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

OFFICE OF
CHIEF COUNSEL

March 8, 1999

CC:DOM:FS:IT&A
TL-N-6823-95
UILC: 162.04-09
Number: **199925009**
Release Date: 6/25/1999

INTERNAL REVENUE SERVICE NATIONAL OFFICE FIELD SERVICE ADVICE

MEMORANDUM FOR

FROM: DEBORAH A. BUTLER
ASSISTANT CHIEF COUNSEL (FIELD SERVICE) CC:DOM:FS

SUBJECT: Field Service Advice
Deduction of Costs of Free Product Samples

This Field Service Advice responds to your request of November 10, 1998. It is not binding on Examination or Appeals and is not a final case determination. This document may not be cited as precedent.

LEGEND:

Taxpayer	=	Parent	=
$	=	X	=
$$	=	Year 1	=
$$$	=	Year 2	=
$$$$	=	Year 3	=
		Year 4	=

ISSUE:

Whether pharmaceutical product samples and starter pack costs may be deducted by Taxpayer as a current trade or business expense when these costs are actually incurred, or must be deferred until the time at which the samples and starter packs are distributed to licensed physicians or pharmacies.

CONCLUSION:

Irrespective of Taxpayer's regular method of accounting, the taxpayer's deduction of the costs of pharmaceutical product samples and starter packs must be deferred until the time at which the samples and starter packs are distributed to licensed physicians or pharmacies.

FACTS:

Since the time of your original request for advice, in response to our specific inquiries, the material facts have been modified. The facts presented herein reflect those subsequent modifications.

For the relevant taxable years, Taxpayer was in the business of marketing prescription pharmaceutical products manufactured by its Parent. As an integral part of Taxpayer's marketing program, product samples were, and are still, distributed to licensed physicians and pharmacies. Drug samples are packaged differently from drugs packaged for sale. Pursuant to Food and Drug Administration (FDA) regulations, samples must be marked "Not for Sale" and/or "Sample." The packaging of the samples in issue was also performed by Parent.

These samples may only be distributed to practitioners licensed to prescribe such drugs. In addition, because of the potential for recall, in order to be able to locate each sample, the FDA regulations also provide that drug manufacturers or distributors shall conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or distributor and shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored.

In addition to product samples, pharmaceutical companies, including Taxpayer, distribute specially packaged drugs called "starter packs" without cost to pharmacies. These drugs, unlike specially marked samples, are actually sold by the pharmacies to patients with prescriptions. These contain promotional literature or labeling demonstrating that the prescription drug products are intended to be provided without charge to a pharmacist for ultimate sale at retail. Starter packs appear to be a widely used selling tool. Manufacturer representatives often make a sales presentation before or at the same time the starter packages are delivered.

Taxpayer made no distinction between product samples and starter packs in its treatment of related expenditures in the years at issue. In Year 1, in anticipation of FDA approval of X, Taxpayer ordered a large supply of X from Parent. The cost, $, was charged to the samples account. Because the FDA delayed approval of X until Year 2, however, no distribution was made during Year 1. A Schedule M-1 adjustment was made by Taxpayer, reducing its Year 1 deduction. In Year 2, Taxpayer deducted product sample expenses of $$ for X, including the $ remaining from the prior year. According to Taxpayer's records, at the end of Year 2, Taxpayer had not distributed $$$ worth of the product from its samples account. The examining agent made an adjustment in that amount of $$$ with respect to Year 2.[1] Product sample costs for Years 3 and 4–the years in issue here--total over $$$$.

LAW AND ANALYSIS:

Apparently, the tax treatment of product sample expenses by taxpayers varies considerably in the pharmaceutical industry. In some cases, for example, an inventory is taken of the ingredients and packaging materials needed for the next period, and a "samples expense" allocation made for the current period. In other cases, the product sample costs are expensed when they come off the production line (or are received by the distributor), when they are shipped to "detailers," or 30 days after the shipment to detailers.

You request Field Service Advice as to the appropriate timing for the deduction of the sample costs.[2] The examining agent takes the position that distribution of pharmaceutical samples is a substantial and integral part of the marketing of pharmaceutical products and that the costs of the samples may not be deducted until the year in which these are disbursed to a licensed physician or pharmacy. The agent and your memorandum request both rely, in part, upon an application of Treas. Reg. § 1.162-3 regarding materials and supplies to support that result. We concur.

---

[1] According to your incoming memorandum, this relatively small amount (in comparison to the subsequent years) will now be conceded by the Service as part of an appeals settlement involving other issues for Year 2.

[2] The samples as well as the starter packs are distributed free by Taxpayer; consequently, we see no reason to treat these particular categories of expense differently for our present purposes. In either category, there is no income flow back to Taxpayer. This is true notwithstanding the fact that the pharmacy may actually sell, and profit, directly out of the starter packs. The differing treatment of these distributions under the FDA regulations is irrelevant in this context.

Treas. Reg. § 1.162-1 discusses in general the types of business expenses eligible for deduction from gross income as ordinary and necessary expenditures directly connected to or pertaining to the taxpayer's trade or business. The regulations that follow provide guidance on the deductibility of specific costs. It is our position that Treas. Reg. § 1.162-3 addresses the treatment of the cost of the samples in issue because these are tangible goods "used or consumed" in the taxpayer's trade or business.

Under Treas. Reg. § 1.162-3, the deduction for materials and supplies is taken "only in the amount that they are consumed and used in operation during the taxable year for which the return is made." In this case, therefore, that consumption and use would be upon actual distribution to the physician or pharmacy.[3] Therefore, Taxpayer must defer the costs in issue until the time at which the samples and starter packs are distributed to licensed physicians and pharmacies.

CASE DEVELOPMENT, HAZARDS, AND OTHER CONSIDERATIONS:

[3] This consumption limitation does not apply to "incidental materials and supplies" under the regulation; yet, given the taxpayer's need to account for samples in this industry, the "incidentals" exception is not applicable here.

[redacted]

[4] We feel compelled to note also that the FDA's mandatory inclusion of such samples in inventories in order to fulfill that agency's own regulatory purposes is immaterial for determining the correct federal tax treatment. The tax analysis necessarily depends on other authorities. See Rev. Rul. 75-407, 1975-2 C.B. 196 (timing of the deduction of fuel costs by public utility for federal income tax purposes was not affected by accounting requirements of the state public service commission that conflicted with that treatment).

[5] [redacted]

[redacted]

By: _____
CLIFFORD M. HARBOURT
Senior Technician Reviewer
Income Tax & Accounting Branch