Supporting Statement for Paperwork Reduction Act Submissions
Exempt Chemical Preparations under the Controlled Substance Act
OMB Approval #1117-NEW

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for a new collection of information, 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.

Part A. Justification

1. Necessity of Information

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. Needs and Uses

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 chemcial 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, which will include the revocation date of each exempt chemical preparation.

3. Use of Information Technology:

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. Efforts to Identify Duplication:

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. Impact on Small Businesses or Entities:

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. Consequences of Less Frequent Collection:

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. Special Circumstances Influencing Collection:

There are no special circumstances applicable to this information collection.

8. Consultation with persons outside the Agency:

Public comment has been solicited in the 60 Day Notice of Information Collection published in the *Federal Register* at 86 FR 22070, on April 26, 2021. No comments were received. Public comment was again solicited in the 30 Day Notice of Information Collection published in the *Federal Register* at 86 FR 35535, on July 6, 2021.

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. Payment or Gift to Claimants:

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

10. Assurance of Confidentiality:

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. Justification for Sensitive Questions:

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

12. Estimate of Hour Burden:

Total number of respondents: 131
Number of responses per respondent per year: 15.98 (calculated average)
Total annual responses: 2,093
Total annual hour burden: 2,093

Average Burden: Per Collection: 1 hour
Per Respondent: 15.98 hours

Total responses received on paper: 2,093
Total responses received electronically: 0
Percentage of responses received electronically: 0%

Burden dollars:

Estimate hourly wage ($/hour):[1]	$37.95
Load for benefits (percent of labor rate):[2]	0.425
Loaded labor rate ($/hour):[3]	$54.07
Number of responses	2,093
Total annual hours	2,093
Average burden per response (hour)	1
Burden dollars per response ($)	$54.07
Total burden dollars	**$113,169**

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 $7.75 per application.[4] The estimated total cost burden is $3,244.[5]

14. Estimated Annualized Costs to Federal Government:

Estimated Annual Labor Cost to Government:

Labor Category	Number	% of time	Cost
Chemist, GS-14, step 5	3	30%	$ 200,967
Unit Chief, GS-14, step 5	1	5%	$ 11,165
Section Chief, GS-15, step 5	1	1%	$ 2,627
Total			**$ 214,758**

1 Used average of median hourly wages for 19-1042 Medical Scientists, Except Epidemiologists and 13-1041 Compliance Officers. U.S. Bureau of Labor Statistics, May 2019 National Occupational Employment and Wage Estimates United States (http://www.bls.gov/oes/current/oes_nat.htm).
2 Bureau of Labor Statistics, "Employer Costs for Employee Compensation – March 2020" (ECEC) reports that average benefits for private industry is 29.8% of total compensation. The 29.8% of total compensation equates to 42.5% (29.8% / 70.2%) load on wages and salaries.
3 $37.95 x (1 + 0.425) = $54.07.
4 USPS Priority Mail Flat Rate, as of August 6, 2020.
5 $7.75 x 2,093 x 80% = $3,244.

Total cost to government: $214,758

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 60.8% for benefits based on the ECEC for "State and local government workers." The ECEC does not include figures for the Federal Government.

15. Reasons for Change in Burden:

This is a new information collection.

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date Approval:

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

18. Exceptions to the Certification Statement:

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

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