

Department of the Treasury
Internal Revenue Service

▶ Attach to your tax return.

Name(s) shown on return

Identifying number

Part I Current Year Credit

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	Pass-through orphan drug credits from an S corporation, partnership, estate, or trust	3		
4	Current year credit. Add lines 2 and 3	4		

Part II Allowable Credit (See **Who must file Form 3800** to find out if you complete Part II or file Form 3800.)

5	Regular tax before credits:			
	• Individuals. Enter the amount from Form 1040, line 43	}	5	
	• Corporations. Enter the amount from Form 1120, Schedule J, line 3; Form 1120-A, Part I, line 1; or the applicable line of your return			
	• Estates and trusts. Enter the sum of the amounts from Form 1041, Schedule G, lines 1a and 1b, or the amount from the applicable line of your return			
6	Alternative minimum tax:			
	• Individuals. Enter the amount from Form 6251, line 35	}	6	
	• Corporations. Enter the amount from Form 4626, line 14			
	• Estates and trusts. Enter the amount from Form 1041, Schedule I, line 56			
7	Add lines 5 and 6		7	
8a	Foreign tax credit	8a		
b	Credits from Form 1040, lines 47 through 53	8b		
c	Possessions tax credit (Form 5735, line 17 or 27)	8c		
d	Credit for fuel from a nonconventional source	8d		
e	Qualified electric vehicle credit (Form 8834, line 20)	8e		
f	Add lines 8a through 8e		8f	
9	Net income tax. Subtract line 8f from line 7. If zero, skip lines 10 through 13 and enter -0- on line 14		9	
10	Net regular tax. Subtract line 8f from line 5. If zero or less, enter -0-	10		
11	Enter 25% (.25) of the excess, if any, of line 10 over \$25,000 (see instructions)	11		
12	Tentative minimum tax (see instructions):			
	• Individuals. Enter the amount from Form 6251, line 33	}	12	
	• Corporations. Enter the amount from Form 4626, line 12			
	• Estates and trusts. Enter the amount from Form 1041, Schedule I, line 54			
13	Enter the greater of line 11 or line 12		13	
14	Subtract line 13 from line 9. If zero or less, enter -0-		14	
15	Credit allowed for the current year. Enter the smaller of line 4 or line 14 here and on Form 1040, line 54; Form 1120, Schedule J, line 6d; Form 1120-A, Part I, line 2; Form 1041, Schedule G, line 2c; or the applicable line of your return. If line 14 is smaller than line 4, see instructions		15	

General Instructions

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

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.

Who Must File

An individual, estate, trust, organization, or corporation that elects to claim an orphan drug credit, or any S corporation, partnership, estate, or trust that allocates the credit to its shareholders, partners, or beneficiaries must complete this form and attach it to its income tax return.

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(j) 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

Part I

Current Year Credit

Figure any orphan drug credit from your own trade or business on lines 1 and 2. Skip lines 1 and 2 if you are claiming only a credit that was allocated to you from an S corporation, a partnership, an estate, or a trust.

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 3

Enter the amount of credit that was allocated to you as a shareholder, partner, or beneficiary.

Line 4

Estates and trusts. 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.

S corporations and partnerships.

Allocate the orphan drug credit on line 4 among the shareholders or partners. Attach Form 8820 to Form 1120S or 1065 and on Schedule K-1 show the credit for each shareholder or partner. Electing large partnerships include this credit in "general credits."

Part II

Allowable Credit

The credit allowed for the current year may be limited based on your tax liability. Use Part II to figure the allowable credit unless you must file Form 3800, General Business Credit.

Who must file Form 3800. You must file Form 3800 if you have:

- An orphan drug credit from a passive activity,
- More than one credit included in the general business credit (other than a credit from Form 8844, Form 8884, or Section B of Form 8835), or
- A carryback or carryforward of any of those credits.

See the instructions for Form 3800 for a list of credits included in the general business credit.

Line 11

See section 38(c)(5) for special rules that apply to married couples filing separate returns, controlled corporate groups, regulated investment companies, real estate investment trusts, and estates and trusts.

Line 12

Although you may not owe alternative minimum tax (AMT), you generally must still compute the tentative minimum tax (TMT) to figure your credit. For a small corporation exempt from the AMT under section 55(e), enter zero. Otherwise, complete and attach the applicable AMT form or schedule.

Line 15

If you cannot use all of the credit because of the tax liability limit (line 14 is smaller than line 4), carry the unused credit back 1 year, then forward up to 20 years. See the instructions for Form 3800 for details.

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 average time is:

Recordkeeping	5 hr., 30 min.
Learning about the law or the form	1 hr.
Preparing and sending the form to the IRS	1 hr., 7 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.