forth the following requirements, as prescribed by E.O. 13891:

- A period of public notice and comment of at least 30 days before issuance, and a public response to major concerns raised in comments, except when we find, for good cause, that notice and public comment are impracticable, unnecessary, or contrary to the public interest.
- Approval on a non-delegable basis by our agency head or by the head of one of our components whom the President appoints, before issuance.
- Review by the Office of Information and Regulatory Affairs under Executive Order 12866, before issuance.
- Compliance with the applicable requirements for regulations or rules, including significant regulatory actions, set forth in Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), 13609 (Promoting International Regulatory Cooperation), 13771 (Reducing Regulation and Controlling Regulatory Costs), and 13777 (Enforcing the Regulatory Reform Agenda).

On October 31, 2019, OMB issued a memorandum, M–20–02 ''Guidance Implementing Executive Order 13891, Titled 'Promoting the Rule of Law Through Improved Agency Guidance Documents''' (Memorandum M–20–02).[5] Memorandum M–20–02 directs that an agency's regulations should require guidance documents to, at minimum:

- Include the term ''guidance.''
- Identify the agency or office issuing the document.
- Identify the activities to which and the persons to whom the document applies.
- Include the date of issuance.
- Note if it is a revision to a previously issued guidance document and, if so, identify the guidance document that it replaces.
- Provide the title of the guidance and the document identification number.
- Include the citation to the statutory provision or regulation to which it applies or which it interprets.
- Include the disclaimer that the guidance document does not have the force and effect of law and is not meant to bind the public, except as authorized by law or incorporated into a contract.
- Include a short summary of the subject matter covered in the guidance document at the top of the document.

Based on the requirements of E.O. 13891 and consistent with the guidance in Memorandum M–20–02, we are adding a new part to our regulations—20 CFR chapter III part 426.

For more information about the documents that we issue, please see *www.socialsecurity.gov/guidance.*

Rulemaking Analyses and Notices

Regulatory Procedures

We follow the Administrative Procedure Act (APA) rulemaking procedures in 5 U.S.C. 553 when we develop regulations. Generally, the APA requires that an agency provide prior notice and opportunity for public comment before issuing a final rule. Under 5 U.S.C. 553 (b)(3)(A), agencies are not required to provide prior notice and opportunity for the public to comment for a rule that is an interpretative rule, a general statement of policy, or a rule of agency organization, procedure, or practice. We find this rule is exempt from the requirement to provide prior notice and opportunity for public comment because it is a rule of ''agency organization, procedure, or practice.'' It merely explains the process we will follow when issuing guidance documents as defined by the E.O., and how we will comply with the requirements of the E.O. Accordingly, we are issuing this final rule without prior public comment.

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with OMB and determined that this final rule does not meet the requirements for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB did not review it.

Executive Order 13771

This final rule is not an Executive Order 13771 regulatory action because it results in costs that are *de minimis.*

Regulatory Flexibility Act

We certify that this final rule will not have a significant economic impact on a substantial number of small entities, because it affects individuals only. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Executive Order 13132

We analyzed this final rule in accordance with the principles and criteria established by Executive Order 13132, and determined that the rule will not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. We also determined that this final rule would not preempt any State law or State regulation or affect the States' abilities to discharge traditional State governmental functions.

Paperwork Reduction Act

This final rule does not impose any new requirements under the Paperwork Reduction Act (PRA), nor does it require modification to any of SSA's existing OMB PRA-approved information collections. If in the future SSA publishes individual guidance documents that involve public information collection, we will seek PRA approval for them in advance of collecting the information.

(Catalog of Federal Domestic Assistance Program Nos. 9601, Social Security—Disability Insurance; 96.006 Supplemental Security Income)

List of Subjects for 20 CFR Part 426

Social security, Guidance.

[4] A significant guidance document is a guidance document that may reasonably be anticipated to: (i) Lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (ii) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (iii) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (iv) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles of Executive Order 12866. E.O. 13891, section 2(c), 84 FR at 55236. The Administrator of the Office of Management and Budget's Office of Information and Regulatory Affairs determines if a guidance document is significant. An exemption applies when the agency and the Administrator agree that exigency, safety, health, or other compelling cause warrants an exemption from some or all requirements. E.O. 13891, section 4(a)(iii), 84 FR at 55237.

[5] Available at *https://www.whitehouse.gov/wp-content/uploads/2019/10/M-20-02-Guidance-Memo.pdf.*

The Commissioner of the Social Security Administration, Andrew Saul, having reviewed and approved this document, is delegating the authority to electronically sign this document to Faye I. Lipsky, who is the primary **Federal Register** Liaison for SSA, for purposes of publication in the **Federal Register**.

Faye I. Lipsky,

Federal Register Liaison, Office of Legislation and Congressional Affairs, Social Security Administration.

■ For the reasons set out in the preamble, we amend 20 CFR chapter III by adding part 426 to read as follows:

PART 426—GUIDANCE DOCUMENTS

Sec.

Authority: Secs. 205(a)–(b) and (d)–(h), and 702(a)(5) of the Social Security Act (42 U.S.C., 405(a)–(b) and (d)–(h) and 902(a)(5)); and E.O. 13891, 84 FR 55235.

§ 426.5 Purpose.

We established this part to comply with the requirements of Executive Order 13891 of October 9, 2019, Promoting the Rule of Law Through Improved Agency Guidance Documents. The rules in this part relate to agency guidance documents. They explain what constitutes guidance documents, describe the non-binding nature of guidance documents, the procedures to request withdrawal or modification of guidance documents, and the additional requirements and procedures for significant guidance documents.

§ 426.10 Explanation of agency guidance documents.

(a) *Guidance documents.* Guidance documents are agency statements of general applicability, intended to have future effect on the behavior of regulated parties, that set forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation.

(b) *Documents not classified as guidance.* Guidance documents do *not* include:

(1) Agency statements of specific, rather than general, applicability.

(2) Agency statements that do not set forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statute or regulation.

(3) Legislative rules promulgated under 5 U.S.C. 553 (or similar statutory provisions), or exempt from rulemaking requirements under 5 U.S.C. 553(a).

(4) Rules of agency organization, procedure, or practice.

(5) Decisions of agency adjudication.

(6) Documents or agency statements that are directed solely to the issuing agency or other agencies (or personnel of such agencies) that are not anticipated to have substantial future effect on the behavior of regulated parties or the public.

(7) Legal briefs and other court filings.

(8) Legal opinions by the Office of Legal Counsel at the Department of Justice.

(9) Legal advice or opinions from our Office of the General Counsel.

(c) *Elements of guidance documents.* In general, each published guidance document should, at a minimum:

(1) Include the term ''guidance.''

(2) Identify the agency or office issuing the document.

(3) Identify the activities to which and the persons to whom the document applies.

(4) Include the date of issuance.

(5) Note if it is a revision to a previously issued guidance document and, if so, identify the guidance document that it replaces.

(6) Provide the title of the guidance and the unique document identification number.

(7) Include the citation to the statutory provision or regulation to which it applies or which it interprets.

(8) Include the disclaimer in 20 CFR 426.15(b).

(9) Include a short summary of the subject matter covered in the guidance document at the top of the document.

(d) *Our guidance documents.* Any document that satisfies the definition in paragraph (a) of this section and that does not meet an exclusion in paragraph (b) of this section qualifies as a guidance document, regardless of name or format. On our internet site, we maintain an indexed, searchable web page, which contains links to all of our guidance documents in effect.

(e) *Rescinded guidance documents.* We will not cite, use, or rely on guidance documents that are rescinded, except to establish historical facts. Any guidance documents that do not appear on our internet site as described in paragraph (d) of this section, will be considered rescinded.

§ 426.15 When guidance documents are nonbinding.

(a) Guidance documents lack the force and effect of law, unless expressly authorized by law or incorporated into a contract.

(b) We will include a disclaimer on guidance documents clarifying that they do not have the force and effect of law and are not meant to bind the public in any way, and are intended only to provide clarity to the public regarding existing requirements under the law or agency policies. When a guidance document is binding because the law authorizes binding guidance or because a contract incorporates the guidance, we will modify the disclaimer to reflect either of those facts.

§ 426.20 Procedures for the public to request withdrawal or modification of a guidance document.

The public may ask us to consider withdrawing or modifying an existing guidance document. The public may direct these requests to the Commissioner of the Social Security Administration by sending an email to *Regulations@ssa.gov* or mail to 3100 West High Rise, 6401 Security Boulevard, Baltimore, Maryland 21235–6401. We will respond within 90 days of receipt.

§ 426.25 Significant guidance documents.

(a) *Significant guidance documents.* Significant guidance documents are guidance documents that may be reasonably anticipated to do one or more of the following:

(1) Lead to an annual effect on the economy of $100 million or more, or adversely and materially affect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

(2) Create a serious inconsistency or otherwise interfere with an action another agency has taken or planned.

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles of Executive Order 12866.

(b) *Significance determination.* We will refer to the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, or the Administrator's designee, the question of whether a guidance document is significant.

(c) *Actions we will take before issuing significant guidance documents.* For significant guidance documents, unless we and the Administrator of the Office of Information and Regulatory Affairs agree that exigency, safety, health, or other compelling cause warrants an exemption from some or all requirements, we will do the following:

(1) Submit the guidance document for review by the Office of Information and Regulatory Affairs under Executive Order 12866.

(2) Publish a document in the **Federal Register** announcing the availability of a significant guidance document and make the draft guidance document available on our website.

(3) Provide a public notice and comment period of at least 30 days before issuance of a final guidance document, and a public response to major concerns raised in comments, except when we for good cause find (and incorporate such finding and a brief statement of reasons therefor into the guidance document) that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.

(4) Obtain approval on a non-delegable basis from the Commissioner of Social Security, or from a component head the President appoints (with or without confirmation by the Senate), or from an official who is serving in an acting capacity as either of the foregoing.

(5) Comply with the applicable requirements for regulations or rules, including significant regulatory actions, set forth in Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), 13609 (Promoting International Regulatory Cooperation), 13771 (Reducing Regulation and Controlling Regulatory Costs), and 13777 (Enforcing the Regulatory Reform Agenda).

[FR Doc. 2020–17878 Filed 8–19–20; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–581]

Schedules of Controlled Substances: Placement of Cenobamate in Schedule V

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts, without change, an interim final rule with request for comments published in the **Federal Register** on March 10, 2020, placing cenobamate [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate, including its salts, in schedule V of the Controlled Substances Act (CSA). With the issuance of this final rule, the Drug Enforcement Administration maintains cenobamate, including its salts, in schedule V of the CSA.

DATES: The effective date of this rulemaking is August 20, 2020.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114–89), when the Drug Enforcement Administration (DEA) receives notification from the Department of Health and Human Services (HHS) that the Secretary has approved a certain new drug and HHS recommends control in the CSA schedule II–V, DEA is required to issue an interim final rule, with opportunity for public comment and to request a hearing, controlling the drug within a specified 90-day timeframe and subsequently to issue a final rule. 21 U.S.C. 811(j). When controlling a drug pursuant to subsection (j), DEA must apply the scheduling criteria of 21 U.S.C. 811 (b) through (d) and 812(b). 21 U.S.C. 811(j)(3).

On March 10, 2020, DEA published an interim final rule in the **Federal Register** to make cenobamate (including its salts) a schedule V controlled substance. 85 FR 13741. The interim final rule provided an opportunity for interested persons to submit comments, as well as file a request for hearing or waiver of hearing, on or before April 9, 2020. DEA received two comments and did not receive any requests for hearing or waiver of hearing.

Comments Received

In response to the interim final rule, DEA received two comments. One comment was blank and the second comment was not related to the scheduling of cenobamate. Therefore, DEA has no responses to those comments.

Based on the rationale set forth in the interim final rule, DEA adopts the interim final rule, without change.

Requirements for Handling Cenobamate

As indicated above, cenobamate has been a schedule V controlled substance by virtue of an interim final rule issued by DEA in March 2020. Thus, this final rule does not alter the regulatory requirements applicable to handlers of cenobamate that have been in place since that time. Nonetheless, for informational purposes, we restate here those requirements. Cenobamate is subject to the CSA's schedule V regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, dispensing, importing, exporting, research, and conduct of instructional activities and chemical analysis with, and possession involving schedule V substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, dispenses, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) cenobamate, or who desires to handle cenobamate, must be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312. Any person who intends to handle cenobamate, and is not registered with DEA, must submit an application for registration and may not continue to handle cenobamate, unless DEA has approved that application for registration, pursuant to 21 U.S.C. 822, 823, 957, and 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who obtains a schedule V registration to handle cenobamate and subsequently determines they are no longer willing or able to maintain such registration must surrender all quantities of currently held cenobamate, or may transfer all quantities of cenobamate to a person registered with DEA in accordance with 21 CFR part 1317, in addition to all other applicable Federal, State, local, and tribal laws.

3. *Security.* Cenobamate is subject to schedule III–V security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.93. Non-practitioners handling cenobamate must also comply with the employee screening requirements of 21 CFR 1301.90–1301.93.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of cenobamate must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302.

5. *Inventory.* Since March 10, 2020, every DEA registrant who possesses any quantity of cenobamate was required to keep an inventory of cenobamate on hand, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.