Form **8820**
(Rev. December 2012)
Department of the Treasury
Internal Revenue Service

Orphan Drug Credit

▶ **Information about Form 8820 and its instructions is available at *www.irs.gov/form8820.***
▶ **Attach to your tax return.**

OMB No. 1545-1505

Attachment Sequence No. **103**

Name(s) shown on return

Identifying number

Part I Current Year Credit

1	Qualified clinical testing expenses paid or incurred during the tax year (see instructions)	**1**		
2a	Current year credit. Multiply line 1 by 50% (.50) (see instructions)	**2a**		
b	Enter the portion of the credit from Form 8932, line 2, that is attributable to wages that were also used to figure the credit on line 2a above	**2b**		
c	Subtract line 2b from line 2a. If zero or less, enter -0-	**2c**		
3	Orphan drug credit from partnerships, S corporations, estates, or trusts	**3**		
4	Add lines 2c and 3. Estates and trusts go to line 5. Partnerships and S corporations, report this amount on Schedule K. All others, report this amount on Form 3800, line 1h	**4**		
5	Amount allocated to the beneficiaries of the estate or trust (see instructions)	**5**		
6	Estates and trusts. Subtract line 5 from line 4. Report this amount on Form 3800, line 1h	**6**		

Part II **Orphan Drug Information** (see instructions)

(a)	(b) Name of orphan drug	(c) Designation application number	(d) Date drug designated (mm/dd/yyyy)
7a			
b			
c			
d			
e			
f			
g			
h			
i			
j			
k			
l			
m			
n			
o			
p			
q			
r			
s			
t			
u			
v			
w			
x			
y			
z			

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form 8820 and its instructions, such as legislation enacted after this form and instructions were published, go to *www.irs.gov/form8820*.

Purpose of Form

Use Form 8820 to claim the orphan drug credit. The credit is 50% of qualified clinical testing expenses paid or incurred during the tax year. See section 45C and Regulations section 1.28-1 for details.

Taxpayers that are not partnerships, S corporations, estates, or trusts, and whose only source of this credit is from those pass-through entities, are not required to complete or file this form. Instead, they can report this credit directly on Form 3800.

Definitions

Qualified clinical testing expenses. Generally, qualified clinical testing expenses are amounts paid or incurred by the taxpayer that would be described as qualified research expenses under section 41, with two modifications:

- In sections 41(b)(2) and (3), "clinical testing" is substituted for "qualified research" and
- 100% (instead of 65% or 75%) of contract research expenses are treated as clinical testing expenses.

Qualified clinical testing expenses do not include expenses to the extent they are funded by a grant, contract, or otherwise by a governmental entity or another person.

Clinical testing. Generally, clinical testing means any human clinical testing that meets all four of the following conditions.

1. The testing is carried out under an exemption for a drug being tested for a rare disease or condition under section 505(i) of the Federal Food, Drug, and Cosmetic Act (Act).

2. The testing occurs after the date the drug is designated under Act section 526 and before the date on which an application for the drug is approved under Act section 505(b) (or, if the drug is a biological product, before the date the drug is licensed under section 351 of the Public Health Service Act).

3. The testing is conducted by or for the taxpayer to whom the designation under Act section 526 applies.

4. The testing relates to the use of the drug for the rare disease or condition for which it was designated under Act section 526.

Rare disease or condition. A rare disease or condition is one which afflicts:

- 200,000 or fewer persons in the United States or
- More than 200,000 persons in the United States, but for which there is no reasonable expectation of recovering the cost of developing and making available a drug in the United States for the disease from sales of the drug in the United States.

The above determinations are made as of the date the drug is designated under Act section 526.

Testing Not Eligible for the Credit

The credit is not allowed for clinical testing conducted outside the United States unless there is an insufficient U.S. testing population and the testing is conducted by a U. S. person or by another person not related to the taxpayer. Testing conducted either inside or outside the United States by a corporation to which section 936 applies is not eligible for the orphan drug credit.

Coordination With the Research Credit

Qualified clinical testing expenses used to figure the orphan drug credit cannot also be used to figure the credit for increasing research activities. However, any of these expenses that are also qualified research expenses must be included in base period research expenses when figuring the credit for increasing research activities in a later tax year.

Member of Controlled Group or Business Under Common Control

For purposes of figuring the credit, all members of a controlled group of corporations (as defined in section 41(f)(1)(A) and (f)(5)) and all members of a group of businesses under common control (as defined in section 41(f)(1)(B)), are treated as a single taxpayer. As a member, your credit is determined on a proportionate basis to your share of the aggregate clinical testing expenses taken into account by the group for the orphan drug credit. Enter your share of the credit on line 2a. Attach a statement showing how your share of the credit was figured, and write "See Attached" next to the entry space for line 2a.

Specific Instructions

Figure any orphan drug credit from your own trade or business on lines 1 and 2a.

Line 1

Complete Part II for each orphan drug for which qualified clinical testing expenses are paid or incurred during the tax year and included in line 1.

Line 2a

Reduce the deduction for qualified clinical testing expenses otherwise allowable on your income tax return by the amount of the credit shown on line 2a. If the credit exceeds the amount allowed as a deduction for the tax year, reduce the amount chargeable to the capital account for the year for such expenses by the amount of the excess. See section 280C(b) for special rules.

Line 2b

If the credit on line 2a includes wages paid to employees, and you are also claiming a credit for employer differential wage payments based on wages paid to the same employees, enter on line 2b the portion of the credit from the employer differential wage credit line (e.g., line 2 of Form 8932 (Rev. December 2012)) that is attributable to wages that were also used to figure the credit on line 2a.

See Form 8932, Credit for Employer Differential Wage Payments, for information on the credit.

Line 5

Allocate the orphan drug credit on line 4 between the estate or trust and the beneficiaries in the same proportion as income was allocated and enter the beneficiaries' share on line 5.

If the estate or trust is subject to the passive activity rules, include on line 3 any orphan drug credit from passive activities disallowed for prior years and carried forward to this year. Complete Form 8582-CR, Passive Activity Credit Limitations, to determine the allowed credit that must be allocated between the estate or trust and the beneficiaries. For details, see the Instructions for Form 8582-CR.

Part II

For each drug for which qualified clinical testing expenses are included on line 1, enter the generic name of the orphan drug, the Designation application number, and the date the drug was designated under section 526 of the Federal Food, Drug, and Cosmetic Act.

Attach as many Part II pages as needed to show all orphan drugs.

Paperwork Reduction Act Notice. We ask for the information on this form to carry out the Internal Revenue laws of the United States. You are required to give us the information. We need it to ensure that you are complying with these laws and to allow us to figure and collect the right amount of tax.

You are not required to provide the information requested on a form that is subject to the Paperwork Reduction Act unless the form displays a valid OMB control number. Books or records relating to a form or its instructions must be retained as long as their contents may become material in the administration of any Internal Revenue law. Generally, tax returns and return information are confidential, as required by section 6103.

The time needed to complete and file this form will vary depending on individual circumstances. The estimated burden for individual taxpayers filing this form is approved under OMB control number 1545-0074 and is included in the estimates shown in the instructions for their individual income tax return. The estimated burden for all other taxpayers who file this form is shown below.

Recordkeeping . . 1 hr., 54 min.

Learning about the law or the form . . . . . 1 hr.

Preparing and sending the form to the IRS . . 1 hr., 4 min.

If you have comments concerning the accuracy of these time estimates or suggestions for making this form simpler, we would be happy to hear from you. See the instructions for the tax return with which this form is filed.