Internal Revenue Service

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Washington, DC 20224

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Date:
March 11, 2015

In Re: Ruling under § 45C of the Internal Revenue Code

LEGEND:

Taxpayer =

State A =

State B =

Drug =

Disease A =

Disease B =

Year 1 =

Year 2 =

Year 3 =

Year 4 =

Date 1 =

Dear :

This letter is in response to your ruling request, submitted by your authorized representatives, concerning the application of § 45C of the Internal Revenue Code to the facts described below.

The facts and representations submitted are summarized as follows:

Taxpayer is a State A corporation with its principal office located in State B. Taxpayer uses a calendar taxable year accounting period and the accrual method of accounting for maintaining its accounting books and records and filing its federal income tax return.

Taxpayer is engaged in the business of developing and marketing pharmaceutical products. For many years, Taxpayer has conducted clinical studies of Drug for use in the treatment of two different types of rare cancer, Disease A and Disease B. Taxpayer has conducted these clinical studies under section 505(i) of the Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-399f) (2012) ("FDCA"). Taxpayer conducted these clinical studies to generate the data necessary to request marketing approvals for Drug under section 505(b) of the FDCA ("section 505(b)").

In Year 1, Taxpayer requested and received an orphan-drug designation for use of Drug in the treatment of Disease A by the Food and Drug Administration (the "FDA") pursuant to section 526 of the FDCA ("section 526"). In Year 2, the FDA, pursuant to section 505(b), approved Taxpayer's application to market Drug for use in the treatment of Disease A. Taxpayer claimed a credit under § 45C for qualified expenses associated with the clinical testing of Drug for use in the treatment of Disease A.

Additionally in Year 1, Taxpayer requested a separate section 526 orphan-drug designation for use of Drug in the treatment of Disease B, and further requested approval to market Drug for second-line use (i.e., use in the treatment of patients who have failed to respond to other therapies) in the treatment of Disease B. In Year 2, Taxpayer received an approval to market Drug for second-line use in the treatment of Disease B pursuant to section 505(b), but did not receive an orphan-drug designation for use of Drug in the treatment of Disease B until Date 1, Year 4.

Starting in or after Year 2 and continuing through Year 3 and Year 4, Taxpayer conducted clinical testing of Drug for first-line use in the treatment of Disease B (i.e., patients are treated right away with Drug, rather than after failing other therapies). In Year 3, prior to receiving a section 526 orphan-drug designation for use of Drug in the treatment of Disease B, Taxpayer submitted an application under section 505(b) seeking FDA approval to market Drug for first-line use in the treatment of Disease B.

Taxpayer represents that the FDA's regulations require a supplemental application and approval under section 505(b) before Taxpayer can expand its marketing of Drug from second-line use to first-line use in the treatment of Disease B. The section 505(b) application for first-line use in the treatment of Disease B remains open as of the date of this ruling request.

Throughout Year 4, Taxpayer continued to incur expenses for human clinical testing of Drug for first-line use in the treatment of Disease B. Taxpayer represents that the expenses related to human clinical testing of Drug after the FDA designated it as an orphan drug for use in the treatment of Disease B, would be described as "qualified research expenses" under § 41(b) if § 41 applied to clinical testing, rather than qualified research, taking into account the modifications to § 41(b) described in § 45C(b)(1)(B).

Taxpayer represents that the clinical testing of Drug for first-line treatment of Disease B meets all other requirements under § 45C and Treas. Reg. § 1.28-1[1] to be characterized as human clinical testing.

Accordingly, Taxpayer requests a ruling that the human clinical testing of Drug after Date 1, Year 4, relating to obtaining the FDA's approval under section 505(b) for Drug's use as a first-line treatment for Disease B, satisfies the requirement in § 45C(b)(2)(A)(ii) that such testing occur after the date Drug is designated as an orphan drug under section 526 and before the date on which an application with respect to Drug is approved for marketing under section 505(b).

Section 45C(a) provides an orphan drug credit in an amount equal to 50 percent of a taxpayer's qualified clinical testing expenses for the taxable year.

In general, § 45C(b)(1)(A) defines "qualified clinical testing expenses" as the amounts which are paid or incurred by the taxpayer during the taxable year which would be described in § 41(b) ("qualified research expenses") upon the modifications set forth in § 45C(b)(1)(B).

Section 45C(b)(1)(B) applies § 41(b) by (i) substituting "clinical testing" for "qualified research" each place it appears in paragraphs (2) (relating to in-house research expenses) and (3) (relating to contract research expenses) of § 41(b), and (ii) substituting "100 percent" for "65 percent" in paragraph (3)(A) of § 41(b).

Section 45C(b)(2)(A) defines the term "clinical testing" as any human clinical testing (i) which is carried out under an exemption for a drug being tested for a rare disease or condition under section 505(i) of the FDCA (or regulations issued under such section),

[1] The regulations governing § 45C were issued under former § 28, the predecessor to § 45C.

(ii) which occurs (I) after the date such drug is designated under section 526, and (II) before the date on which an application with respect to such drug is approved under section 505(b), and (iii) which is conducted by or on behalf of the taxpayer to whom the designation under such section 526 applies.

Section 45C(b)(2)(B) provides that human clinical testing shall be taken into account under subparagraph (A) only to the extent such testing is related to the use of a drug for the rare disease or condition for which it was designated under section 526.

Section 45C(d)(2)(A) provides that, in general, no credit is allowed for clinical testing conducted outside the United States.

Treas. Reg. § 1.28-1(c)(2) provides, in relevant part, that 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 to be approved under section 505(b) and the regulations thereunder. 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.

Treas. Reg. § 1.28-1(c)(3) provides, in relevant part, that human clinical testing is not carried out under section 505(i) and the regulations thereunder 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.

Section 45C provides a credit for qualified clinical testing expenses for clinical testing, which, as defined by § 45C(b)(2), is limited to human clinical testing which occurs "*after* the date" a drug is designated as an orphan drug under section 526 and "*before* the date on which *an* application" with respect to such drug is approved for marketing under section 505(b) (emphasis added).

Taxpayer represents that the FDA may approve a drug for use in the treatment of a rare disease or condition or only for select indication(s) or use(s) within the rare disease or condition for which the drug was orphan-designated. If the FDA approves an initial application to market the drug for only select indications or uses within a rare disease or condition, a supplemental application and approval is necessary to market the drug for additional indications or uses within the rare disease or condition. Moreover, an additional application and approval would be necessary to market the drug for another disease. Thus, Taxpayer represents that it is not uncommon in the FDA approval process for multiple section 505(b) applications to be submitted and approved with respect to the same drug.

Prior to Date 1, Year 4, the date the FDA designated Drug as an orphan drug for use in the treatment of Disease B, Taxpayer had previously obtained approval under section 505(b) to market Drug for use in the treatment of Disease A and for use as a second-line therapy in the treatment of Disease B. Taxpayer represents that a supplemental application was necessary to obtain approval under section 505(b) to market Drug as a first-line treatment for Disease B, thereby expanding the portion of the orphan population that can be treated with Drug.

Accordingly, based solely upon the facts submitted and representations made, we conclude that Taxpayer's human clinical testing of Drug after Date 1, Year 4, relating to obtaining the FDA's approval under section 505(b) for Drug's use as a first-line treatment for Disease B, satisfies the requirement in § 45C(b)(2)(A)(ii) that such testing occur after the date Drug is designated as an orphan drug under section 526 and before the date on which an application with respect to such drug is approved for marketing under section 505(b).

Except as specifically set forth above, we express or imply no opinion regarding the tax consequences of any aspect of any transaction or item discussed or referenced in this letter. Specifically, we express or imply no opinion as to whether Taxpayer satisfies any other requirement of § 45C or Treas. Reg. § 1.28-1. We also express or imply no opinion as to whether any sales of Drug qualify for an exclusion from the branded prescription drug fee under section 9008 of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by section 1404 of the Health Care Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010), or the regulations thereunder.

This ruling is directed only to the taxpayer requesting it. Section 6110(k)(3) provides that it may not be used or cited as precedent.

In accordance with the Power of Attorney on file with this office, a copy of this letter is being sent to your authorized representatives.

Sincerely,

Jaime C. Park
Chief, Branch 6
Office of the Associate Chief Counsel
(Passthroughs & Special Industries)

Enclosures (2):
Copy of this letter
Copy for § 6110 purposes

cc: