

Application for Permit to Export Controlled Substances – DEA Form 161,
Application for Permit to Export Controlled Substances for Subsequent Re-export – DEA Form 161R, Application
for Permit to Export Controlled Substances for Subsequent Re-export Among Members of the European Economic
Area – DEA Form 161R–EEA
OMB Control Number: 1117-0004
OMB Expiration Date: 11/30/2023

SUPPORTING STATEMENT FOR
Application for Permit to Export Controlled Substances – DEA Form 161,
Application for Permit to Export Controlled Substances for Subsequent Re-export – DEA
Form 161R, Application for Permit to Export Controlled Substances for Subsequent Re-
export Among Members of the European Economic Area – DEA Form 161R–EEA

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for a revision of an existing collection of information that was previously approved by OMB – OMB Approval# 1117-0004, Application for Permit to Export Controlled Substances – DEA Form 161, Application for Permit to Export Controlled Substances for Subsequent Re-export – DEA Form 161R, Application for Permit to Export Controlled Substances for Subsequent Re-export Among Members of the European Economic Area – DEA Form 161R–EEA.

A. JUSTIFICATION

1. Section 1003 of the Controlled Substances Import and Export Act (21 U.S.C. 953) and Title 21, Code of Federal Regulations (21 CFR), Sections 1312.21 and 1312.22 require that any person who desires to export or re-export controlled substances listed in Schedules I or II, any narcotic substance listed in Schedules III or IV, or any non-narcotic substance in Schedule III which the Administrator has specifically designated by regulation in §1312.30, or any non-narcotic substance in Schedule IV or V which is also listed in Schedule I or II of the Convention on Psychotropic Substances, must have an export permit. To obtain the export permit, an application for the permit must be made by electronic filing to DEA on DEA Form 161 for exports, DEA Form 161R for re-exports to countries that are not members of the European Economic Area, and Form 161R-EEA for re-exports among members of the European Economic Area.

2. These forms and the information collection help maintain a closed system of distribution. DEA Form 161, Application for Permit to Export Controlled Substances, DEA Form 161r, Application for Permit to Export Controlled Substances for Subsequent Re-export, and DEA Form 161–EEA, Application for Permit to Export Controlled Substances for Subsequent Re-export Among Members of the European Economic Area, are intended to enable DEA to monitor and control the export of certain controlled substances to other countries. This information is also necessary for DEA to prepare a Permit to Export, DEA Form 236, which is required in order to lawfully export specific controlled substances. The permit for exportation and re-exportation of specific controlled substances enables DEA to enforce the Controlled Substances Import and Export Act.

Through § 1312.22, DEA requires that within 30 calendar days after a controlled substance is released by a customs officer at the port of export from the United States in accordance with the

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permitting process, or within 10 calendar days after receipt of a written request by the Administration to the exporter, whichever is sooner, the exporter must file a report with the Administration utilizing the secure network application available on DEA’s Diversion Control Division Web site that such export has occurred and the specifics of the transaction. The report must include information relating to key dates of the transaction(s) and actual quantities involved in the export process.

DEA Form 161R-EEA, “Application for Permit to Export Controlled Substances for Subsequent Re-export Among Members of the European Economic Area,” is used by registrants who export controlled substances for re-export among members of the European Economic Area. Specifically, in § 1312.22, DEA requires within 30 calendar days after the controlled substance is released by a customs officer at the port of export the exporter to file a report with the Administration through DEA’s Diversion Control Division secure network application of the particulars of the transaction. Furthermore, the exporter must file similar return information within 30 days of the controlled substances being exported from the first country to the second country and for each subsequent re-export among members of the European Economic Area.

3. Pursuant to § 1312.22, DEA requires applicants for a permit to export controlled substances to access, complete, and submit DEA Forms 161, 161R, and 161R-EEA, and associated return information, as appropriate, through DEA’s Diversion Control Diversion secure network application. Currently, 100% of DEA Forms 161, 161R, and 161R-EEA are submitted electronically.

DEA transmits the original permit to the pertinent foreign competent national authorities. The “copies” issued by DEA to registrants are only accessible through DEA Diversion Control Division’s secure network application.

4. DEA has made efforts to identify and prevent duplication of the collection of information. DEA Forms 161, 161R, 161R-EEA are not duplicative. The collection of this information is unique to DEA.

5. DEA does not anticipate any additional impact on small business or other small entities since the last approval of this form. The revised collection will not have a significant economic impact on small business or other small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601-612.

6. Information is provided by registrants each time registrants propose to export or re-export certain controlled substances and therefore cannot be collected less frequently. The Attorney General may authorize 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. Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States delivers to the Attorney General documentation certifying that such export from the first country has occurred. 21 USC 953(f)(6). This is required by statute. Failure to collect the information would impair DEA’s enforcement of the statute and compliance with requirements under international treaties. Businesses and other for-profit entities participating in this information collection maintain the requested data as part of usual and customary business practices.

7. There are no special circumstances applicable to this information collection.

8. The 60-Day Notice was published in the Federal Register on September 11, 2023 (88 FR 62399). The comment period ended on November 13, 2023. No comments were received.

9. This collection of information does not propose to provide any payment or gift to respondents.

10. Information requested in this collection may be considered confidential business information if marked as such in accordance with 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). Submitters who are required to furnish commercial or financial information to the government are protected from the competitive disadvantages that could result from disclosure of such information. This information is protected by DEA through secure storage, limited access, and federal regulatory and DEA procedures. In the event a FOIA request is made to obtain information that has been designated as confidential business information in accordance with 28 CFR 16.8(c) and Exemption 4 of FOIA, DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by DEA.

11. This collection of information does not ask any questions of a sensitive nature.

12.

Estimated Annualized Respondent Cost and Hour Burden

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Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response	Total Annual Burden (Hours)	Hourly Rate ¹	Monetized Value of Respondent Time ²
DEA-161 (Online)		49.3950617 3	8,002	30min	4,001	\$67.67	\$ 270,765
DEA-161/161R/161R-EEA (Paper)	162	13.44444	2,178	45min	1,634	\$67.67	\$ 110,580
Unduplicated Totals	162		10,180		5,635		\$ 381,345

* Based on the number of registration numbers. A respondent may use any of the three form/versions above. Separately counting the number of respondents for each form/version would result in multiple counts of the same respondent. Therefore, the number of combined respondents is used.

Total number of respondents:	162
Number of responses per respondent per year:	62.83
	951 (average)
Total annual responses	10,180
Total annual hour burden	5,635
	0.5535
Average burden, per collection:	364
	34.78
Average burden, per respondent:	395

Burden dollars:

Estimate hourly wage (\$/hour): ³	\$47.39
Load for benefits (percent of labor rate): ⁴	42.7%
Loaded labor rate (\$/hour): ⁵	\$67.67

¹ Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2022, 11-3071 Transportation, Storage, and Distribution Managers (https://www.bls.gov/oes/current/oes_nat.htm).

² Monetized value is based on the loaded wage multiplied by the total annual burden, in hours. Bureau of Labor Statistics, “Employer Costs for Employee Compensation – March 2023” (ECEC) reports that average benefits for private industry is 29.97% of total compensation. The 29.97% of total compensation equates to 42.8% (29.97% / 70.07%) load on wages and salaries. The median wage of \$47.39 times (1 + 0.428) = \$67.67 per hour for the loaded wage.

³ Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2023, 11-3071 Transportation, Storage, and Distribution Managers (https://www.bls.gov/oes/current/oes_nat.htm).

⁴ Bureau of Labor Statistics, “Employer Costs for Employee Compensation – March 2023” (ECEC) reports that average benefits for private industry is 29.97% of total compensation. The 29.9% of total compensation equates to 42.8% (29.97% / 70.07%) load on wages and salaries.

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Burden by form	DEA 161	DEA 161R/ 161R-EEA	Total
Number of responses	8,002	2,178	10,180
Burden per response (hour)	0.50	0.75	N/A
Total burden hours	4,001	1,634	5,635
Burden dollars per response (\$)	33.83 722	50.75 583	N/A
Total burden dollars (\$)	270,765. 44	110,546. 20	381,311. 64

13. There are/are no start up costs associated with this collection.

14. The estimated annual cost to the Federal Government is \$419,035. This includes the annual salaries for a GS-14 Staff Coordinator, GS-13 Program Analyst, and GS-13 Import/Export Specialist. The Program Analyst is available for 60% of total time, while other staff are available for 25% of their total available time.

Labor Category	Number	Annual rate (\$)*	Load**	% of time	Cost (\$)
Staff Coordinator - GS-14	1	150,016.00	1.7414649 3	25%	65,312
Program Analyst - GS-13	1	126,949.00	1.7414649 3	60%	132,646
Import/Export Specialist - GS-13	2	126,949.00	1.7414649 3	25%	221,077
Total					419,035

*Government salary figures are based on Washington, DC locality pay at step 5 for each grade level.

**Load of 74.15% for benefits based on the ECEC for “State and local government.” The ECEC does not include figures for the Federal Government.

15. Explain the reasons for any program changes or adjustments.

The increase in annual responses and annual burden hours reflect adjustments related to normal business activity. There have been no statutory or regulatory changes affecting this information collection. The table below summarizes the changes since the last renewal of this information collection.

	2020 Approved Burden	2023 Requested Burden	Difference

⁵ \$47.39 x (1 + 0.428) = \$67.67.

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Annual responses	7,282	10,180	2,898
Annual burden hours	3,839	5,635	1,796
Annual cost (\$)	249,018	381,435	132,417

16. DEA will not publish the results of the information collected.

17. DEA is not seeking approval not to display the expiration date for OMB approval of this information collection.

18. This collection of information does not include any exceptions to the certificate statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS.

This collection does/does not contain statistical data.