

**SUPPORTING STATEMENT**  
Internal Revenue Service  
Form 8820, Orphan Drug Credit  
OMB Control Number 1545-1505

**1. CIRCUMSTANCES NECESSITATING THE COLLECTION OF INFORMATION**

Internal Revenue Code Section (IRC) 38, General business credit; provides a credit against the tax imposed by chapter 1 (Normal Taxes and Surtaxes) of the Internal Revenue Code. IRC 45C, Clinical testing expenses for certain drugs for rare diseases or conditions; states the credit determined under Section 38 for the taxable year is an amount equal to 25 percent of the qualified clinical testing expenses. IRC 280C, Certain expenses for which credits are allowable; allows taxpayers who claimed a credit for qualified clinical testing expenses the option to reduce the federal deduction of those testing expenses by the credit claimed.

Filers use Form 8820 to figure and claim the orphan drug credit and to elect the reduced credit under section 280C. The credit equals 25% of qualified clinical testing expenses paid or incurred during the tax year.

**2. USE OF DATA**

The data collected by Form 8820 is used by the IRS to verify that the orphan drug credit has been figured correctly.

**3. USE OF IMPROVED INFORMATION TECHNOLOGY TO REDUCE BURDEN**

Electronic filing for Form 8820 is currently available.

**4. EFFORTS TO IDENTIFY DUPLICATION**

5. The information obtained through this collection is unique and is not already available or use or adaption from another source.

**5. METHODS TO MINIMIZE BURDEN ON SMALL BUSINESSES OR OTHER SMALL ENTITIES**

The IRS proactively works with both internal and external stakeholders to minimize the burden on small businesses, while maintaining tax compliance. The Agency also seeks input regarding the burden estimates from the public via notices and tax product instructions. Taxpayers can file Form 8820 electronically, which further reduces any burden to small businesses.

**6. CONSEQUENCES OF LESS FREQUENT COLLECTION ON FEDERAL PROGRAMS**

A less frequent collection would result in the IRS unable to verify the correct amount of orphan drug credit that should be allowed on the tax return thereby engendering the inability of IRS to meet its mission.

7. **SPECIAL CIRCUMSTANCES REQUIRING DATA TO BE INCONSISTENT WITH GUIDELINES IN 5 CFR 1320.5(d)(2)**

There are no special circumstances requiring data collection to be inconsistent with Guidelines in 5 CFR 1320.5(d)(2).

8. **CONSULTATION WITH INDIVIDUALS OUTSIDE OF THE AGENCY ON AVAILABILITY OF DATA, FREQUENCY OF COLLECTION, CLARITY OF INSTRUCTIONS AND FORMS AND DATA ELEMENTS**

The IRS received no comments during the comment period in response to the **Federal Register** notice (86 FR 51451), dated September 15, 2021, regarding Form 8820.

9. **EXPLANATION OF DECISION TO PROVIDE ANY PAYMENT OR GIFT TO RESPONDENTS**

No payment or gift has been provided to any respondents.

10. **ASSURANCE OF CONFIDENTIALITY OF RESPONSES**

Generally, tax returns and tax return information are confidential as required by 26 USC 6103.

11. **JUSTIFICATION OF SENSITIVE QUESTIONS**

A privacy impact assessment (PIA) has been conducted for information collected under this request as part of the "Business Master File (BMF)" system and a Privacy Act System of Records notice (SORN) has been issued for this system under IRS 24.046-Customer Account Data Engine Business Master File. The Internal Revenue Service PIAs can be found at <https://www.irs.gov/uac/Privacy-Impact-Assessments-PIA>.

Title 26 USC 6109 requires inclusion of identifying numbers in returns, statements, or other documents for securing proper identification of persons required to make such returns, statements, or documents and is the authority for social security numbers (SSNs) in IRS systems.

12. **ESTIMATED BURDEN OF INFORMATION COLLECTION**

The estimated burden for individual and business taxpayers filing this form is approved under OMB control number 1545-0074 and 1545-0123 and is included in the estimates shown in the instructions for their individual and business income tax return. The estimated burden for estates, trust, and organizations who file this form are reported under 1545-1505.

The burden estimate is as follows:

Authority	Description	# of Respondents	# Responses per Respondent	Annual Responses	Hours per Response	Total Burden
IRC §§38, 280C, 45C	Form 8820	67	1	67	4.71	316
Totals		67				316

The following regulation imposes no additional burden. Please continue to assign OMB number 1545-1505 to this regulation. **1.28-1**

**13. ESTIMATED ANNUAL COST TO RESPONDENTS**

To ensure more accuracy and consistency across its information collections, IRS is currently in the process of revising the methodology it uses to estimate burden and costs. Once this methodology is complete, IRS will update this information collection to reflect a more precise estimate of burden and costs.

**14. ESTIMATED ANNUALIZED FEDERAL COST TO FEDERAL GOVERNMENT**

The Federal government cost estimate is based on a model that considers the following three cost factors for each information product: aggregate labor costs for development, including annualized start up expenses, operating and maintenance expenses, and distribution of the product that collects the information.

The government computes cost using a multi-step process. First, the government creates a weighted factor for the level of effort to create each information collection product based on variables such as; complexity, number of pages, type of product and frequency of revision. Second, the total costs associated with developing the product such as labor cost, and operating expenses associated with the downstream impact such as support functions, are added together to obtain the aggregated total cost. Then, the aggregated total cost and factor are multiplied together to obtain the aggregated cost per product. Lastly, the aggregated cost per product is added to the cost of shipping and printing each product to IRS offices, National Distribution Center, libraries and other outlets. The result is the Government cost estimate per product.

The government cost estimate for this collection is summarized in the table below.

<b>REASONS FOR CHANGE IN BURDEN</b>	<b>Aggregate Cost per Product (factor applied)</b>		<b>Printing and Distribution</b>		<b>Government Cost Estimate per Product</b>
Form 8820	\$22,848	+	\$0	=	\$22,848
<b>Grand Total</b>	<b>\$22,848</b>		<b>\$0</b>		<b>\$22,848</b>
Table costs are based on 2021 actuals obtained from IRS Chief Financial Office and Media and Publications					

There are no changes to the form or response/respondent estimates that would affect burden at this time.

**16. PLANS FOR TABULATION, STATISTICAL ANALYSIS AND PUBLICATION**

There are no plans for tabulation, statistical analysis, and publication.

**17. REASONS WHY DISPLAYING THE OMB EXPIRATION DATE IS INAPPROPRIATE**

IRS believes that displaying the OMB expiration date is inappropriate because it could cause confusion by leading taxpayers to believe that the regulation sunsets as of the expiration date. Taxpayers are not likely to be aware that the Service intends to request renewal of the OMB approval and obtain a new expiration date before the old one expires.

**18. EXCEPTION TO THE CERTIFICATION STATEMENT**

There are no exceptions to the certification statement.

Note: The following paragraph applies to all of the collection of information in this submission:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax return and tax return information are confidential, as required by 26 U.C.S.C. 6103.