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Department of the Treasury
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Person To Contact:
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Date:
October 10, 2017

Re:

LEGEND

Taxpayer =

Company B =

Company C =

Company D =

Company E =

Company F =

State A =

State B =

Country =

Drug =

Condition 1 =

Condition 2 =

Date 1 =

Date 2 =

Date 3 =

Date 4 =

Date 5 =

Date 6 =

Dear :

This letter responds to a request for a private letter ruling dated April 13, 2017, and subsequent correspondence submitted on behalf of Taxpayer by your authorized representatives concerning § 45C of the Internal Revenue Code. The relevant facts as represented in your submissions are set forth below.

FACTS

Taxpayer is a State A corporation with its headquarters in State B. Taxpayer is wholly owned by Company B (a State A corporation), which is wholly owned by Company C (a State A limited liability company). Company C is the wholly owned subsidiary of Company D (a State A limited liability company), which is the wholly owned subsidiary of Company E (a Country corporation). Company D files a consolidated return for the Taxpayer consolidated group. On Date 1, Company C acquired Company B and its subsidiary, Company F, which held the rights to Drug. Company F was then renamed as Taxpayer, and continues to be the legal owner of Drug.

On Date 2, the FDA granted Drug orphan drug designation under section 526 of the FDCA for the treatment of Condition 1. On Date 3, Company F submitted a new drug application (NDA) to the Food and Drug Administration (FDA) to obtain marketing approval for Drug. Company F submitted the Drug NDA under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) (under which all NDAs are submitted),

and subsequently amended the pending NDA several times prior to its eventual approval.

In a letter dated Date 4, the FDA approved the Drug NDA for the treatment of Drug for the treatment of Condition 2, under the accelerated approval program described in section 506(c) of the FDCA and FDA regulations at 21 C.F.R. Part 314, Subpart H. The section 506(c) accelerated approval provision of the FDCA authorizes the FDA to approve an application for a product for a serious or life-threatening disease or condition, including a fast track product upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

As set forth in section 506(c)(2) of the FDCA, the FDA can subject a product approved under accelerated approval to the limitation that the sponsor conduct appropriate post-approval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit. Depending on the outcome of the required confirmatory studies, or if the sponsor fails to conduct the required studies, the FDA could move to withdraw the approval of an accelerated approval product. Section 506(c)(3) of the FDCA authorizes the FDA to expedite the withdrawal of an accelerated approval for several reasons, including if a sponsor fails to conduct any required post-approval study of the drug with due diligence, or a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit.

Specific requirements of the accelerated approval program are described in the FDA's accelerated approval regulations, which predate the FDCA section 506 accelerated approval provisions. In the Drug approval letter, the FDA cites to those regulations, explaining that the NDA, as amended, "is approved under the provisions of accelerated approval regulations (21 CFR 314.500), effective on the date of this letter… Marketing of this drug product and related activities must adhere to the substance and procedures of the referenced accelerated approval regulations."

The Drug approval letter further provides:

Regarding the confirmatory study that the FDA required for Drug, as described in the Date 4 Drug approval letter, the FDA required a Post Marketing Requirement (PMR) study to verify the Drug clinical benefit. Also included in the approval letter was a schedule with the trial requirements and required completion dates.

Following the acquisition of Company B, Taxpayer reviewed the PMR study for Drug, and determined that the study was not feasible, given the required sample size and limited patient population for the orphan indication. Taxpayer met with the FDA on Date 5 to discuss an alternative study design, and revised completion milestones. The FDA agreed with Taxpayer's proposal for an amended study design. In a letter dated Date 6, the FDA released Taxpayer from the original PMR and conveyed a new PMR. Additionally, PMR completion dates were updated.

Taxpayer represents that Company F submitted the NDA to obtain marketing approval for Drug under section 505(b)(1) of the FDCA. Final approval of the NDA is under section 505(b) of the FDCA, as contemplated in § 45C(b)(2)(A)(ii)(II). Further, Taxpayer represents that the PMR study is being carried out under an exemption under section 505(i) of the FDCA (or regulations issued under such section) applicable to the NDA application.

RULING REQUESTED

Taxpayer requests a ruling that Taxpayer's qualified clinical testing expenses, as defined in § 45C(b)(1)(A), may include expenses for clinical trials that occur after the date the FDA granted Drug accelerated approval under 21 CFR 314.500, and which were required as a condition of the accelerated approval of that NDA, and before the date Taxpayer receives FDA notification that such Drug condition of approval post-marketing study requirements are no longer necessary for the safe and effective use of Drug, or the date the FDA determines that the required Drug post-marketing study verifies and describes the drug's clinical benefit, pursuant to 21 CFR 314.560.

LAW AND ANALYSIS

Section 45C provides a general business credit in an amount equal to 50 percent of the qualified clinical testing expenses for the taxable year. Section 45C(b)(1)(A) defines the term "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) if § 41(b) were applied with certain modifications set forth in § 45C(b)(1)(B). Section 45C(1)(B)(i) provides that § 41(b)(A) shall be applied by substituting "clinical testing" for "qualified research" each place it appears in § 41(b)(2) and (3).

Section 45C(b)(2)(A) defines the term "clinical testing" as any human clinical testing 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 that

section), which occurs (i) after the drug is designated under section 526 of the FDCA and (ii) before the date on which an application with respect to such drug is approved under section 505(b) of the FDCA. Section 45C(b)(1)(B) applies § 41(b) by (i) substituting "clinical testing" for "qualified research" each place it appears in paragraphs (2) and (3) of § 41(b), and (ii) substituting "100 percent" for "65 percent" in § 41(b)(3)(A).

Section 1.28-1(c)(1) of the Income Tax Regulations provides, in relevant part, that the term "clinical testing" means any human clinical testing which occurs before the date on which an application for the designated drug is approved under section 505(b) of the FDCA.

Section 45C(b)(2)(A), does not refer to accelerated approval, which was first formally established in the FDA's New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 58942 (Dec. 11, 1992) (the "1992 FDA Regulations"). The preamble to the 1992 FDA Regulations states, "these new procedures are intended to provide expedited marketing of drugs for patients suffering from such illnesses when the drugs provide meaningful therapeutic benefit compared to existing treatment." In 2012, Congress wanted to expand the FDA's authority to approve drugs on an accelerated basis, and as part of the Food and Drug Administration Safety and Innovation Act (FDASIA), provided statutory rules in section 506 that are largely consistent with the FDA rules for accelerated approval. Although provisions governing accelerated approval are now also found in section 506 of the FDCA, those provisions were not added to the FDCA until enactment of the FDASIA in 2012. They were not part of the FDCA in 1983, when the Orphan Drug Act was first enacted, establishing the tax credit and the type of clinical testing that would be eligible for the credit.

The "accelerated approval" process is described in section 506(c) of the FDCA, which includes various provisions governing expedited approval of drugs for serious or life-threatening disease or conditions. For accelerated approval drugs, the initial approval is based only on an effect on a surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict a drug's clinical benefit. For the drug to be able to remain on the market, a post-approval study is typically required as a condition of approval to verify and describe the anticipated clinical benefit. When a confirmatory study is required for an accelerated approval drug (as is the case of Drug), and the study is not conducted, the FDA could withdraw approval of the drug.

Post-marketing studies required as conditions of approval for accelerated approval drugs are clinical testing within the meaning of § 45C. Accelerated approval is not a final approval as contemplated by the cross reference to section 505(b) in § 45C(b)(2)(A)(ii)(II). The preamble to the 1992 FDA Regulations states:

> Where a drug's approval under these provisions is based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or

> irreversible morbidity, the applicant will be required to conduct clinical studies necessary to verify and describe the drug's clinical benefit and to resolve remaining uncertainty as to the relation of the surrogate endpoint upon which approval was based to clinical benefit, or the observed clinical benefit to ultimate outcome. The requirement for any additional study to demonstrate actual clinical benefit will not be more stringent than those that would normally be required for marketing approval; it is expected that the studies will usually be underway at the time of approval. The proposed regulations have been revised to clarify that required post-marketing studies must also be adequate and well-controlled.

The preamble further provides that approval "under these procedures is dependent on compliance with certain additional requirements, such as timely completion of studies to document the expected clinical benefit."

In section 901(a)(1)(C) of the FDASIA, Congress provided that in enacting section 506 of the FDCA, it hoped to provide the FDA additional authority to grant approval for drugs in limited circumstances "without compromising or altering the high standards of the FDA for the approval of drugs." Section 506(e)(1) and (2), provides that FDASIA amendments to the FDCA are "intended to encourage the Secretary to utilize innovative and flexible approaches to the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs… [and that] [n]othing in this section shall be construed to alter the standards of evidence under subsection (c) or (d) of section 505."

Based on the foregoing, we conclude that Taxpayer's qualified clinical testing expenses, as defined in § 45C(b)(1)(A), may include expenses for clinical trials that occur after the date the FDA granted Drug accelerated approval under 21 CFR 314.500, and which were required as a condition of the accelerated approval of that NDA, and before the date it receives FDA notification that such Drug condition of approval post-marketing study requirements are no longer necessary for the safe and effective use of Drug, or the date the FDA determines that the required Drug post-marketing study verifies and describes the drug's clinical benefit, pursuant to 21 CFR 314.560.

Except as specifically set forth above, no opinion is expressed or implied concerning the federal income tax consequences of the above described facts under any other provision of the Code or regulations.

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

This ruling is based upon information and representations submitted by Taxpayer and accompanied by penalty of perjury statements executed by an appropriate party.

While this office has not verified any of the material submitted in support of the request for rulings, it is subject to verification on examination.

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,

David A. Selig
Senior Counsel, Branch 6
Office of Associate Chief Counsel
(Passthroughs and Special Industries)

Enclosure: 6110 copy