2006 Form 8820, Orphan Drug Credit (Rev. Dec. 2006)

Circulation: This is the first circulated draft of the 2006 Form 8820 (Rev. Dec. 2006) for your review and comments. See below for a discussion of the major changes.

TPCC Meeting: None, but one may be arranged if requested.

Prior version: The 2005 Form 8820 is available at: http://www.irs.gov/pub/irs-pdf/f8820.pdf

Other Products: Circulations of draft tax forms, instructions, notices, and publications are posted at:http://taxforms.web.irs.gov/draft_products.html

Comments: Please email, fax, call, or mail any comments by **June 23, 2006.**

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Major Changes

On the Form-

[1] The text "Rev. December 2006" is added under the form number in the upper left corner because the form was converted from annual use to continuous use. Accordingly, the text "20**05**" was eliminated from the upper right corner and the bottom right corner (replaced with the text "Rev. 12-2006" in the bottom right corner).

[2] The **Part I** and **Part II** headings are eliminated because the function of the old Part II (to compute the allowable credit) is now on Form 3800. Since there is no longer a Part II, a Part I designation is unnecessary.

[3] Line **3** is rewritten to eliminate the text "pass-through."

[4] Line **4** is rewritten. The text "**Current year credit**" is removed. Estates and trusts are now directed to line 5 so that an allocation to beneficiaries can be shown. Now partnerships and S corporations are directed to report the amount on Schedule K. All others are directed to line 1k of the 2006 Form 3800 (as an example since this will now be a continuous use form, revised only when necessary).

[5] Lines **5** and **6** are added to allow estates and trusts to show allocations to beneficiaries and figure the resulting amount to show on Form 3800.

In the Instructions-

[1] A **What's New** section is added with the following bulleted items.

- The tax liability limit is no longer figured on this form; instead, it must be figured on Form 3800, General Business Credit.

- Taxpayers that are not partnerships, S corporations, cooperatives, estates, trusts, or members of a controlled group, 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 line 1k of Form 3800.
- The IRS will revise this December 2006 version of the form only when necessary. Continue to use this version for tax years beginning after 2005 until a new revision is issued.

[2] The **Who Must File** section is removed as it is unnecessary.

[3] In the first paragraph, under **Specific Instructions** the text "Skip lines 1 and 2 if you are only claiming a credit that was allocated to you from an S corporation or partnership" is removed as it is unnecessary.

[4] The instructions for line **3** are removed because new lines 5 and 6 on the form (in conjunction with Schedules K) now explain the allocation of the credit to beneficiaries, partners, and shareholders.

[4] The instructions for S corporations, partnerships, and electing large partnerships, in the second paragraph under **Specific Instructions,** are eliminated as the information is now shown on Schedules K.

[4] All of the **Part II** instructions are removed to conform to the removal of the Part II on the form. Accordingly, the Part I heading is removed.

Form **8820**
(Rev. December 2006)
Department of the Treasury
Internal Revenue Service

Orphan Drug Credit

► **Attach to your tax return.**

OMB No. 1545-1505

Attachment Sequence No. **103**

Name(s) shown on return

Identifying number

1	Qualified clinical testing expenses paid or incurred during the tax year	**1**		
2	Current year credit. Multiply line 1 by 50% (.50) (see instructions)	**2**		
3	Orphan drug credit from S corporations, partnerships, estates, or trusts	**3**		
4	Add lines 2 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 the applicable line of Form 3800 (e.g., line 1k of the 2006 Form 3800)	**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 the applicable line of Form 3800 (e.g., line 1k of the 2006 Form 3800)	**6**		

General Instructions

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

What's New

- The tax liability limit is no longer figured on this form; instead, it must be figured on Form 3800, General Business Credit.
- 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 line 1k of Form 3800.
- The IRS will revise this December 2006 version of the form only when necessary. Continue to use this version for tax years beginning after 2005 until a new revision is issued.

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.

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.

Specific Instructions

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

Line 1

Members of a controlled group of corporations or group of businesses under common control. The group is treated as a single taxpayer and the credit allowed each member is based on its proportionate share of the qualified clinical testing expenses of the group. Enter on line 1 your share of the group's qualified clinical testing expenses.

Line 2

Reduce the deduction for qualified clinical testing expenses otherwise allowable on your income tax return by the amount of the credit shown on line 2. 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 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. On the dotted line to the left of line 4, the estate or trust should enter its share of the credit. Label it "1041 Portion" and use this amount in Part II (or on Form 3800, if required) to figure the credit to take on Form 1041. On Schedule K-1, show each beneficiary's share of the portion allocated to beneficiaries.

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 . . . X hr., XX min.
Learning about the law or the form . . . X hr.
Preparing and sending the form to the IRS . . X hr., X 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.