

## **SUPPORTING STATEMENT FOR Exempt Chemical Preparations under the Controlled Substance Act**

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for an existing collection of information that was previously approved by OMB – OMB Approval #1117-0058, Exempt Chemical Preparations under the Controlled Substance Act.

This information collection would require any person, wishing to exempt a chemical preparation, to submit an application.

### **A. JUSTIFICATION**

1. In accordance with the Controlled Substances Act (CSA), 21 U.S.C. 811(g)(3)(B), DEA may exempt from specific provisions of the CSA, any compound, mixture, or preparation containing any controlled substance, which is not for administration to a human being or animal, and which is packaged in a certain manner, so that as packaged it does not present any significant potential for abuse. 21 U.S.C. 811(g)(3)(B). DEA must conduct a case-by-case analysis of each application under 21 CFR 1308.23 to ensure that exempt chemical preparations are compliant with current statutory and regulatory requirements. To best serve the public interest, DEA must remain vigilant to ensure that exempt chemical preparations are consistent with the standards set forth in the CSA and implementing regulations. In addition, DEA must routinely evaluate requests from applicants industry, and the public related to exempt chemical preparations. The review and response to these requests provides the requestor with the necessary information to apply, make requests related to their current exemptions, or gain clarification about the exemption process.

2. DEA's regulations require any person wishing to have any preparation of mixture containing a controlled substance and one or more noncontrolled substances exempted from any part of the CSA to apply to the Drug and Chemical Evaluation Section within the Diversion Control Division of DEA. 21 CFR 1308.23(b). This application would provide a uniform method of applying for an exemption. The application would help DEA determine whether the exemption should be granted. The application for an exemption will include: (1) the name, address, and registration number, if any, of the applicant; (2) the name, address, and registration number, if any, of the manufacturer or importer of the preparation or mixture, if not the applicant; (3) the exact trade name or other designation of the preparation or mixture; (4) the complete qualitative and quantitative composition of the preparation or mixture (including all active and inactive ingredients and all controlled and non-controlled substances); (5) the form of the immediate container in which the preparation or mixture will be distributed with sufficient descriptive detail to identify the preparation or mixture (e.g., bottle, packet, vial, soft plastic pillow, agar gel plate, etc.); (6) the dimensions or capacity of the immediate container of the preparation or mixture; (7) the label and labeling of the immediate container and the commercial containers, if any, of the preparation or mixture

such as a Laboratory Use Only statement; (8) a brief statement of the facts which the applicant believes justify the granting of an exemption under this paragraph, including information on the use to which the preparation or mixture will be put; (9) the date of the application; and (10) which of the information submitted on the application, if any, is deemed by the applicant to be a trade secret or otherwise confidential and entitled to protection under subsection 402(a)(8) of the CSA ([21 U.S.C. 842\(a\) \(8\)](#)) or any other law restricting public disclosure of information.

Additionally, to streamline the process of submitting requests related to exempt chemical preparations, the application will allow applicants to: (11) create a web user account; (12) submit importer or exporter semi-annual reports of narcotic exempt chemical preparations as required by 21 CFR 1308.24(d); (13) submit requests to remove previously approved exempt chemical preparations from the approval listing; (14) submit requests for a letter showing currently approved exempt chemical preparations; (15) identify which exempt chemical preparations they may be reapplying for; (16) submit requests for changes to previously approved solvents; and (17) submit questions related to submitted exempt chemical preparation requests.

DEA will maintain a current list of exempt chemical preparations on its Web site as, [http://www.deadiversion.usdoj.gov/schedules/exempt/exempt\\_chemlist.pdf](http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_chemlist.pdf), which will include the revocation date of each exempt chemical preparation.

3. The Exempt Chemicals Application will be available electronically on the DEA Diversion Control Division's website at <https://www.deadiversion.usdoj.gov>, as well as by paper. DEA estimates that 80% of the application will be submitted online and 20% by paper.

4. DEA has made efforts to identify and prevent duplication of the collection of information. DEA does not believe this is a duplication of an existing collection of information.

5. In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this proposed rule on small entities. DEA's evaluation of economic impact by size category indicated that this collection will not have a significant economic impact on a substantial number of these small entities.

6. The collection of information must take place to allow registrants to apply for an exemption from the CSA. This information must be collected every five years to ensure that exempt chemical preparations remain consistent with the standards set forth in the CSA and DEA's implementing regulations. If the collection is conducted less frequently, there may be an increased risk of diversion.

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

8. Public comment has been solicited in the 60 Day Notice of Information Collection published in the *Federal Register* at 89 FR 68205, on August 23, 2024. No comments were received. Public comment was again solicited in the 30 Day Notice of Information Collection published in the *Federal Register* at 89 FR 85239, on October 25, 2024.

DEA meets regularly with the affected industry to discuss policies, programs, and regulations. These meetings provide an open forum to discuss matters of mutual concern with representatives of those entities from whom the information is obtained.

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. The 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 per 28 CFR 16.8(c) and Exemption 4 of FOIA, the 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. Estimate of Hour Burden:

Activity	Number of Respondents	Frequency	Total Annual Responses	Time Per Response	Total Annual Burden (Hours)	Hourly Rate <sup>1</sup>	Monetized Value of Respondent Time
Exempt Chemical Preparations	131	15.98	2,093	1 hour	2,093	\$60.10	\$125,789
<b>Unduplicated Totals</b>	<b>131</b>		<b>2,093</b>				<b>\$125,789</b>

13. Estimate of Cost Burden:

DEA initially estimates 80% of responses will be online applications, not incurring shipping expenses, while 20% of responses will be paper application, incurring shipping expenses. The estimated shipping cost is \$8.50 per application.<sup>2</sup> The estimated total cost burden is \$3,558.<sup>3</sup>

1 According to Bureau of Labor Statistics (BLS) May 2023 National Occupational Employment and Wage Estimates, the median hourly wages for 19-1042 Medical Scientists, Except Epidemiologists and 13-1041 Compliance Officers are \$48.50 and \$36.38. The labor cost is the average of the Medical Scientist and Compliance Officers wages, or \$42.44. Bureau of Labor Statistics, “Employer Costs for Employee Compensation – June 2023” (ECEC) reports that average benefits for private industry is 29.4% of total compensation which equates to 41.6% (29.4% / 70.6%) load on wages and salaries. The loaded hourly wage is \$42.44 x (1 + 0.416) = \$60.10

2 USPS Priority Mail Flat Rate, as of August 6, 2020.

3 \$8.50 x 2,093 x 20% = \$3,558.

14. Estimated Annualized Costs to Federal Government:

Estimated Annual Labor Cost to Government:

Labor Category	Number	% of time	Cost <sup>4</sup>
Chemist, GS-14, step 5	3	30%	\$ 229,342
Unit Chief, GS-14, step 5	1	5%	\$ 12,741
Section Chief, GS-15, step 5	1	1%	\$ 2,548
<b>Total</b>			<b>\$ 244,631<sup>5</sup></b>

Total cost to government: \$244,631

All costs are recovered from registrants through registration fees, as required by the CSA. 21 U.S.C. 886a. Government salaries above include a load of 61.3% for benefits based on the ECEC for “State and local government workers.” The ECEC does not include figures for the Federal Government.

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

	2021 Approved Burden	2024 Requested Burden	Difference
Annual responses	2,093	2,093	0
Annual burden hours	2,093	2,093	0
Annual cost (\$)	113,169	125,789	12,620

Changes in annual cost reflects adjustments related to increase in estimated labor rates and normal business activity. There have been no statutory or regulatory changes affecting this information collection.

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

17. DEA does not object to displaying the expiration date for this collection.

18. DEA is not seeking an exception to the certification statement “Certification for Paperwork Reduction Act Submissions” for this collection of information.

**Part B. Statistical Methods**

<sup>4</sup> The salary of a GS-14, step 5 government employee in the Washington-Baltimore-Arlington area is \$157,982. Load of 61.3% (38/62) for benefits based on the ECEC for State and local government workers. The ECEC does not include figures for the Federal Government. The cost for 3 Chemists is  $3 \times \$157,982 \times (1 + 0.613) \times 30\% = \$229,342$ . The cost for the Unit Chief is  $\$157,982 \times (1 + 0.613) \times 5\% = \$12,741$ . The cost for Section Chief is  $\$157,982 \times (1 + 0.613) \times 1\% = \$2,548$

<sup>5</sup>  $30\% \times 229,342 + 5\% \times 12,741 + 1\% \times 2,548 = 244,631$

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OMB Control Number: 1117-0058

OMB Expiration Date: 11/30/2024

The Drug Enforcement Administration will not be employing statistical methods in this information collection.