Internal Revenue Service

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Department of the Treasury
Washington, DC 20224

Third Party Communication: None
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Person To Contact:
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Date:
August 30, 2013

In Re:

Legend

Taxpayer	=
A	=
B	=
C	=
D	=
E	=
Foreign Country	=
Special Program	=

Dear :

This is in response to your authorized representative's letter dated February 26, 2013, requesting rulings regarding the medical device excise tax under § 4191 of the Internal Revenue Code (Code).

According to the facts submitted, A, a domestic corporation, is the common parent of an affiliated group that includes Taxpayer, B, C, D, and E. Taxpayer, B and C are domestic entities. D and E are foreign entities located in Foreign Country.

Taxpayer is in the business of manufacturing taxable medical devices and producing convenience kits that Taxpayer sells in the United States. Many of Taxpayer's convenience kits are themselves taxable medical devices, as defined in § 4191(b) and § 48.4191-2(a)(1) of the Manufacturers and Retailers Excise Tax Regulations (regulations).

Some of Taxpayer's convenience kits include both taxable medical devices that Taxpayer manufactures (Taxpayer devices), and taxable medical devices that Taxpayer purchases from unrelated domestic parties (third party devices). Taxpayer represents that it does not manufacture or import these third party devices.

Some of Taxpayer's convenience kits include articles that are not taxable medical devices, and/or articles that are taxable medical devices but that Taxpayer represents qualify for the retail exemption under § 4191(b)(2)(D).

Taxpayer produces convenience kits in both the United States and in Foreign Country. With regard to the convenience kits produced in Foreign Country, Taxpayer typically gathers the Taxpayer devices, the third party devices, and the other articles that are to be packaged into convenience kits in a warehouse located in the United States. Taxpayer then ships the items from the warehouse to D's kitting facility in Foreign Country where D assembles the convenience kits.

Pursuant to the contract between Taxpayer and D: (1) title to the Taxpayer devices, third party devices, and other articles remains with Taxpayer; (2) D combines the Taxpayer devices, third party devices, and other articles into convenience kits; (3) D ships the convenience kits back to the United States as directed by Taxpayer; (4) Taxpayer pays D for its services; (5) Taxpayer carries the Taxpayer devices, third party devices, and articles on its books during the time they are in Foreign Country; and (6) Taxpayer has title to the convenience kits assembled by D pursuant to the contract between D and Taxpayer. During this process, D does not alter the Taxpayer devices, the third party devices, or the other articles.

Many of the convenience kits produced by D contain only the taxable medical devices and other articles shipped by Taxpayer to D pursuant to the contract between Taxpayer and D. In some cases, however, the kits also contain additional taxable medical devices that are produced for Taxpayer by E under a contract manufacturing agreement. Those devices are shipped, at the direction of Taxpayer, directly from E to D. Taxpayer represents that Taxpayer is the manufacturer of these devices for chapter 32 purposes. Therefore, for purposes of this letter, the term "Taxpayer devices" includes the taxable medical devices that E produces for Taxpayer.

D is part of the Special Program in Foreign Country. As such, D causes the taxable medical devices and other articles it receives from Taxpayer to be brought into Foreign Country under a temporary importation regime. Under this regime, the taxable medical devices and other articles are exempt from both import duties and Foreign Country's value added tax.

Taxpayer requests rulings regarding the application of the convenience kit rules in Section 5 of Notice 2012-77, 2012-52 I.R.B. 781, to the facts set forth above.

Section 4191(a) imposes a 2.3 percent tax on the sale of a taxable medical device by its manufacturer, producer, or importer.

Under section 4191(b)(1), a "taxable medical device" is a device defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA) that is intended for humans. Under § 48.4191-2(a) of the regulations, a device defined in section 201(h) of the FFDCA that is intended for humans means a device that is listed with the Food and Drug Administration FDA) under section 510(j) of the FFDCA and 21 CFR part 807, pursuant to FDA requirements.

In Notice 2012-77, the Internal Revenue Service and the Treasury Department provided interim guidance relating to the medical device excise tax. This Notice includes guidance on the tax treatment of medical convenience kits.

Convenience kits that are listed with the FDA under section 510(j) of the FFDCA and 21 CFR part 807 are taxable medical devices under the § 48.4191 regulations unless they fall within an exemption under section 4191(b) or § 48.4191-2(b). See section 5(a) of the Notice.

Under Section 5(b) of Notice 2012-77, a "convenience kit" is a set of two or more devices within the meaning of section 201(h) of the FFDCA that is enclosed in a single package, such as a bag, tray, or box for the convenience of a health care professional or the end user. A convenience kit may contain a combination of devices within the meaning of section 201(h) of the FFDCA and other articles.

Section 5(c) of Notice 2012-77 provides that until the IRS and the Treasury Department issue further guidance (interim period), no tax will be imposed upon the sale of a domestically-produced convenience kit that is a "taxable medical device" under § 4191 and § 48.4191-2(b) of the regulations. During this interim period, the sale of a taxable medical device that goes into a domestically-produced convenience kit will be subject to tax upon its sale by the manufacturer or importer, pursuant to the normal rules of § 4191 and the regulations thereunder; however, the sale of the convenience kit by the kit producer will not be subject to tax.

Section 5(d) of Notice 2012-77 provides that during the interim period, tax is imposed under § 4191 on the sale by an importer of a convenience kit that is a taxable medical device under § 4191 and § 48.4191-2(b) of the regulations, but only on that portion of the importer's sale price of the convenience kit that is properly allocable to the individual taxable medical devices included in the convenience kit.

Section 4191 was added to chapter 32, subtitle D of the Internal Revenue Code. Therefore, existing chapter 32 rules apply to the medical device excise tax.

Section 48.0-2(a)(4)(i) of the regulations defines the term “manufacturer”, in relevant part, as any person who produces a taxable article from new or raw material, by processing, manipulating, or changing the form of an article or by combining or assembling two or more articles. Under certain circumstances, as where a person manufactures or produces a taxable article for another person who furnishes materials under an agreement whereby the person who furnished the materials retains title thereto and to the finished article, the person for whom the taxable article is manufactured or produced, and not the person who actually manufactures or produces it, will be considered the manufacturer. See § 48.0-2(a)(4)(ii) of the regulations.

Section 48.0-2(a)(10) of the regulations defines the term “exportation” as the severance of an article from the mass of things belonging within the United States with the intention of uniting it with the mass of things belonging within some foreign country.

Section 4216 defines the term “price” for purposes of the manufacturers excise taxes. Where a taxable article and a nontaxable article are sold by the manufacturer as a unit, the tax attaches to that portion of the manufacturer’s sale price of the unit which is properly allocable to the taxable article. Normally the taxable portion of such a unit may be determined by applying to the manufacturer’s sale price of the unit the ratio which the manufacturer’s separate sale price of the taxable article bears to the sum of the sale prices of both the taxable and nontaxable articles, if such articles are sold separately by the manufacturer. Where the articles (or either one of them) are not sold separately by the manufacturer and do not have established sale prices, the taxable portion is to be determined from a comparison of the actual costs of the articles to the manufacturer. Thus, if the cost of the taxable article represents four-fifths of the total cost of the complete unit, the tax applies to four–fifths of the price charged by the manufacturer for the unit. See § 48.4216(a)-1(e) of the regulations.

Taxpayer is the producer of the convenience kits assembled at D’s kitting facility in Foreign Country, because Taxpayer retained title to Taxpayer’s devices, third party devices, other articles that Taxpayer (or E, at the direction of Taxpayer) furnished to D for assembly into convenience kits, as well as title to the convenience kits themselves. See § 48.0-2(a)(10) of the regulations. Therefore, for purposes of section 5(c) of Notice 2012-77, Taxpayer is the kit producer.

When Taxpayer ships Taxpayer’s devices, third party devices, and other articles to D’s kitting facility in Foreign Country, Taxpayer is not exporting these devices and articles because Foreign Country has a Special Program that ensures that these devices and articles are returned in their entirety to the United States. See § 48.0-2(a)(10) of the regulations. Consequently, Taxpayer does not import these devices and articles when D ships them in convenience kits to the United States. Therefore, for purposes of section 5(c) of Notice 2012-77, Taxpayer’s convenience kits are domestically-produced.

Although Taxpayer's domestically-produced convenience kits are not taxable as a unit upon their sale by Taxpayer, any Taxpayer device that goes into Taxpayer's domestically-produced convenience kits is subject to tax under § 4191 upon the sale of the kit. See section 5(c) of the Notice.

Section 4216 and § 48.4216(a)-1(e) of the regulations describe how to determine the price of a taxable article where a taxable article and a nontaxable article are sold by the manufacturer as a unit. Taxpayer must use this methodology to determine the price of Taxpayer devices that Taxpayer includes in its convenience kits.

The medical device excise tax is imposed on the sale of a taxable medical device by its manufacturer, producer, or importer. Taxpayer represents that it buys its third party devices from the devices' manufacturers or importers. Therefore, Taxpayer is not liable for the medical device excise tax on the third party devices it includes in its convenience kits.

Accordingly, for as long as Notice 2012-77 remains in effect, we conclude that:

1. For purposes of section 5(c) of Notice 2012-77, Taxpayer is the "kit producer" of the convenience kits assembled by D in D's kitting facility in Foreign Country.

2. For purposes of section 5(c) of Notice 2012-77, the convenience kits that D assembles in D's kitting facility pursuant to D's contract with Taxpayer are "domestically-produced" convenience kits.

3. Any Taxpayer device that goes into Taxpayer's domestically-produced convenience kits is subject to tax under § 4191 upon the sale of the kit pursuant to the normal rules of § 4191 and the regulations thereunder. Taxpayer is liable for the tax.

4. Taxpayer must determine the price of Taxpayer devices included in Taxpayer's domestically-produced convenience kits pursuant to § 4216 of the Code and § 48.4216(a)-1(e) of the regulations.

5. Taxpayer is not liable for the § 4191 tax on third party devices that Taxpayer purchases for inclusion in its domestically-produced convenience kits.

6. Apart from the § 4191 tax imposed on Taxpayer's sale of Taxpayer device(s) included in Taxpayer's convenience kits, Taxpayer's sales of its domestically-produced convenience kits are not subject to § 4191 tax.

The rulings contained in this letter are based upon information and representations submitted by the taxpayer and accompanied by a penalty of perjury statement 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.

Except as specifically ruled herein, we express or imply no opinion on the federal tax consequences of the transaction under the cited provisions or under any other provisions of the Code. Further, these rulings are contingent on the compliance of Taxpayer and D with the rules of the Special Program and the duration of the Special Program. In addition, nothing in this letter is to be construed as an opinion of the legality of the importation of goods into the United States or the exportation of goods from the United States.

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

In accordance with the power of attorney on file with this office, a copy of this letter is being sent to your authorized representative.

Sincerely,

Stephanie Bland
Senior Technician Reviewer, Branch 7
(Passthroughs & Special Industries)