

SUPPORTING STATEMENT  
1545-1505  
(Form 8820)

1. CIRCUMSTANCES NECESSITATING COLLECTION OF INFORMATION

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

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 50 percent of the qualified clinical testing expenses (as defined in paragraph (b) of 26 CFR 1.28-1) for the taxable year.

Filers use Form 8820 to elect to claim the orphan drug credit. The credit equals 50% 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

IRS uses the information shown on Form 8820 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

We have attempted to eliminate duplication within the agency wherever possible.

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

There are no small entities affected by this collection.

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 claimed. This would affect both the taxpayer and the government in ensuring proper tax compliance.

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, dated February 27, 2015 (80 F.R. 10746), 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 <http://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:

	<u>Number of Responses</u>	<u>Time per Response</u>	<u>Total Hours</u>
Form 8820	67	5.19	348

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. When cleared, this burden will reflect the “business” filers entitled to claim this credit.

The estimated labor costs will be \$12,716.

## 13. ESTIMATED TOTAL ANNUAL COST BURDEN TO RESPONDENTS

As suggested by OMB, our **Federal Register** notice dated February 27, 2015, requested public comments on estimates of cost burden that are not captured in the estimates of burden hours, i.e., estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. However, we did not receive any response from taxpayers on this subject. As a result, estimates of the cost burdens are not available at this time.

There is no start-up costs associated with this collection.

## 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

There is no change in the burden previously approved by OMB.

We are making this submission for renewal purposes only.

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

See attachment.

18. EXCEPTIONS TO THE CERTIFICATION STATEMENT ON OMB FORM 83-I

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.