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[T.D. 8232, 53 FR 38710, Oct. 3, 1988; 53 FR 40879, Oct. 19, 1988]

**§ 1.28-1 Credit for clinical testing expenses for certain drugs for rare diseases or conditions.**

(a) *General rule.* 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 this section) for the taxable year. The credit applies to qualified clinical testing expenses paid or incurred by the taxpayer after December 31, 1982, and before January 1, 1991. The credit may not exceed the taxpayer's tax liability for the taxable year (as determined under paragraph (d)(2) of this section).

(b) *Qualified clinical testing expenses—*  
 (1) *In general.* Except as otherwise provided in paragraph (b)(3) of this section, the term "qualified clinical testing expenses" means the amounts which are paid or incurred during the taxable year which would constitute "qualified research expenses" within the meaning of section 41(b) (relating to the credit for increasing research activities) as modified by section 28(b)(1)(B) and paragraph (b)(2) of this section. For example, amounts paid or incurred for the acquisition of depreciable property used in the conduct of clinical testing (as defined in paragraph (c) of this section) are not qualified clinical testing expenses.

(2) *Modification of section 41(b).* For purposes of paragraph (b)(1) of this sec-

tion, section 41(b) is modified by substituting "clinical testing" for "qualified research" each place it appears in paragraph (2) of section 41(b) (relating to in-house research expenses) and paragraph (3) of section 41(b) (relating to contract research expenses). In addition, "100 percent" is substituted for "65 percent" in paragraph (3)(A) of section 41(b).

(3) *Exclusion for amounts funded by another person—*(i) *In general.* The term "qualified clinical testing expenses" shall not include any amount which would otherwise constitute qualified clinical testing expenses, to the extent such amount is funded by a grant, contract, or otherwise by another person (or any governmental entity). The determination of the extent to which an amount is funded shall be made in light of all the facts and circumstances. For a special rule regarding funding between commonly controlled businesses, see paragraph (d)(5)(iv) of § 1.28-1.

(ii) *Clinical testing in which taxpayer retains no rights.* If a taxpayer conducting clinical testing with respect to the designated drug for another person retains no substantial rights in the clinical testing under the agreement providing for the clinical testing the taxpayer's clinical testing expenses are treated as fully funded for purposes of section 28(b)(1)(C). Thus, for example, if the taxpayer incurs clinical testing expenses under an agreement that confers on another person the exclusive right to exploit the results of the clinical testing, those expenses do not constitute qualified clinical testing expenses because they are fully funded under this paragraph (b)(3)(ii). Incidental benefits to the taxpayer from the conduct of the clinical testing (for example, increased experience in the field of human clinical testing) do not constitute substantial rights in the clinical testing.

(iii) *Clinical testing in which taxpayer retains substantial rights—*(A) *In general.* If a taxpayer conducting clinical testing with respect to the designated drug for another person retains substantial rights in the clinical testing under the agreement providing for the clinical testing, the clinical testing expenses are funded to the extent of the payments (and fair market value of any

property at the time of transfer) to which the taxpayer becomes entitled by conducting the clinical testing. The taxpayer shall reduce the amount paid or incurred by the taxpayer for the clinical testing expenses that would, but for section 28(b)(1)(C) constitute qualified clinical testing expenses of the taxpayer by the amount of the funding determined under the preceding sentence. Rights retained in the clinical testing are not treated as property for purposes of this paragraph (b)(3)(iii)(A). If the property that is transferred to the taxpayer is to be consumed in the clinical testing (for example, supplies), the taxpayer should exclude the value of that property from both the payments received and the expenses paid or incurred for the clinical testing.

(B) *Drug by drug determination.* The provisions of this paragraph (b)(3) shall be applied separately to each designated drug tested by the taxpayer.

(iv) *Funding for qualified clinical testing expenses determinable only in subsequent taxable years.* If, at the time the taxpayer files its return for a taxable year, it is impossible to determine to what extent some or all of the qualified clinical testing expenses may be funded, the taxpayer shall treat the clinical testing expenses as fully funded for purposes of that return. When the amount of funding for qualified clinical testing expenses is finally determined, the taxpayer should amend the return and any interim returns to reflect the amount of funding for qualified clinical testing expenses.

(4) *Special rule governing the application of section 41(b) beyond its expiration date.* For purposes of section 28 and this section, section 41(b), as amended, and the regulations thereunder shall be deemed to remain in effect after December 31, 1988.

(c) *Clinical testing*—(1) *In general.* The term “clinical testing” means any human clinical testing which—

(i) Is carried out under an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) and the regulations relating thereto (21 CFR part 312) for the purpose of testing a drug for a rare disease or condition as defined in paragraph (d)(1) of this section,

(ii) Occurs after the date the drug is designated as a drug for a rare disease or condition under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb),

(iii) Occurs before the date on which an application for the designated drug is approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) or, if the drug is a biological product (other than a radioactive biological product intended for human use), before the date on which a license for such drug is issued under section 351 of the Public Health Services Act (42 U.S.C. 262), and

(iv) Is conducted by or on behalf of the taxpayer to whom the designation under section 526 of the Federal Food, Drug, and Cosmetic Act applies.

Human clinical testing shall be taken into account under this paragraph (c)(1) only to the extent that the testing relates to the use of a drug for the rare disease or condition for which the drug was designated under section 526 of the Federal Food, Drug, and Cosmetic Act. For purposes of paragraph (c)(1)(i) of this section the testing under section 505(i) exemption procedures (21 CFR part 312) of a biological product (other than a radioactive biological product intended for human use) pursuant to 21 CFR §601.21 is deemed to be carried out under an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act.

(2) *Definition of “human clinical testing.”* Testing is considered to be human clinical testing only to the extent that it uses human subjects to determine the effect of the designated drug on humans and is necessary for the designated drug either to be approved under section 505(b) of the Federal Food, Drug, and Cosmetic Act and the regulations thereunder (21 CFR part 314), or if the designated drug is a biological product (other than a radioactive biological product intended for human use), to be licensed under section 351 of the Public Health Services Act and the regulations thereunder (21 CFR part 601). For purposes of this paragraph (c)(2), a human subject is an individual who is a participant in research, either as a recipient of the drug or as a control. A subject may be either a healthy individual or a patient.

(3) *Definition of “carried out under” section 505(i).* Human clinical testing is not carried out under section 505(i) of the Federal Food, Drug, and Cosmetic Act and the regulations thereunder (21 CFR part 312) unless the primary purpose of the human clinical testing is to ascertain the data necessary to qualify the designated drug for sale in the United States, and not to ascertain data unrelated or only incidentally related to that needed to qualify the designated drug. Whether or not this primary purpose test is met shall be determined in light of all of the facts and circumstances.

(d) *Definition and special rules—(1) Definition of “rare disease or condition”—(i) In general.* The term “rare disease or condition” means any disease or condition which—

(A) Afflicts 200,000 or fewer persons in the United States, or

(B) Afflicts more than 200,000 persons in the United States but for which there is no reasonable expectation that the cost of developing and making available in the United States (as defined in section 7701(a)(9)) a drug for such disease or condition will be recovered from sales in the United States (as so defined) of such drug.

Determinations under paragraph (d)(1)(i)(B) of this section with respect to any drug shall be made on the basis of the facts and circumstances as of the date such drug is designated under section 526 of the Federal Food, Drug, and Cosmetic Act. Examples of diseases or conditions which in 1987 afflicted 200,000 or fewer persons in the United States are Duchenne dystrophy, one of the muscular dystrophies; Huntington’s disease, a hereditary chorea; myoclonus; Tourette’s syndrome; and amyotrophic lateral sclerosis (ALS or Lou Gehrig’s disease).

(ii) *Cost of developing and making available the designated drug—(A) In general.* Except as otherwise provided in this paragraph (d)(1)(ii), the taxpayer’s computation of the cost of developing and making available in the United States the designated drug shall include only the costs that the taxpayer (or any person whose right to make sales of the drug is directly or indirectly derived from the taxpayer, e.g., a licensee or transferee) has in-

curred or reasonably expects to incur in developing and making available in the United States the designated drug for the disease or condition for which it is designated. For example, if, prior to designation under section 526, the taxpayer incurred costs of \$125,000 to test the drug for the rare disease or condition for which it is subsequently designated and incurred \$500,000 to test the same drug for other diseases, and if, on the date of designation, the taxpayer expects to incur costs of \$1.2 million to test the drug for the rare disease or condition for which it is designated, the taxpayer shall include in its cost computation both the \$125,000 incurred prior to designation and the \$1.2 million expected to be incurred after designation to test the drug for the rare disease or condition for which it is designated. The taxpayer shall not include the \$500,000 incurred to test the drug for other diseases.

(B) *Exclusion of costs funded by another person.* In computing the cost of developing and making available in the United States the designated drug, the taxpayer shall not include any cost incurred or expected to be incurred by the taxpayer to the extent that the cost is funded or is reasonably expected to be funded (determined under the principles of paragraph (b)(3)) by a grant, contract, or otherwise by another person (or any governmental entity).

(C) *Computation of cost.* The cost computation shall use only reasonable costs incurred after the first indication of an orphan application for the designated drug. Such costs shall include the costs of obtaining data needed, and of meetings to be held, in connection with a request for FDA assistance under section 525 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 360aa) or a request for orphan designation under section 526 of that Act; costs of determining patentability of the drug; costs of screening, animal and clinical studies; costs associated with preparation of a Notice of Claimed Investigational Exemption for a New Drug (IND) and a New Drug Application (NDA); costs of possible distribution of drug under a “treatment” protocol; costs of development of a dosage

form; manufacturing costs; distribution costs; promotion costs; costs to maintain required records and reports; and costs of the taxpayer in acquiring the right to market a drug from the owner of that right prior to designation. The taxpayer shall also include general overhead, depreciation costs and premiums for insurance against liability losses to the extent that the taxpayer can demonstrate that these costs are properly allocable to the designated drug under the established standards of financial accounting and reporting of research and development costs.

(D) *Allocation of common costs.* *Costs for developing and making available the designated drug for both the disease or condition for which it is designated and one or more other diseases or conditions.* In the case where the costs incurred or expected to be incurred in developing and making available the designated drug for the disease or condition for which it is designated are also incurred or expected to be incurred in developing and making available in the United States the same drug for one or more other diseases or conditions (whether or not they are also designated or expected to be designated), the costs shall be allocated between the cost of developing and making available the designated drug for the disease or condition for which the drug is designated and the cost of developing and making available the designated drug for the other diseases or conditions. The amount of the common costs to be allocated to the cost of developing and making available the designated drug for the disease or condition for which it is designated is determined by multiplying the common costs by a fraction the numerator of which is the sum of the expected amount of sales in the United States of the designated drug for the disease or condition for which the drug is designated and the denominator of which is the total expected amount of sales in the United States of the designated drug. For example, if prior to designation, the taxpayer incurs (among other costs) costs of \$100,000 in testing the designated drug for its toxic effect on animals (without reference to any disease or condition), and if the taxpayer

expects to recover \$500,000 from sales in the United States of the designated drug for disease X, the disease for which the drug is designated, and further expects to recover another \$1.5 million from the sales in the United States of the designated drug for disease Y, the taxpayer must allocate a proportionate amount of the common costs of \$100,000 to the cost of developing and making available the designated drug for both disease X and disease Y. Since the ratio of the expected amount of sales in the United States of the designated drug for disease X to the total of both the expected amount of sales in the United States of the designated drug for disease X and the expected amount of sales in the United States of the designated drug for disease Y is \$500,000/\$2,000,000, 25% of the common costs of \$100,000 (*i.e.*, \$25,000) is allocated to the cost of developing and making available the designated drug for disease X.

(iii) *Recovery from sales.* In determining whether the taxpayer's cost described in paragraph (d)(1)(ii) of this section will be recovered from sales in the United States of the designated drug for the disease or condition for which the drug is designated, the taxpayer shall include anticipated sales by the taxpayer or any person whose right to make such sales is directly or indirectly derived from the taxpayer (such as a licensee or transferee). The anticipated sales shall be based upon the size of the anticipated patient population for which the designated drug would be useful, including the following factors: the degree of effectiveness and safety of the designated drug, if known; the projected fraction of the anticipated patient population expected to be given the designated drug and to continue to take it; other available agents and other types of therapy; the likelihood that superior agents will become available within a few years; and the number of years during which the designated drug would be exclusively available, *e.g.*, under a patent.

(iv) *Recordkeeping requirements.* The taxpayer shall keep records sufficient to substantiate the cost and sales estimates made pursuant to this paragraph (d)(1). The records required by this paragraph (d)(1)(iv) shall be retained so

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long as the contents thereof may become material in the administration of section 28.

(2) *Tax liability limitation*—(i) *Taxable years beginning after December 31, 1986.* The credit allowed by section 28 shall not exceed the excess (if any) of—

(A) The taxpayer's regular tax liability for the taxable year (as defined in section 26(b)), reduced by the sum of the credits allowable under—

(1) Section 21 (relating to expenses for household and dependent care services necessary for gainful employment),

(2) Section 22 (relating to the elderly and permanently and totally disabled),

(3) Section 23 (relating to residential energy),

(4) Section 25 (relating to interest on certain home mortgages), and

(5) Section 27 (relating to taxes on foreign countries and possessions of the United States), over

(B) The tentative minimum tax for the taxable year (as determined under section 55(b)(1)).

(ii) *Taxable years beginning before January 1, 1987, and after December 31, 1983.* The credit allowed by section 28 shall not exceed the taxpayer's tax liability for the taxable year (as defined in section 26 (b) prior to its amendment by the Tax Reform Act of 1986 (Pub. L. 99-514)), reduced by the sum of the credits allowable under—

(A) Section 21 (relating to expenses for household dependent care services necessary for gainful employment),

(B) Section 22 (relating to the elderly and permanently and totally disabled),

(C) Section 23 (relating to residential energy),

(D) Section 24 (relating to contributions to candidates for public office),

(E) Section 25 (relating to interest on certain home mortgages), and

(F) Section 27 (relating to the taxes on foreign countries and possessions of the United States).

(iii) *Taxable years beginning before January 1, 1984.* The credit allowed by section 28 shall not exceed the amount of the tax imposed by chapter 1 of the Internal Revenue Code for the taxable year, reduced by the sum of the credits allowable under the following sections as designated prior to the enactment of

the Tax Reform Act of 1984 (Pub. Law 98-369):

(A) Section 32 (relating to tax withheld at source on nonresident aliens and foreign corporations and on tax-free covenant bonds),

(B) Sections 33 (relating to taxes of foreign countries and possessions of the United States),

(C) Section 37 (relating to the retirement income),

(D) Section 38 (relating to investment in certain depreciable property),

(E) Section 40 (relating to expenses of work incentive programs).

(F) Section 41 (relating to contributions to candidates for public office).

(G) Section 44 (relating to purchase of new principal residence).

(H) Section 44A (relating to expenses for household and dependent care services necessary for gainful employment).

(I) Section 44B (relating to employment of certain new employees).

(J) Section 44C (relating to residential energy).

(K) Section 44D (relating to producing fuel from a nonconventional source).

(L) Section 44E (relating to alcohol used as fuel).

(M) Section 44F (relating to increasing research activities), and

(N) Section 44G (relating to employee stock ownership).

The term "tax imposed by chapter 1" as used in this paragraph (d)(2)(iii) does not include any tax treated as not imposed by chapter 1 of the Internal Revenue Code under the last sentence of section 53(a).

(3) *Special limitations on foreign testing*—(i) *Clinical testing conducted outside of the United States—In general.* Except as otherwise provided in this paragraph (d)(3), expenses paid or incurred with respect to clinical testing conducted outside the United States (as defined in section 7701(a)(9)) are not eligible for credit under this section. Thus, for example, wages paid an employee clinical investigator for clinical testing conducted in medical facilities in the United States and Mexico generally must be apportioned between the clinical testing conducted within the United States and the clinical testing conducted outside the United States,

and only the wages apportioned to the clinical testing conducted within the United States are qualified clinical testing expenses.

(ii) *Insufficient testing population in the United States*—(A) *In general.* If clinical testing is conducted outside of the United States because there is an insufficient testing population in the United States, and if the clinical testing is conducted by a United States person (as defined in section 7701(a)(30)) or is conducted by any other person unrelated to the taxpayer to whom the designation under section 526 of the Federal Food, Drug, and Cosmetic Act applies, then the expenses paid or incurred for clinical testing conducted outside of the United States are eligible for the credit provided by section 28.

(B) *“Insufficient testing population.”* The testing population in the United States is insufficient if there are not within the United States the number of available and appropriate human subjects needed to produce reliable data from the clinical investigation.

(C) *“Unrelated to the taxpayer.”* For the purpose of determining whether a person is unrelated to the taxpayer to whom the designation under section 526 of the Federal Food, Drug, and Cosmetic Act and the regulations thereunder applies, the rules of section 613A(d)(3) shall apply except that the number “5” in section 613A(d)(3) (A), (B), and (C) shall be deleted and the number “10” inserted in lieu thereof.

(4) *Special limitations for certain corporations*—(i) *Corporations to which section 936 applies.* Expenses paid or incurred for clinical testing conducted either inside or outside the United States by a corporation to which section 936 (relating to Puerto Rico and possessions tax credit) applies are not eligible for the credit under section 28.

(ii) *Corporations to which section 934(b) applies.* For taxable years beginning before January 1, 1987, expenses paid or incurred for clinical testing conducted either inside or outside the United States by a corporation to which section 934(b) (relating to the limitation on reduction in income tax liability incurred to the Virgin Islands), as in effect prior to its amendment by the Tax Reform Act of 1986, applies are not eli-

gible for the credit under section 28. For taxable years beginning after December 31, 1986, see section 1277(c)(1) of the Tax Reform Act of 1986 (100 Stat. 2600) which makes the rule set forth in the preceding sentence inapplicable with respect to corporations created or organized in the Virgin Islands only if (and so long as) an implementing agreement described in that section is in effect between the United States and the Virgin Islands.

(5) *Aggregation of expenditures*—(i) *Controlled group of corporations; organizations under common control*—(A) *In general.* In determining the amount of the credit allowable with respect to an organization that at the end of its taxable year is a member of a controlled group of corporations or a member of a group of organizations under common control, all members of the group are treated as a single taxpayer and the credit (if any) allowable to the member is determined on the basis of its proportionate share of the qualified clinical testing expenses of the aggregated group.

(B) *Definition of controlled group of corporations.* For purposes of this section, the term “controlled group of corporations” shall have the meaning given to the term by section 41(f)(5).

(C) *Definition of organization.* For purposes of this section, an organization is a sole proprietorship, a partnership, a trust, an estate, or a corporation, that is carrying on a trade or business (within the meaning of section 162). For purposes of this section, any corporation that is a member of a commonly controlled group shall be deemed to be carrying on a trade or business if any other member of that group is carrying on any trade or business.

(D) *Determination of common control.* Whether organizations are under common control shall be determined under the principles set forth in paragraphs (b) through (g) of 26 CFR 1.52-1.

(ii) *Tax accounting periods used*—(A) *In general.* The credit allowable to a member of a controlled group of corporations or a group of organizations under common control is that member’s share of the aggregate credit computed as of the end of such member’s taxable year.

(B) *Special rule where the timing of clinical testing is manipulated.* If the timing of clinical testing by members using different tax accounting periods is manipulated to generate a credit in excess of the amount that would be allowable if all members of the group used the same tax accounting period, the district director may require all members of the group to calculate the credit in the current taxable year and all future years by using the “conformed years” method. Each member computing a credit under the “conformed years” method shall compute the credit as if all members of the group had the same taxable year as the computing member.

(iii) *Membership during taxable year in more than one group.* An organization may be a member of only one group for a taxable year. If, without application of this paragraph (d)(5)(iii), an organization would be a member of more than one group at the end of its taxable year, the organization shall be treated as a member of the group in which it was included for its preceding taxable year. If the organization was not included for its preceding taxable year in any group in which it could be included as of the end of its taxable year, the organization shall designate in its timely filed return the group in which it is being included. If the return for a taxable year is due before May 1, 1985, the organization may designate its group membership through an amended return for that year filed on or before April 30, 1985. If the organization does not so designate, then the district director with audit jurisdiction of the return will determine the group in which the business is to be included.

(iv) *Intra-group transactions—* (A) *In general.* Because all members of a group under common control are treated as a single taxpayer for purposes of determining the credit, transactions between members of the group are generally disregarded.

(B) *In-house research expenses.* If one member of a group conducts clinical testing on behalf of another member, the member conducting the clinical testing shall include in its qualified clinical testing expenses any in-house research expenses for that work and shall not treat any amount received or

accrued from the other member as funding the clinical testing. Conversely, the member for whom the clinical testing is conducted shall not treat any part of any amount paid or incurred as a contract research expense. For purposes of determining whether the in-house research for that work is clinical testing, the member performing the clinical testing shall be treated as carrying on any trade or business carried on by the member on whose behalf the clinical testing is performed.

(C) *Contract research expenses.* If a member of a group pays or incurs contract research expenses to a person outside the group in carrying on the member’s trade or business, that member shall include those expenses as qualified clinical testing expenses. However, if the expenses are not paid or incurred in carrying on any trade or business of that member, those expenses may be taken into account as contract research expenses by another member of the group provided that the other member—

(1) Reimburses the member paying or incurring the expenses, and

(2) Carries on a trade or business to which the clinical testing relates.

(D) *Lease payments.* Amounts paid or incurred to another member of the group for the lease of personal property owned by a person outside the group shall be taken into account as in-house research expenses for purposes of section 28 only to the extent of the lesser of—

(1) The amount paid or incurred to the other member, or

(2) The amount of the lease expense paid to a person outside the group.

The amount paid or incurred to another member of the group for the lease of personal property owned by a member of the group is not taken into account for purposes of section 28.

(E) *Payment for supplies.* Amounts paid or incurred to another member of the group for supplies shall be taken into account as in-house research expenses for purposes of section 28 only to the extent of the lesser of—

(1) The amount paid or incurred to the other member, or

(2) The amount of the other member’s basis in the supplies.

(6) *Allocations*—(i) *Pass-through in the case of an S corporation*. In the case of an S corporation (as defined in section 1361), the amount of the credit for qualified clinical testing expenses computed for the corporation for any taxable year shall be allocated among the persons who are shareholders of the corporation during the taxable year according to the provisions of section 1366 and section 1377.

(ii) *Pass-through in the case of an estate or a trust*. In the case of an estate or a trust, the amount of the credit for qualified clinical testing expenses computed for the estate or trust for any taxable year shall be apportioned between the estate or trust and the beneficiaries on the basis of the income of the estate or trust allocable to each.

(iii) *Pass-through in the case of a partnership*—(A) *In general*. In the case of a partnership, the credit for qualified clinical testing expenses computed for the partnership for any taxable year shall be apportioned among the persons who are partners during the taxable year in accordance with section 704 and the regulations thereunder.

(B) *Certain partnership non-business expenditures*. A partner's share of an in-house research expense or contract research expense paid or incurred by a partnership other than in carrying on a trade or business of the partnership constitutes a qualified clinical testing expense of the partner if—

(1) The partner is entitled to make independent use of the result of the clinical testing, and

(2) The clinical testing expense paid or incurred in carrying on the clinical testing would have been paid or incurred by the partner in carrying on a trade or business of the partner if the partner had carried on the clinical testing that was in fact carried on by the partnership.

(C) *Apportionment*. Qualified clinical testing expenses to which paragraph (d)(6)(iii)(B) of this section applies shall be apportioned among the persons who are partners during the taxable year in accordance with section 704 and the regulations thereunder. For purposes of section 28, these expenses shall be treated as paid or incurred directly by the partners rather than by the partnership. Thus, the partnership

shall disregard these expenses in computing the credit to be apportioned under paragraph (d)(6)(iii)(A) of this section, and each partner shall aggregate the portion of these expenses allocated to the partner with other qualified clinical testing expenses of the partner in making the computations under section 28.

(iv) *Year in which taken into account*. An amount apportioned to a person under paragraph (d)(6) of this section shall be taken into account by the person in the taxable year of such person in which or with which the taxable year of the corporation, estate, trust, or partnership (as the case may be) ends.

(v) *Credit allowed subject to limitation*. Any person to whom any amount has been apportioned under paragraph (d)(6)(i), (ii), or (iii) of this section is allowed, subject to the limitation provided in section 28(d)(2), a credit for that amount.

(7) *Manner of making an election*. To make an election to have section 28 apply for its taxable year, the taxpayer shall file Form 6765 (Credit for Increasing Research Activities (or for claiming the orphan drugs credit)) containing all the information required by that form.

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#### CREDITS AGAINST TAX

#### CREDITS ALLOWABLE UNDER SECTIONS 30 THROUGH 45D

#### § 1.30-1 Definition of qualified electric vehicle and recapture of credit for qualified electric vehicle.

(a) *Definition of qualified electric vehicle*. A qualified electric vehicle is a motor vehicle that meets the requirements of section 30(c). Accordingly, a qualified electric vehicle does not include any motor vehicle that has ever been used (for either personal or business use) as a non-electric vehicle.

(b) *Recapture of credit for qualified electric vehicle*—(1) *In general*—(i) *Addition to tax*. If a recapture event occurs with respect to a taxpayer's qualified electric vehicle, the taxpayer must add the recapture amount to the amount of tax due in the taxable year in which