

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	Flow-through orphan drug credit(s) from an S corporation, partnership, estate, or trust	3		
4	Total current year orphan drug credit. Add lines 2 and 3	4		

Part II Tax Liability Limit (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 amount from Form 1040, line 40 • Corporations. Enter amount from Form 1120, Schedule J, line 3 (or Form 1120-A, Part I, line 1) • Other filers. Enter regular tax before credits from your return	5		
6a	Credit for child and dependent care expenses (Form 2441, line 9)	6a		
b	Credit for the elderly or the disabled (Schedule R (Form 1040), line 20)	6b		
c	Child tax credit (Form 1040, line 43)	6c		
d	Education credits (Form 8863, line 18)	6d		
e	Mortgage interest credit (Form 8396, line 11)	6e		
f	Adoption credit (Form 8839, line 15)	6f		
g	District of Columbia first-time homebuyer credit (Form 8859, line 11)	6g		
h	Foreign tax credit	6h		
i	Possessions tax credit (Form 5735, line 17 or 27)	6i		
j	Credit for fuel from a nonconventional source	6j		
k	Qualified electric vehicle credit (Form 8834, line 19)	6k		
l	Add lines 6a through 6k	6l		
7	Net regular tax. Subtract line 6l from line 5	7		
8	Alternative minimum tax: • Individuals. Enter amount from Form 6251, line 28 • Corporations. Enter amount from Form 4626, line 15 • Estates and trusts. Enter amount from Form 1041, Schedule I, line 39	8		
9	Net income tax. Add lines 7 and 8	9		
10	Tentative minimum tax (see instructions): • Individuals. Enter amount from Form 6251, line 26 • Corporations. Enter amount from Form 4626, line 13 • Estates and trusts. Enter amount from Form 1041, Schedule I, line 37	10		
11	If line 7 is more than \$25,000, enter 25% (.25) of the excess (see instructions)	11		
12	Enter the greater of line 10 or line 11	12		
13	Subtract line 12 from line 9. If zero or less, enter -0-	13		
14	Orphan drug credit allowed for current year. Enter the smaller of line 4 or line 13 here and on Form 1040, line 47; Form 1120, Schedule J, line 4d; Form 1120-A, Part I, line 2a; Form 1041, Schedule G, line 2c; or the applicable line of your return	14		

General Instructions

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

Purpose of Form

File Form 8820 if you elect to claim the orphan drug credit. The credit equals 50% of qualified clinical testing expenses paid or incurred during the tax year. See section

45C and Regulations section 1.28-1 for more details.

Who Must File

An individual, estate, trust, organization, or corporation claiming 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 the following modifications:

1. In sections 41(b)(2) and (3), "clinical testing" is substituted for "qualified research," and

2. 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 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:

1. 200,000 or fewer persons in the United States, OR
2. 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. 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 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 this member's share of the group's qualified clinical testing expenses.

Line 2. You must 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."

Who Must File Form 3800

If for this year you have more than one of the credits included in the general business credit, a carryback or carryforward of any of these credits, an orphan drug credit from a passive activity, or general credits from an electing large partnership (Schedule K-1 (Form 1065-B)), you must complete **Form 3800**, General Business Credit, instead of completing Part II of Form 8820, to figure the tax liability limit.

The general business credit consists of the following credits:

- Investment (Form 3468),
- Work opportunity (Form 5884),
- Welfare-to-work (Form 8861),
- Alcohol used as fuel (Form 6478),
- Research (Form 6765),
- Low-income housing (Form 8586),
- Enhanced oil recovery (Form 8830),

- Disabled access (Form 8826),
- Renewable electricity production (Form 8835),
- Indian employment (Form 8845),
- Employer social security and Medicare taxes paid on certain employee tips (Form 8846),
- Orphan drug (Form 8820),
- Contributions to selected community development corporations (Form 8847), and
- Trans-Alaska pipeline liability fund.

The empowerment zone employment credit (Form 8844), while a component of the general business credit, is figured separately on Form 8844 and is never carried to Form 3800.

Line 10. 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 and enter the TMT on line 10.

Line 11. See section 38(c)(3) 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 14. If you cannot use part of the credit because of the tax liability limit (line 13 is smaller than line 4), carry it back 1 year and then forward 20 years. See the separate **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** 6 hr., 13 min.
- Learning about the law or the form** 1 hr., 23 min.
- Preparing and sending the form to the IRS** 1 hr., 8 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.

