

Supporting Statement
Internal Revenue Service
Form 8820, Orphan Drug Credit
OMB Control No. 1545-1505

1. CIRCUMSTANCES NECESSITATING COLLECTION OF INFORMATION

Credit for clinical testing expenses for certain drugs for rare diseases or conditions (26 CFR 1.28-1).

Internal Revenue Code Section 28 provides a credit against the tax imposed by chapter 1 of the Internal Revenue Code. The amount of the credit is equal to 25 percent of the qualified clinical testing expenses (as defined in P.L.115-97, section 13401) for the taxable year beginning after December 31, 2017. 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. The orphan drug credit is part of the general business credit and is figured under section 45C of the Code.

2. USE OF DATA

The information shown on Form 8820 is used by the IRS to verify that the credit has been figured correctly.

3. USE OF IMPROVED INFORMATION TECHNOLOGY TO REDUCE BURDEN

Form 8820 has been enabled for electronic filing with 1065 and/or 1041 returns.

4. EFFORTS TO IDENTIFY DUPLICATION

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

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

There is no burden on small businesses or entities by this collection due to the inapplicability of the authorizing statute to this type of entity.

6. CONSEQUENCES OF LESS FREQUENT COLLECTION ON FEDERAL OR POLICY ACTIVITIES.

If the information were not collected, the IRS would not be able to verify that the proper credit was figured correctly under section 45C of the Code. This would affect both the taxpayer and the government in ensuring proper tax compliance and hinder the IRS from meeting its mission.

7. SPECIAL CIRCUMSTANCES REQUIRING DATA COLLECTION 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

Periodic meetings are held between IRS personnel and representatives of the American Bar Association, the National Society of Public Accountants, the American Institute of Certified Public Accountants, and other professional groups to discuss tax law and tax forms. During these meetings, there is an opportunity for those attending to make comments regarding Form 8820.

In response to the Federal Register notice (83 FR 12081), dated March 19, 2018, we received no comments during the comment period 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-Business Master File and IRS 34.037-Audit Trail and Security Records System. 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 burden estimate is as follows:

Authorizing Statute	Description	# of Respondents	# Responses per Respondent	Annual Responses	Hours per Response	Total Burden
IRC 28	Form 8820	67	1	67	4.71 hrs.	316
	Totals	67	1	67	4.71 hrs.	316

This ICR was submitted to address the "Businesses or other for-profits" taxpayers, that do not file Form 1040, and may be entitled to claim this credit in any given year. The burden associated with the Form 1040 filers is reported with the burden under 1545-0074. The IRS is also seeking separate approval for this form under 1545-0123. The burden in this collection reflects the "business" filers entitled to claim the credit.

13. ESTIMATED TOTAL ANNUAL COST BURDEN 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 COST TO THE FEDERAL GOVERNMENT

The primary cost to the government consists of the cost of printing Form 8820. We estimate that the cost of printing the form is \$50.00.

15. REASONS FOR CHANGE IN BURDEN

The reduction in burden was achieved, due to the previous burden calculation was not based on the most current revision of the form, which reduced the burden hours by (32 hrs.) Also, we are making this submission to renew the OMB approval.

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	67	0	0	0	0	67
Annual Time Burden (Hrs.)	316	0	0	-32	0	348

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 regulations sunset 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. EXCEPTIONS TO THE CERTIFICATION STATEMENT

There are no exceptions to the certification statement.

Note: The following paragraph applies to all of the collections 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 the collection of information 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 returns and tax return information are confidential, as required by 26 U.S.C. 6103.