LARGE AND MID-SIZE
BUSINESS DIVISION

DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
WASHINGTON, D.C. 20224

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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 Industry

SUBJECT: LMSB Directive on the Planning and Examination of Research Credit Issues in a Branded Pharmaceutical Company

Introduction

This memorandum provides guidelines for the efficient use of audit time and resources devoted to the examination of Research Credit issues in the context of a pharmaceutical company whose principal products are branded and covered by patents or other intellectual property protections. 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

The Research Credit Technical Advisor recently issued a broad discussion of appropriate examination techniques for agents to follow in considering claims by taxpayers generally with respect to the credit under I.R.C. § 41. That paper is available on the PFTG web site, and should be consulted for general examination procedures in this area. However, there are some unique aspects to the research process of branded pharmaceutical companies. Therefore, the attached paper has

been prepared to analyze and recommend specific examination considerations to be used in the context of those examinations.

In general, section 41 provides for a credit against tax for increased efforts in qualified research and experimentation. The examination of these claims, whether on the return as originally filed or on claims for refund filed after the original return, has consumed significant examination resources.

In the context of a branded pharmaceutical company, it is clear that qualified research is being conducted, though the exact scope of that determination can only be made on a case-by-case basis after examination of the particular circumstances of the taxpayer. With that in mind, however, it is also clear that some activities of a branded pharmaceutical company raise fewer questions and concerns than other activities.

Planning and Examination Risk Analysis

Attached to this memorandum is a paper and related exhibits, which describe the research process of a branded pharmaceutical company. This paper makes recommendations for risk analysis and the scope of examination activity in this area. The Industry Director expects examination teams conducting examinations of branded pharmaceutical companies to apply these considerations in determining the scope of their examination activity in connection with research credit claims.

Definitions

1. Branded Pharmaceutical Company: As used in this directive and the attached paper, the term "branded pharmaceutical company" means a company whose principal business activity is developing, manufacturing and selling chemical or biological products for human use that are licensed by the United States Food and Drug Administration or a similar regulatory agency of a foreign government for the treatment of human disease conditions and illness.

If you have any questions, please contact Jolanta B. Sander, Senior Program Analyst, Retailers, Food, Pharmaceuticals & Healthcare, at 630-493-5935 or Mario Perez, Technical Advisor, Pharmaceuticals at 732-819-3184.

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