

§ 48.4221-1 Tax-free sales; general rule.

- (a) * * *
- (2) * * *

(vii) The exemptions under section 4221(a)(3) through (a)(6) do not apply to the tax imposed by section 4191 (medical device tax).

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Par. 5. Section 48.4221-2 is amended by adding headings to paragraphs (b)(1) and (b)(2) and adding paragraph (b)(3). The additions read as follows:

- (b) * * *

(1) *In general.* * * *

(2) *Material in the manufacture or production of another article.* * * *

(3) *Kits*—(i) The process of producing or assembling a kit that is a taxable medical device (as defined in § 48.4191-2) constitutes further manufacture. Under such circumstances, the taxable and nontaxable articles used in the production or assembly of the kit lose their identity as separate articles once they are incorporated into the kit because the kit is a new taxable article. Accordingly, the provisions of § 48.4216(a)-1(e) do not apply upon the sale of a kit that is a taxable medical device, and the entire sale price of the kit is subject to tax under section 4191.

(ii) For purposes of this section, the term *kit* means a set of two or more articles that is enclosed in a single package, such as a bag, tray, or box, for the convenience of a medical or health care professional or the end user. A kit may contain a combination of one or more taxable medical devices and other articles.

(iii) The following example illustrates the rule of this paragraph (b)(3).

Example. X is a manufacturer of scalpels. X is registered with the IRS as a manufacturer of taxable medical devices in accordance with § 48.4222(a)-1. Y is a distributor of taxable medical devices. Y is registered with the IRS as a manufacturer of taxable medical devices and as a buyer of taxable medical devices for use in further manufacture in accordance with § 48.4222(a)-1. Y purchases scalpels from X for inclusion in surgical kits that Y produces. Both the scalpels and the kits are “taxable medical devices” as defined in § 48.4191-2. Accordingly, X may sell the scalpels to Y tax free, provided Y furnishes its registration number to X and certifies in writing that the scalpels will be used in further manufacture.

(iv) This paragraph (b)(3) applies to sales of taxable medical devices on and after January 1, 2013.

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Par. 6. Section 48.6416(b)(2)-2 is amended by adding paragraph (a)(4) to read as follows:

§ 48.6416(b)(2)-2 Exportations, uses, sales and resales included.

- (a) * * *

(4) Beginning on January 1, 2013, sections 6416(b)(2)(B), (C), (D), and (E) do not apply to any tax paid under section 4191 (medical device tax).

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Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

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DEPARTMENT OF THE TREASURY**Alcohol and Tobacco Tax and Trade Bureau****27 CFR Part 19**

[Docket No. TTB-2011-0010; Notice No. 124A; Re: Notice No. 124]

RIN 1513-AB89

Revisions to Distilled Spirits Plant Operations Reports and Regulations; Comment Period Extension

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau is extending the comment period for Notice No. 124, Revisions to Distilled Spirits Plant Operations Reports and Regulations, a notice of proposed rulemaking published in the **Federal Register** on December 5, 2011. TTB is taking this action in response to a request from a distilled spirits industry association.

DATES: Written comments on Notice No. 124 are now due on or before March 5, 2012.

ADDRESSES: You may send comments on Notice No. 124 to one of the following addresses:

- <http://www.regulations.gov>: To submit comments via the Internet, use the comment form for Notice No. 124 as posted within Docket No. TTB-2011-0010 on “Regulations.gov,” the Federal e-rulemaking portal;

- *U.S. Mail:* Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 14412, Washington, DC 20044-4412.

- *Hand Delivery/Courier in Lieu of Mail:* Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 200-E, Washington, DC 20005.

See the Public Participation section of this notice for specific instructions and requirements for submitting comments, and for information on how to request a public hearing.

You may view copies of all published notices, the proposed two new report

forms, and any public comments associated with the proposal outlined in Notice No. 124 within Docket No. TTB-2011-0010 at <http://www.regulations.gov>. A link to the Regulations.gov comment form for proposal is posted on the TTB Web site at http://www.ttb.gov/regulations_laws/all_rulemaking.shtml under Notice No. 124. You also may view copies of all documents and comments associated with Notice No. 124 by appointment at the TTB Information Resource Center, 1310 G Street NW., Washington, DC 20220. Please call (202) 453-2270 to make an appointment.

FOR FURTHER INFORMATION CONTACT: Rita D. Butler, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, at (202) 453-1039, extension 101, or rita.butler@ttb.gov.

SUPPLEMENTARY INFORMATION: In Notice No. 124, the Alcohol and Tobacco Tax and Trade Bureau (TTB) proposes to replace the current four report forms used by distilled spirits plants to report their operations with two new report forms that would be submitted on a monthly or quarterly basis. The proposal would streamline the reporting process and would result in savings for the industry and for TTB by significantly reducing the number of reports that must be completed and filed by industry members and processed by TTB.

On February 2, 2012, TTB received an email from the Distilled Spirits Council of the United States (DISCUS) requesting additional time to prepare its comment on Notice No. 124. The email stated:

This additional time will allow us to further collate comments about the technical aspects for the data entries pertaining to the proposed reporting forms. Similarly, this additional time also will afford a better opportunity to respond to TTB's request about the length of time needed by industry members to transition their business procedures so as to comply with the proposed reporting requirements.

In response to that request, TTB is extending the comment period for Notice No. 124 for an additional 30 days. Therefore, comments on Notice No. 124 are now due on or before March 5, 2012.

Drafting Information

Michael D. Hoover of the Regulations and Rulings Division drafted this notice.

Signed: February 2, 2012.

John J. Manfreda,
Administrator.

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