Planning & Examination of Research Credit – Generic Drugs

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MEMORANDUM FOR INDUSTRY DIRECTORS
DIRECTORS, FIELD OPERATIONS
DIRECTOR, FIELD SPECIALISTS
DIRECTOR, PRE-FILING AND TECHNICAL GUIDANCE

FROM: Robert E. Brazzil /s/ Robert E. Brazzil
Industry Director
Retailers, Food, Pharmaceuticals & Healthcare Industry

SUBJECT: LMSB Directive on the Planning & Examination of Research Credit – Generic Drugs

General Guidance

These procedures provide the guidelines for examiners when they encounter taxpayers that have claimed entitlement for the research credit under I.R.C. § 41 for expenses related to the development of a generic drug.

Generic Drugs

Generic drugs, like all other new drugs, must be approved by the Food and Drug Administration (FDA) before they are marketed in interstate commerce. Generally, new drug products are approved by the FDA on the basis of a "new drug application" (NDA). Generic drugs are approved by the FDA on the basis of an "abbreviated new drug application" (ANDA). ANDAs are permitted for new drugs containing the same active ingredient(s) as a "listed drug." A listed drug is a new drug product that has an effective approval under section 505(c) of the Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 355(c), for safety and effectiveness or under section 505(j) of the Act, 21 U.S.C. 355(j).

The significant difference between an ANDA and an NDA is that the NDA must contain data demonstrating the safety of the new drug and substantial evidence establishing the effectiveness of the new drug for its intended use. The safety and effectiveness of a listed drug is demonstrated through clinical testing of the product.

The information contained in an ANDA must show that the active ingredient, the route of administration, the dosage form, the strength and the conditions of use recommended in the labeling of the generic drug are the same as the listed drug. In addition, the information contained in the ANDA must show that the generic drug is the bioequivalent1 of the listed drug.2 An ANDA applicant must certify that the generic drug will not infringe any patents held by the maker of the listed drug, that any patents on the listed drug have expired or the date on which the relevant patents will expire, or that the patent on the listed drug is invalid. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1586, 21 USC § 355(j). An ANDA does not need to include safety and effectiveness information and the ANDA applicant does not need to perform clinical studies. The ANDA applicant relies on information available to the FDA from tests conducted on the listed drug to demonstrate that the active ingredient is safe and effective. The generic drug is presumed safe and effective on the basis of the bioequivalence studies.

For purposes of this guidance, we are concerned only with taxpayers that are claiming the research credit for activities related to drugs developed under an ANDA. If you have any questions concerning whether the drug in question is a generic drug, please contact the Technical Advisor for the Pharmaceutical Industry.

Law

Section 41 provides a credit for increasing research activities. The term "qualified research expenses" is defined in section 41(b). Qualified research expenses include in-house expenses for wages paid in the conduct of qualified research and for supplies used in the conduct of qualified research, and 65 percent of any contract expenses for qualified research.

Section 41(d)(1) defines the term "qualified research" as research--

> (A) with respect to which expenditures may be treated as expenses under section 174,
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> (B) that is undertaken for the purpose of discovering information that is technological in nature and the application of which is intended to be useful in the development of a new or improved business component of the taxpayer, and
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> (C) substantially all of the activities of which constitute elements of a process of experimentation for a functional purpose.

However, section 41(d)(4) excludes several activities from the definition of the term "qualified research." Under section 41(d)(4)(C), any research related to the reproduction of an existing business component (in whole or in part) from a physical examination of the business component itself or from plans, blueprints, detailed specifications, or publicly available information with respect to such business component is not considered qualified research for purposes of section 41(d)(1).

Discussion

The recent final regulations issued under section 41 do not contain a specific rule on the development of generic drugs. The regulations apply to generic drugs in the same manner they apply to other business components. Treas. Reg. § 1.41-4(a)(3) provides, "[f]or purposes of section 41(d) and this section, research is undertaken for the purpose of discovering information only if it is undertaken to obtain knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in a particular field of science or engineering." Treas. Reg. § 1.41-4(a)(3)(ii) provides that the common knowledge of skilled professionals in a particular field of science or engineering means information that should be known to skilled professionals had they performed, before the research in question is undertaken, a reasonable investigation of the existing level of information in the particular field of science or engineering. In addition, Treas. Reg. § 1.41-4(a)(3)(iii) states that in seeking to obtain knowledge that exceeds, expands, or refines the common knowledge of skilled professionals in a particular field of science or engineering, a taxpayer may employ existing technologies and rely on existing principles. Treas. Reg. § 1.41-4(a)(3)(ii) provides that the common knowledge of skilled professionals in a particular field of science or engineering means information that should be known to skilled professionals had they performed, before the research in question is undertaken, a reasonable investigation of the existing level of information in the particular field of science or engineering and explicitly states that knowledge may exceed, expand, or refine the common knowledge of skilled professionals even where such knowledge has previously been obtained by others. For example, trade secrets generally are not within the common knowledge of skilled professionals in a particular field of science or engineering because they are not reasonably available to skilled professionals not employed, hired, or licensed by the owners of such trade secrets.

In addition to satisfying the general rules for credit eligibility, taxpayers claiming the research credit for any activity, including activities for the development of generic drugs, must establish that the activity is not an excluded activity under section 41(d)(4). Taxpayers who develop generic drugs may be able to satisfy the discovery test and avoid the duplication exclusion when undertaking

research directed toward the development of a generic drug. See Treas. Reg. § 1.41-4(c)(10), Example 6. Accordingly, we will not assert a per se rule to exclude all generic drug research activities from credit eligibility.

Examination Guidance

Eligibility for the research credit is to be determined on a case by case basis. We will not assert a per se rule to exclude all research credit with respect to generic drug research activities. To avoid inconsistent and inequitable treatment of taxpayers, we are establishing the following procedures.

Each Team Manager must notify the Industry Director, the Area Counsel, and the Technical Advisor for Pharmaceuticals (who will act as a generic drug review team) whenever an examination team intends to raise a section 41 credit issue in a generic drug context. This notification is required whenever an examination team intends to either disallow or allow the section 41 credit for research done to develop a generic drug. The generic drug review team, in consultation with the team manager, will determine the IRS's field position regarding whether to allow the section 41 credit for the research done for the generic drug.

We believe that the best mechanism to resolve this issue may be prospective pre-filing agreements entered into at the beginning of research. The data we gather as a result of each team reporting any generic drug case will assist us in shaping any future pre-filing agreements. Further, it may assist us in developing Industry Issue Resolution Program guidance.

If you have any questions regarding this new procedure, please call David Carter, PFTG Technical Advisor Manager at 404-338-9444.

1 The term "bioequivalence" means the absence of a significant difference in the rate and extent to which the active ingredient in pharmaceutical equivalents becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. 21 CFR 320.1.

2 Section 355(j)(2)(C) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(C) (1992), does allow variances from these requirements in limited circumstances. Applicants under this provision must submit a separate petition requesting permission to file an abbreviated new drug application.