



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1312

[Docket No. DEA-730]

RIN 1117-AB87

Extension of Reexportation Period.

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: This proposed rule would amend the regulations of the Drug Enforcement Administration (DEA) to extend the time allowed for reexports of controlled substances outside of the European Economic Area from 180 days from the date of original release from U.S. Customs and Border Protection to 365 days from that original release date.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-730” on all correspondence, including any attachments.

- *Electronic comments:* 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. 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. Should you wish to mail a paper comment in lieu of an electronic comment it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, VA 22152.

- *Paperwork Reduction Act comments:* All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, OMB, Attn: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117-AB87/Docket No. DEA-730.

FOR FURTHER INFORMATION CONTACT: Heather E. Achbach, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, VA 22152; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

I. Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by 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 or confidential business information identified as directed above will be made publicly available in redacted form. 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 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 confidential as directed above.

An electronic copy of this proposed rule and a plain language summary are available at <http://www.regulations.gov> for easy reference.

II. Legal Authority

The Controlled Substances Act (CSA) grants the Attorney General authority to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals and the efficient execution of his statutory functions under the CSA.¹ The Attorney General is further authorized by the CSA to promulgate rules and regulations relating to the registration and

¹ 21 U.S.C. 821, 822(a), 871(b), and 957(b).

control of importers and exporters of controlled substances and listed chemicals.² The Attorney General has delegated this authority to the Administrator of DEA.³

III. Background and Purpose of the Proposed Rule

The Controlled Substances Export Reform Act of 2005, Pub. L. 109-57, 119 Stat. 592 (CSERA) amended the CSA to allow “any controlled substance that is in schedule I or II, or is a narcotic drug in schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country” if specific conditions are met.⁴ Prior to enactment of the CSERA, it was impermissible to export a controlled substance in schedules I and II or a narcotic controlled substance in schedules III and IV for the purpose of reexport to another country. Such controlled substances could lawfully be exported only to the immediate country where they would be consumed. DEA issued a final rule implementing the CSERA in 2007.⁵ Although the Notice of Proposed Rulemaking (NPRM) corresponding to that final rule proposed a 90-day time period for reexports,⁶ the final rule extended this time period to 180 days in response to the public comments received.⁷

The Improving Regulatory Transparency for New Medical Therapies Act was enacted in 2015 as Public Law 114-89, 129 Stat. 698 (IRTNMTA). In relevant part, the IRTNMTA allows reexports from one European Economic Area (EEA) member to another⁸ if certain conditions are met by each country to which the controlled substance is subsequently exported. The IRTNMTA requires, within 30 days of the reexportation, that the person who exported the controlled substance from the United States deliver to the Attorney General documentation certifying the reexport and information concerning the consignee, country, and product.⁹ Furthermore, the Attorney General cannot promulgate or enforce any

² 21 U.S.C. 958(f).

³ 28 CFR 0.100(b).

⁴ 21 U.S.C. 953(f).

⁵ 72 FR 72921 (Dec. 26, 2007).

⁶ 71 FR 61436, 61437 (Oct. 18, 2006).

⁷ 72 FR at 72923.

⁸ 21 U.S.C. 953(f)(5).

⁹ 21 U.S.C. 953(f)(6).

regulation, subregulatory guidance, or enforcement policy that impedes reexportation of any controlled substance among EEA countries, including any requirement that reexportation from the first country to the second or from the second to another country occur within a specified period of time.¹⁰ DEA issued a final rule implementing the IRTNMTA in 2016.¹¹

Except for reexports among countries of the EEA in accordance with 21 U.S.C. 953(f), DEA's current regulation on reexportation, codified at 21 CFR 1312.22(h)(6), allows any controlled substance listed in schedule I or II or any narcotic drug listed in schedule III or IV to be reexported only within 180 days of the date when the controlled substance was released by U.S. Customs and Border Protection (CBP). The purpose of this proposed rule is to extend the time period during which such controlled substances may be reexported once released by CBP (except for reexports among countries of the EEA in accordance with 21 U.S.C. 953(f)). DEA has found that the current limit of 180 days is often too short to allow reexportation because of circumstances beyond the control of the initial exporter. When these circumstances occur, they create additional difficulties for the exporter and DEA. These additional difficulties include delays in facilities receiving their licenses, which can cause receipt of shipments to be postponed; issues fulfilling back orders, and supply chain issues. This proposed rule would amend DEA regulations to extend the reexportation period from up to 180 days to a limit of 365 days after the release by a customs officer of the United States. This change will ease the difficulties facing exporters and DEA when uncontrollable circumstances delay reexportation.

IV. Need for Regulatory Changes

Regulatory changes to existing DEA regulations are needed to extend the time period necessary for the reexportation of certain controlled substances once released by a customs officer of the United States. DEA has found that the current limit of 180 days is being

¹⁰ 21 U.S.C. 953(g).

¹¹ 81 FR 96992 (Dec. 30, 2016).

exceeded because of circumstances beyond the control of the initial exporter. DEA has found that 180 days has not been a sufficient amount of time for companies to perform logistical operations needed for reexportation, such as storing and moving exports. Compliance with the 180-day limit can be infeasible because of manufacturing issues; geopolitical issues, like closures of airspace; facility licensing delays; and the inability to fulfill back orders. Therefore, this proposed rule would amend existing DEA regulations in 21 CFR 1312.22(h)(6) in order to increase the limit from a maximum of 180 days to a maximum of 365 days for reexportation of certain controlled substances.

V. Regulatory Analyses

Executive Orders 12866, 13563, and 14192 (Regulatory Review)

The Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB) has determined that this rulemaking is a “significant regulatory action” under section 3(f) of Executive Order (EO) 12866, *Regulatory Planning and Review*, 58 FR 51735, 51738 (Sep. 30, 1993), but it is not an economically significant action under section 3(f)(1). Accordingly, DEA has submitted this proposed rule to OMB for review. This proposed rule has been drafted and reviewed in accordance with section 1(B) of EO 12866, as well as section 1(b) of EO 13563, *Improving Regulation and Regulatory Review*, 76 FR 3821, 3821 (Jan. 18, 2011), and EO 14192 *Unleashing Prosperity Through Deregulation*, 90 FR 9065 (Jan. 31, 2025).

This proposed rule is expected to be a deregulatory action under EO 14192 because it has a total cost less than zero. DEA estimates a total cost savings of \$349 annually as a result of the proposed rule, which equates to a present value of \$2,451 at a seven percent discount rate over a 10-year analysis period.

Assessment of Benefits and Costs

Currently, except in the case of reexports among countries in the EEA, the deadline for reexports is 180 days from the date of original release from CBP. If the exporter

anticipates that the reexport deadline will be exceeded, it must notify DEA of the anticipated delay and request a one-time waiver of this requirement. This proposed rule would amend DEA regulations to extend the time allowed for reexportation from 180 days to 365 days. By extending the deadline to 365 days, DEA estimates these notifications and requests for waivers from exporters will be virtually eliminated, generating cost savings for exporters and DEA. DEA has examined the benefits and costs of this proposed rule as described below.

As stated above, currently the deadline is 180 days for reexport for non-EEA countries. The U.S. exporter must notify DEA and request a one-time waiver if there will be a delay. There is no standard method for reporting the delay. Typically, the registrant calls or emails DEA's Import/Export Section, the registration call center, or a field office to notify DEA about the probable delay and to request guidance. The exporter is referred to DEA's Office of Diversion Control Policy, Policy Section for guidance, and the Policy Section generally suggests that the exporter needs to submit a request for a waiver of the anticipated violation of the 180-day deadline.

DEA estimates that, on average, there are currently three delays per year, where the exporter notifies DEA of the anticipated delay and the exporter submits a request for a waiver. By extending the deadline to 365 days, DEA estimates these notifications and requests for waivers from exporters will be virtually eliminated, generating cost savings for exporters. The primary cost savings from this proposed rule would result from registrants not needing to notify DEA of the delay and submit a request for a waiver. Based on an estimated two hours for the exporter to contact DEA and to submit a request for a waiver, DEA estimates a cost savings of \$116.20 per each event (notification and request for waiver) or annual cost savings associated with this rule for exporters of \$348.60.¹²

¹² These figures are based on the U.S. Bureau of Labor Statistics (BLS) estimates for occupation code 13-1041: Compliance Officer. The mean hourly wage for that position according to the May 2024 National Occupational Employment and Wage Estimates United States, https://www.bls.gov/oes/current/oes_nat.htm, is \$40.86. Based on the BLS report, "Employer Costs for Employee Compensation – March 2025," <https://www.bls.gov/news.release/pdf/ecec.pdf>, for private industry workers, total benefits is 29.7 percent and

There are also some benefits that cannot be quantified. By extending the deadline from 180 to 365 days, exporters will gain more flexibility in adjusting to any unforeseen logistical circumstances and conducting reexports. Currently, exporters may make decisions that are not economically optimal in order to meet the 180-day deadline. By essentially doubling the deadline to 365 days, the proposed rule would allow exporters to explore economically optimal options and minimize the costs associated with meeting the 180-day deadline.

DEA may also save costs from not having to respond to inquiries and not processing waiver requests. However, there are only approximately three such inquiries per year, so any cost savings to DEA would be minimal.

In summary, this proposed rule would essentially eliminate the need for an exporter to contact DEA and request a waiver of the requirement to reexport before the deadline. DEA estimates a cost savings of \$116.20 per request not made, resulting in annual cost savings of \$348.60 (\$349 rounded) for an estimated three delays per year. An annual cost savings of \$349 over a 10-year time horizon equates to a present value of cost savings of \$2,451 at seven percent discount rate.

Executive Order 12988 (Civil Justice Reform)

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of EO 12988, 61 FR 4729 (Feb. 5, 1996), to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burdens.

Executive Order 13132 (Federalism)

This proposed rule does not have federalism implications warranting the application of EO 13132, 64 FR 43255 (Aug. 4, 1999). The proposed rule does not have substantial

¹ ‘wages and salaries’ is 70.3 percent of total compensation. The 30 percent of total compensation equates to 42.2 percent of wages and salaries ($29.7 / 70.3 = 0.422$). Therefore, an additional 42.2 percent load is added to the wage rate to account for benefits. Factoring in benefits, then, the cost of one hour’s work for a compliance officer is \$40.86 multiplied by 1.422, or \$58.10. The estimated two hours for a compliance officer to write and submit exception requests therefore equates to \$116.20 ($2 \times \58.10) per delay. Multiplying \$116.20 by the three delays that occur annually equates to a total annual cost saving of \$348.60.

direct effects on the States, on the relationship between the national government and the States, or on 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 EO 13175, 65 FR 67249 (Nov. 6, 2000). The 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.

Executive Order 14267 (Reducing Anti-Competitive Regulatory Barriers)

The proposed rule does not reduce competition, entrepreneurship, and innovation and therefore does not run afoul of EO 14267, 90 FR 15629 (Apr. 15, 2025).

Executive Order 14294 (Overcriminalization of Federal Regulations)

EO 14294, 90 FR 20363 (May 14, 2025), specifies that all NPRMs and final rules published in the *Federal Register*, the violation of which may constitute criminal regulatory offenses, should include a statement identifying that the rule or proposed rule is a criminal regulatory offense, the authorizing statute, and the mens rea requirement for each element of the offense. This final rule does not involve a criminal regulatory offense and thus EO 14294 does not apply.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a Regulatory Impact Analysis to evaluate options for regulatory relief of small entities unless it can certify that the proposed rule will not have a significant impact on a substantial number of small entities. DEA has analyzed the economic impact of each provision of this proposed rule and estimates that it will have minimal economic impact on affected entities, including small businesses, nonprofit organizations, and small governmental jurisdictions.

This proposed rule would amend DEA regulations to extend the time allowed for reexportation of controlled substances from 180 days to 365 days. As discussed above, by extending the deadline to 365 days, this proposed rule would essentially eliminate the need for an exporter to contact DEA and request a waiver of the requirement to reexport before the deadline. DEA estimates cost savings of \$116.20 per request or an annual cost savings of \$348.60 for the estimated three delays that occur each year.

Based on the number of inquiries received per year, DEA estimates there are three controlled substances exporters affected by this proposed rule. DEA assumes the three registrations represent three different entities, meaning that, at most, three small entities are affected by this proposed rule. The North American Industry Classification System (NAICS) code 424210 (Drugs and Druggists' Sundries Merchant Wholesalers) best represents the industry affected by this proposed rule. Based on data from the U.S. Small Business Administration¹³ and the U.S. Census Bureau's Statistics of U.S. Businesses (SUSB), 6,703 of the total 7,012 firms in NAICS industry code 424210 are small businesses with fewer than 250 employees.¹⁴ The three small entities affected by this proposed rule thus account for 0.04 percent of the relevant small businesses, and they accordingly do not amount to a "substantial" number of the small entities in NAICS code 424210. Therefore, DEA certifies that this proposed rule will not, if promulgated, have 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 of 1995 (UMRA),¹⁵ 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

¹³ Table of size standards, U.S. Small Business Administration, <https://www.sba.gov/document/support-table-size-standards> (last accessed Sept. 30, 2025).

¹⁴ 2022 SUSB Annual Datasets by Establishment Industry, "U.S. & states, NAICS, detailed employment sizes (U.S., 6-digit and states, NAICS sectors)," <https://www.census.gov/data/tables/2022/econ/susb/2022-susb-annual.html> (last accessed Sept. 30, 2025).

¹⁵ 2 U.S.C. 1501 *et seq.*

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 the UMRA.

Paperwork Reduction Act

This proposed rule would modify existing collections of information requirements under the Paperwork Reduction Act (PRA).¹⁶ Pursuant to the PRA,¹⁷ DEA has identified the collections of information below related to this proposed rule. A person is not required to respond to a collection of information unless it displays a valid OMB control number.¹⁸

A. Collections of Information Associated with the Proposed Rule

Title: Application for Permit to Export Controlled Substances-DEA 161, Application for Permit to Export Controlled Substances for Subsequent Reexport-DEA 161R

OMB Control Number: 1117-0004

Form Number: DEA-161/161R/161R-EEA

DEA is proposing to amend its regulations in order to extend the time allowed for reexportation of certain controlled substances from 180 days from the date of original release from CBP to 365 days from that original release date. This change will affect the instructions for completing form DEA-161R, but it will not require submission of additional information to complete that form, nor will it affect form DEA-161.

DEA anticipates no change in the number of respondents or the burden associated with this information collection as a result of this proposed rule. DEA estimates the following number of respondents and burden associated with this collection of information:¹⁹

- Number of respondents: 162
- Number of responses: 10,180

¹⁶ 44 U.S.C. 3501 *et seq.*

¹⁷ 44 U.S.C. 3507(d).

¹⁸ Copies of existing information collections approved by OMB may be obtained at <http://www.reginfo.gov/public/do/PRAMain>.

¹⁹ This information collection request pertains to the use of DEA Forms 161 and 161R generally, and not just to the proposed revision to the time allowed for reexportation. Accordingly, the burden estimates provided here are for all uses of Forms 161 and 161R.

- Frequency of response: 62.83951 (as needed, calculated average)
- Burden per response: 0.5535363²⁰
- Total annual hour burden: 5,635

B. Request for Comments Regarding the Proposed Collections of Information

Written comments and suggestions from the public and affected entities concerning the proposed collections of information are encouraged. Under the PRA, DEA is required to provide a notice regarding the proposed collections of information in the *Federal Register* with the proposed rule and solicit public comment. Pursuant to section 3506(c)(2) of the PRA (44 U.S.C. 3506(c)(2)), DEA solicits comments on the following issues:

- Whether the proposed collection of information is necessary for the proper performance of the functions of DEA, including whether the information will have practical utility.
- The accuracy of DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Recommendations to enhance the quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

All comments concerning collections of information under the PRA must be submitted to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117-AB87/Docket No. DEA-730. All comments must be submitted to OMB on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL

²⁰ This is the weighted average burden per response for forms DEA-161, 161R, and 161R-EEA.

REGISTER]. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposed rule.

If you need a copy of the proposed information collection instrument(s) with instructions or additional information, please contact the Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, VA 22152; Telephone: (571) 362-3261.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

21 CFR Part 1312

Administrative practice and procedure, Drug traffic control, Exports, Imports.

21 CFR Part 1321

Administrative practice and procedure.

For the reasons stated in the preamble, DEA proposes to amend 21 CFR part 1312 as follows:

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

1. The authority citation for part 1312 continues to read as follows:

Authority: 21 U.S.C. 821, 871(b), 952, 953, 954, 957, 958.

2. In § 1312.22, revise paragraph (h)(6) to read as follows:

§ 1312.22 Application for export or reexport permit; return information.

* * * * *

(h) * * *

(6) Except in the case of reexports among countries of the European Economic Area in accordance with section 1003(f) of the Act (21 U.S.C. 953(f)), the controlled substance will be reexported from the first country to the second country (or second countries) no later than 365 calendar days after the controlled substance was released by a customs officer from the United States.

* * * * *

SIGNING AUTHORITY

This document of the Drug Enforcement Administration was signed on September 21, 2026, by DEA Administrator Terrance C. Cole. That document with the original signature and date is maintained by DEA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DEA Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DEA. This administrative process in no way alters the legal effect of this document upon publication in the Federal Register.

Heather Achbach,
Federal Register Liaison Officer,
Drug Enforcement Administration.

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