LARGE AND MID-SIZE
BUSINESS DIVISION

DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
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MEMORANDUM FOR INDUSTRY DIRECTORS
DIRECTORS, FIELD OPERATIONS
DIRECTOR, FIELD SPECIALISTS
DIRECTOR, PREFILING AND TECHNICAL GUIDANCE

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

SUBJECT: LMSB Directive on the Examination of Legally Mandated Research and Experimentation Expenses in the Biotech and Pharmaceutical Industries

Introduction

The purpose of this memorandum is twofold. First, it provides guidelines for examiners on categories of contemporaneous documentation that may be useful in determining whether a taxpayer's research and experimentation expenses for biotech and pharmaceutical products fall within the exclusive apportionment rule for legally mandated research and experimentation expenses provided in Treasury Regulation Section 1. 861-17(a)(4).

Second, this memorandum in conjunction with the Coordinated Issue Paper provides guidelines on the efficient use of audit time and resources devoted to the examination of the issue for all tax years. The Coordinated Issue Paper formalizes the IRS position on the conditions under which the legally mandated standard is met. This memorandum introduces materiality thresholds that are recommended for examiners to consider in developing their examination plan. This represents a management decision to focus limited examination resources on the development of this factually intensive issue on taxpayer positions that fall above the materiality thresholds presented herein, while taking into

consideration recent relevant international developments in the drug approval process.

This LMSB Directive is not an official pronouncement of the law or the Service's position and cannot be used, cited, or relied upon as such.

Background

On June 18, 2003, a Coordinated Issue Paper for the biotech and pharmaceutical industries on legally mandated research and experimentation expenses was released. That paper is available on the LMSB Pre-Filing and Technical Guidance and the publicly accessible IRS.gov web sites. It should be consulted for general examination procedures in this area.

The paper concludes that research and experimentation expenses do not fall within the exclusive apportionment rule for legally mandated research and experimentation expenditures under Treasury Regulation Section 1.861-17(a)(4) unless they meet certain quite specific requirements. The subject regulation specifies the following criteria for research and experimentation expenses that are necessary to meet the legally mandated standard:

- The expenses were incurred solely to meet legal requirements by a political entity;
- The expenses were incurred with respect to improvement or marketing of specific products or processes; ***and*,**
- The research and experimentation results cannot reasonably be expected to generate amounts of gross income, beyond de minimis amounts, outside of a single geographic source.

In the context of the biotech and pharmaceutical industries, the legally mandated standard for allocating research and experimentation expenses solely to gross income within the United States is demonstrated in the following scenarios:

- If a drug first receives approval for sale in the United States, it must be established that research and experimentation was undertaken solely to meet the United States Food and Drug Administration (FDA) requirements and were not required or used to obtain foreign approval.
- If a drug first receives approval in a foreign jurisdiction before receiving approval in the United States, it must be established that the expenditures incurred were attributable to research and experimentation undertaken solely to meet the United States FDA requirements and were not required or previously used to obtain foreign approval, and will not be used to expand other areas of foreign approval.

Whether first approved in the United States or in a foreign jurisdiction, the results of the research and experimentation must not be reasonably expected to generate more than de minimis amounts of gross income outside the United States.

The process of establishing amounts of research and experimentation expenditures that meet the legally mandated standard is highly fact intensive, and may differ from case to case. It requires substantiation with contemporaneous documentation of the data generated as a result of the mandated research and experimentation, as well as other relevant data that is contemporaneous with the period for which the legally mandated expenses were claimed.

To assist in the determination of whether research and experimentation expenses meet the legally mandated standard, a listing of documents has been compiled for examiners to consider reviewing. It consists of both internally and externally generated information. It should be stressed that this listing does not represent a pro-forma Information Document Request (IDR), and should not be used as such.

Suggested Documentation

1) Internal Drug Review Process – This is an internal document which describes the steps a company takes in order to bring a product from discovery to development. The document should include the committees and or persons involved in the decision making checkpoints throughout the drug development process. All reports and analyses submitted to these committees should also be requested for any drug candidate for which legally mandated expenditures are being claimed.

2) Research Budget – This document would provide a listing of projects the company is funding and the dollar amounts committed to such development. It might be helpful to also request the budget funding requests in an effort to determine which drug candidates received funding and why. This way a comparison of the funding request to the final budget can be made.

3) Worldwide Organizational Chart - This provides a schematic of the company's worldwide operations. It will identify subsidiaries, partnerships, joint ventures etc. in which the company has an ownership interest, the countries in which the various entities are located, and the type of business those entities are conducting.

4) Common Technical Document – This document is an internationally agreed upon format for the submission of a well structured application for marketing approval to be submitted to regulatory authorities in the three International Committee on Harmonization (ICH) regions. They consist of Europe, the United States and Japan. This document is intended to facilitate regulatory review and communication. It is based on guidance implemented by the ICH. Two important areas of guidance are:

> a) ICH Guidance E3 – Structure and Content of Clinical Study Reports. This guidance provides for a single compilation in a uniform format and

content of world wide core clinical study reports for inclusion in new product applications to regulatory authorities for drug approvals in the three ICH regions. This ensures more efficient generation of data and submission of applications to regulatory authorities.

b) ICH Guidance E5 – Acceptability of Foreign Clinical Data for Approval in other jurisdictions – This guidance is based on the premise that it is not necessary to repeat the entire clinical drug development program in a new region. It recommends regulatory and developmental strategies for accepting foreign clinical data either as primary or partial support for approval of an application in a new region.

5) Strategic Marketing Plans/Clinical Development Plans – Most companies have multiple drug candidates. Decisions must be made regarding the drug candidates that take into account the size of the potential patient population, the potential market for the drug, whether or not the market is already well served, potential sales for the product, including third party payments such as government and insurance reimbursements, type of product launch campaigns, and the company's financial situation. These decisions typically take place prior to the beginning of a clinical trial. Strategic Marketing Committees and Clinical Development Committees consider these factors when determining which drug candidates to continue funding for the next phase.

6) Annual Reports/10Ks - These documents provide an overview of the company, products, research and development projects and phase of development, business relationships (joint ventures, alliances etc.), marketing, financial results, and business goals.

7) Foreign Applications – This document is submitted to the regulatory authorities for review and approval. The document section that is of interest is the foreign clinical data section. This section will encompass all trials performed to prove a drug is safe and effective for its intended use. A summary or excerpt from this foreign clinical data section as to whether U.S. clinical trials were utilized would be required.

8) FDA Correspondence Files – These files are communications between the drug sponsor and the FDA during the various phases of drug development and post marketing approval. These communications are typically housed in the Regulatory Affairs department of the drug company and can provide insight into what the FDA may require of the taxpayer during the drug approval process.

9) Federal Tax Forms – The following forms should be reviewed:

a) Form 5471 – Information return of U.S. Persons with respect to Certain Foreign Corporations. This return is an annual requirement of a U.S. person for each corporation that person controls (see Treas. Reg. 1.6038-2 for definitions of control and U.S. person). The types of information contained in this return

are: name of the foreign corporation, principal place of business, nature of the business and financial transactions between the corporation and the person required to file the return, any other corporation controlled by that person, or any U.S. person owning 10% or more of any class of stock of the foreign corporation, or any corporation controlling that foreign corporation.

b) Form 5472 - Information Return of a 25% Foreign owned U.S. Corporation or a Foreign Corporation engaged in a U.S. Trade or Business under sections 6038A and 6038C of the Internal Revenue Code. This return is an annual requirement and must be attached to a reporting corporation's income tax return if it had a reportable transaction with a foreign or domestic related party. Reportable transactions can be found in Parts IV and V of the form. The permanent books and records supporting these transactions must be kept by the reporting corporation as required by IRC Section 6001.

c) Form 1118 – Foreign Tax Credits Corporations – Review Schedule H Parts 1 and 2 in order to determine the total amount of research and experimentation to be allocated and apportioned under either the sales method or the gross income method. Request taxpayer workpapers as to the breakdown of total research and experimentation expenses to be allocated and apportioned. Determine that total research and experimentation as defined by IRC 174, and reported on Line 1 of Schedule H Part 1 or 2, has not been netted by any legally mandated amount. Line 1 total research and experimentation to be allocated and apportioned is never a net amount.

d) Form 1120 FSC – Foreign Sales Corporation – Review Schedule P for the combined taxable income computation between the FSC and its related supplier. Submit an IDR for a breakdown of expenses that were allocated and apportioned to combined taxable income, especially research and experimentation. This is because expenses are allocated and apportioned on a fully loaded basis in accordance with Treasury Regulation Section 1.861-8 and 1.861-17. Determine that total research and experimentation to be allocated and apportioned is total research and experimentation defined by Internal Revenue Code (IRC) Section 174 and has not been netted by any legally mandated amount.

e) Form 1120 Possession Corporation – Review Form 5735 Schedule P of the Possession Corporation return in order to determine the total amount of research and experimentation that was allocated and apportioned under either the cost sharing or profit split methods between the Possession Corporation and its affiliated group. Expenses are to be allocated and apportioned on a fully loaded basis in accordance with Treasury Regulation Sections 1.861-8 and 1.861-17. Determine that total research and experimentation to be allocated and apportioned is total research and experimentation defined by IRC Section 174 and has not been netted by any legally mandated amount.

This compilation of documents does not constitute an all-inclusive listing of relevant information, which may vary on a case by case basis. It is highly recommended that examiners ask taxpayers for their input regarding the type of documents they retain, including the names of the documents that should be requested so that the proper determination of expenditures that meet the legally mandated standard can be made.

Examination Planning and Guidance

The Service's position on the legally mandated issue was formalized on June 18, 2003 with the release of the Coordinated Issue Paper. It is recommended that examiners follow its guidelines in conjunction with the documentation requirement set forth above and materiality thresholds set forth below. This will ensure that limited resources are effectively directed towards the development of this highly fact intensive issue on positions that fall above the thresholds presented below.

The Retailers, Food, Pharmaceuticals and Healthcare (RFPH) Industry has reviewed the costs and efforts associated with developing the legally mandated research and experimentation issue as set forth in the Coordinated Issue Paper. Based on that consideration:

- For tax years prior to 1998, it is recommended that examiners do not pursue the issue if legally mandated research and experimentation expense as claimed on the taxpayer's original filed return, or amended taxable return, is less than 10 percent of the total Internal Revenue Code Section 174 research and experimentation pool of expense to be allocated and apportioned, as defined in Treasury Regulation Sections 1.861-8(e)(3) for years prior to 1996 and 1.861-17(a)(1)-(4) for years after 1995.

- For tax years 1998 through 2002, it is recommended that examiners do not pursue the issue if legally mandated research and experimentation expense as claimed on the taxpayer's original filed return, or amended taxable return, is less than 5 percent of the total Internal Revenue Code Section 174 research and experimentation pool of expense to be allocated and apportioned, as defined in Treasury Regulation Section 1.861-17(a)(1)-(4).

The materiality standard outlined above does not necessitate obtaining a deviation from the Coordinated Issue Paper as set forth in IRM Section 4.5. However, it is requested that in the event a taxpayer files an amended return to come within the above materiality standards, the Technical Advisor for Biotech or Pharmaceuticals be notified.

Factors Considered in Establishing Timeline and Materiality Thresholds

The timeline and materiality thresholds are based on the following factors. They are based on the observations and trends by RFPH of compliance in the area of legally mandated research and experimentation in the biotech and pharmaceutical industries.

They also take into consideration the changing international regulatory environment reflected in the trend towards the harmonization of the drug approval process that is making it more difficult for the biotech and pharmaceutical industries to meet the legally mandated standard.

The significant benchmark that defined the timeline for establishing the initial materiality threshold set for tax years filed prior to 1998 was based on the adoption in the United States of guidance that was published by the FDA, under the auspices of the International Conference on Harmonization (ICH) which is committed to eliminating duplication of testing among the three member regions. In 1997, the FDA published guidance entitled, "E5: Ethnic Factors in the Acceptability of Foreign Clinical Data" that recommends regulatory and developmental strategies to permit clinical data collected in one region to be used for support of drug or biologic registration in another region. The guidance was adopted in 1998.

If you have any questions, please contact Lou Milano, Technical Advisor, Biotech at (908) 301-2106, or Mario Perez, Technical Advisor, Pharmaceuticals at 732-819-3182 ext. 354, or Jolanta Sander, Senior Program Analyst, Retailers, Food, Pharmaceuticals & Healthcare at 630-493-5935.

cc: Commissioner and Deputy Commissioner, LMSB
Director, Quality Assurance and Performance Management