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1. DEN150028: De novo request from Advanced Surgical Concepts, dated June 19, 2015.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 1. The authority citation for part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 884.4050 to subpart E to read as follows:

§ 884.4050 Gynecologic laparoscopic power morcellation containment system.

(a) *Identification.* A gynecologic laparoscopic power morcellation containment system is a prescription device consisting of an instrument port and tissue containment method that creates a working space allowing for direct visualization during a power morcellation procedure following a laparoscopic procedure for the excision of benign gynecologic tissue that is not suspected to contain malignancy.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient-contacting components of the device must be demonstrated to be biocompatible;

(2) Device components that are labeled sterile must be validated to a sterility assurance level of 10^{-6} ;

(3) Performance data must support shelf life by demonstrating continued sterility of the device or the sterile components, package integrity, and device functionality over the intended shelf life;

(4) Non-clinical performance data must demonstrate that the device meets all design specifications and performance requirements. The following performance characteristics must be tested:

(i) Demonstration of the device impermeability to tissue, cells, and fluids;

(ii) Demonstration that the device allows for the insertion and withdrawal of laparoscopic instruments while maintaining pneumoperitoneum;

(iii) Demonstration that the containment system provides adequate space to perform morcellation and

adequate visualization of the laparoscopic instruments and tissue specimen relative to the external viscera;

(iv) Demonstration that intended laparoscopic instruments and morcellators do not compromise the integrity of the containment system; and

(v) Demonstration that intended users can adequately deploy the device, morcellate a specimen without compromising the integrity of the device, and remove the device without spillage of contents;

(5) Training must be developed and validated to ensure users can follow the instructions for use; and

(6) Labeling must include the following:

(i) A contraindication for use in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy;

(ii) Unless clinical performance data demonstrates that it can be removed or modified, a contraindication for removal of uterine tissue containing suspected fibroids in patients who are: Peri- or postmenopausal, or candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision;

(iii) The following boxed warning: “Warning: Information regarding the potential risks of a procedure with this device should be shared with patients. Uterine tissue may contain unsuspected cancer. The use of laparoscopic power morcellators during fibroid surgery may spread cancer. The use of this containment system has not been clinically demonstrated to reduce this risk.”

(iv) A statement limiting use of device to physicians who have completed the training program; and

(v) An expiration date or shelf life.

Dated: June 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Parts 40, 41, and 44

[Docket No. TTB-2013-0006; T.D. TTB-137; Re: T.D. TTB-115; Notice No. 137; T.D. ATF-421; T.D. ATF-422; ATF Notice Nos. 887 and 888]

RIN 1513-AB37

Importer Permit Requirements for Tobacco Products and Processed Tobacco, and Other Requirements for Tobacco Products, Processed Tobacco and Cigarette Papers and Tubes

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

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau is adopting as a final rule, without change, a temporary rule concerning permit and other requirements related to importers and manufacturers of tobacco products and processed tobacco published in the **Federal Register** on June 27, 2013. The regulatory amendments adopted in this final rule include an extension in the duration of new permits for importers of tobacco products and processed tobacco from three years to five years, a technical correction amending the definition of “Manufacturer of tobacco products” to reflect a statutory change, and a technical correction related to references to the sale price of large cigars. This final rule also permanently incorporates and reissues other TTB regulations pertaining to importer permit requirements for tobacco products as well as minimum manufacturing and marking requirements for tobacco products and cigarette papers and tubes that also were incorporated in the June 27, 2013, temporary rule.

DATES: Effective July 21, 2016, the temporary regulations published in the **Federal Register** as T.D. TTB-115 at 78 FR 38555 on June 27, 2013, are adopted as final, and those temporary regulations will no longer have a sunset date of August 26, 2016.

FOR FURTHER INFORMATION CONTACT: Jessie Longbrake, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, Box 12, Washington, DC 20005; telephone 202-453-2265; email TobaccoRegs@ttb.gov.

SUPPLEMENTARY INFORMATION:

Background

TTB Authority

Chapter 52 of the Internal Revenue Code of 1986 (IRC) contains excise tax and related provisions pertaining to tobacco products and cigarette papers and tubes. Section 5701 of the IRC (26 U.S.C. 5701) imposes various rates of tax on such products manufactured in, or imported into, the United States. Section 5704 of the IRC (26 U.S.C. 5704) provides for certain exemptions from those taxes. Sections 5712 and 5713 of the IRC (26 U.S.C. 5712 and 5713) provide that manufacturers and importers of tobacco products or processed tobacco and export warehouse proprietors must apply for and possess a permit in order to engage in such businesses. Section 5712 also allows for the promulgation of regulations prescribing minimum manufacturing and activity requirements for such permittees, and section 5713 also sets forth standards regarding the suspension and revocation of permits. Section 5754 of the IRC (26 U.S.C. 5754) sets forth restrictions on the importation of previously exported tobacco products. Section 5761 of the IRC (26 U.S.C. 5761) sets forth civil penalties for, among other things, selling, relanding, or receiving any tobacco products or cigarette papers or tubes that were labeled or shipped for exportation.

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers these statutory provisions pursuant to section 1111(d) of the Homeland Security Act of 2003, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120-01 (dated December 10, 2013, superseding Treasury Order 120-01 (Revised), "Alcohol and Tobacco Tax and Trade Bureau," dated January 24, 2003), to the TTB Administrator to perform the functions and duties in the administration and enforcement of these laws.

Regulations implementing the Chapter 52 provisions are contained in chapter I of title 27 of the Code of Federal Regulations (27 CFR). Those regulations include: Part 40 (Manufacture of tobacco products, cigarette papers and tubes, and processed tobacco); part 41 (Importation of tobacco products, cigarette papers and tubes, and processed tobacco); and part 44 (Exportation of tobacco products and cigarette papers and tubes, without payment of tax, or with drawback of tax).

Publication of Temporary Regulations and Notice of Proposed Rulemaking

On June 27, 2013, TTB published in the **Federal Register** at 78 FR 38555, T.D. TTB-115 amending the regulations in 27 CFR parts 40, 41, and 44. The temporary rule was effective on August 26, 2013, and would have expired on August 26, 2016, if not finalized prior to that date. In the same issue of the **Federal Register**, TTB also requested public comments on the temporary rule via a notice of proposed rulemaking, Notice No. 137 (78 FR 38646). TTB received one comment in response to Notice No. 137 by the close of the comment period on August 26, 2013. That comment is discussed in more detail below.

Notice No. 137 and the Comment Received

TTB received one comment in response to Notice No. 137, submitted by a Washington, DC law firm on behalf of an individual who imports cigars.

The comment regards the amendment in the temporary rule, in which TTB inserted the words "United States" before the word "manufacturer" in 27 CFR 41.39, Determination of Sale Price of Large Cigars. Under 26 U.S.C. 5701(a)(2), the Federal excise tax on large cigars manufactured in or imported into the United States is a percentage of the "price for which sold" but not more than a maximum. Currently, the tax is 52.75 percent of the price for which sold but not more than 40.26 cents per cigar. The commenter objects to the "price for which sold" being the price for which the cigars are sold by the importer, and concludes by requesting that TTB not insert "United States" before the word "manufacturer" in § 41.39, Determination of Sale Price of Large Cigars, and, instead, adopt a regulation to authorize importers of large cigars to base their Federal excise tax calculations on the foreign manufacturer's sales price.

TTB Response

In the temporary rule, T.D. TTB-115, TTB did not propose to change its interpretation regarding the Federal excise tax determination of large cigars. Rather, the addition of "United States" before the word "manufacturer" in § 41.39 is a technical correction intended to bring § 41.39 more clearly into conformity with other regulatory provisions in parts 40 and 41 which already reflect the interpretation by TTB and TTB's predecessor agency, the Bureau of Alcohol, Tobacco and Firearms (ATF), of the text of section 5701(a)(2), that is, that the Federal

excise tax for large cigars is based on the sale price at which the cigars are sold by the importer or the United States manufacturer. This interpretation dates to the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508, 104 Stat. 1388), which changed the basis of taxation on large cigars, from the "wholesale price" (generally, the manufacturer's or importer's suggested delivered price at which the cigars are sold to retailers) to the "price for which sold."

In T.D. ATF-307 (December 21, 1990; 55 FR 52742), ATF amended its regulations to reflect the new text of section 5701(a)(2). On March 19, 1991, ATF issued Industry Circular 91-3, which provided guidance concerning the implementation of the tax on large cigars and included specific guidance regarding the tax on imported large cigars. The Industry Circular explains how an importer determines the tax on large cigars when the release from customs custody (the taxable event) occurs before the sale of the cigars. In T.D. TTB-78 (June 22, 2009; 74 FR 29401), TTB clarified the definition of "sale price" in § 41.11 by adding the words "United States" before "manufacturer." (That temporary rule was finalized by T.D. TTB-104 (June 21, 2012, 77 FR 37287).) However, when this change was made, TTB inadvertently failed to make a corresponding change to the operative regulation in § 41.39. Therefore in T.D. TTB-115, TTB made the necessary technical change by adding "United States" before the word "manufacturer" in § 41.39.

As stated above, the temporary rule did not introduce a substantive change to the TTB regulations regarding the application of the sale price but, rather, made a technical correction to bring § 41.39 more clearly into conformity with other TTB regulatory provisions and with the position stated in Industry Circular 91-3. Thus, the request of the commenter is beyond the scope of the rulemaking.

Adoption of Final Rule

TTB adopts as a final rule, without change, the temporary regulatory amendments contained in T.D. TTB-115, effective 30 days from the publication of this document. As a result, TTB is permanently amending its regulations in 27 CFR parts 40, 41, and 44 pertaining to permits for importers of tobacco products and processed tobacco by extending the duration of new permits from three years to five years. In addition, TTB is permanently amending the definition of "Manufacturer of tobacco products" to reflect a recent

statutory change, and is amending a reference to the sale price of large cigars to incorporate a clarification published in a prior TTB temporary rule that was finalized in 2012. Finally, this final rule makes permanent regulatory changes pertaining to importer permit requirements for tobacco products, and minimum manufacturing and marking requirements for tobacco products and cigarette papers and tubes.

Please see T.D. TTB-115 for a detailed discussion of the temporary regulatory amendments finalized by this document, as well as a detailed discussion of the various statutory changes and court actions necessitating regulatory amendments, the earlier related temporary rules and notices of proposed rulemaking issued by ATF (T.D. ATF-421, December 22, 1999, 64 FR 71918; Notice No. 887, December 22, 1999, 64 FR 71927; T.D. ATF-422, December 22, 1999, 64 FR 71947; and Notice No. 888, December 22, 1999, 64 FR 71955), the comments received by ATF on its temporary rules, and other ATF and TTB regulatory documents related to this rulemaking.

Public Disclosure

On the Federal e-rulemaking portal, “*Regulations.gov*,” within Docket No. TTB-2013-0006, you may view copies of this final rule, the related temporary and proposed rules, the comment received in response to the proposed rule, and all other related final and temporary rules and notices of proposed rulemaking issued by ATF and TTB related to this matter. A direct link to that docket is posted on the TTB Web site at <https://www.ttb.gov/tobacco/tobacco-rulemaking.shtml> under Notice No. 137. You may also reach that docket through the *Regulations.gov* search page at <https://www.regulations.gov>.

You also may view copies of those documents at the TTB Information Resource Center, 1310 G Street NW., Washington, DC 20220. You may also obtain copies at 20 cents per 8.5- x 11-inch page. Contact TTB’s information specialist at the above address or by telephone at 202-453-2270 to schedule a viewing appointment or to request copies.

Regulatory Flexibility Act

Pursuant to the requirements of the Regulatory Flexibility Act (5 U.S.C. chapter 6), we certify that these regulations will not have a significant economic impact on a substantial number of small entities. Any effects of this rulemaking on small businesses flow directly from the underlying statutes. Accordingly, a regulatory flexibility analysis is not required.

These regulations also reduce the administrative burden on importers of tobacco products and processed tobacco by requiring that they renew their permits only every five years rather than every three years. Pursuant to 26 U.S.C. 7805(f), TTB submitted the temporary regulations and notice of proposed rulemaking to the Chief Counsel for Advocacy of the Small Business Administration for comment on the impact of the regulations on small businesses; TTB received no comment in reply.

Executive Order 12866

Certain regulations issued pursuant to the IRC, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required.

Paperwork Reduction Act

The collections of information in the regulations contained in this final rule have been previously reviewed and approved by Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3504(h)) and assigned control numbers 1513-0002, 1513-0068, 1513-0070, 1513-0078, 1513-0106, and 1513-0107. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB. The temporary rule did not impose a new collection of information, and this final rule makes no changes to the temporary rule.

The list of collections of information in the regulations contained in the temporary rule inadvertently omitted control number 1513-0002, which authorizes the collection of information on TTB Form 5000.9, the Personnel Questionnaire. The changes made in the temporary rule increased the paperwork burden associated with the control number by requiring additional submissions of the form. TTB requested comment on the increased number of respondents and total annual burden hours in a document published in the **Federal Register** on March 12, 2015 (Comment Request No. 51, 80 FR 13072). Based on a comment on TTB Form 5000.9, TTB proposed revisions to the form in a document published in the **Federal Register** on January 13, 2016 (Comment Request No. 57, 81 FR 1679); comments on this notice were due on March 14, 2016.

TTB will submit the information collection requirements described in the notice to the Office of Management and

Budget for approval. When OMB takes action on the changes, TTB will publish a document in the **Federal Register**.

Drafting Information

Michael D. Hoover of the Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, drafted this document.

List of Subjects

27 CFR Part 40

Cigars and cigarettes, Claims, Electronic funds transfers, Excise taxes Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Surety bonds, Tobacco.

27 CFR Part 41

Cigars and cigarettes, Claims, Customs duties and inspection, Electronic fund transfers, Excise taxes, Imports, Labeling, Packaging and containers, Puerto Rico, Reporting and recordkeeping requirements, Surety bonds, Tobacco, Virgin Islands, Warehouses.

27 CFR Part 44

Aircraft, Armed forces, Cigars and cigarettes, Claims, Customs duties and inspection, Excise taxes, Exports, Foreign trade zones, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Surety bonds, Tobacco, Vessels, Warehouses.

Amendments to the Regulations

Accordingly, the temporary rule that amended 27 CFR, chapter I, parts 40, 41, and 44, and published as T.D. TTB-115 at 78 FR 38555 on June 27, 2013, is adopted as a final rule without change.

Signed: March 28, 2016.

John J. Manfreda,

Administrator.

Approved: April 12, 2016.

Timothy E. Skud,

Deputy Assistant Secretary. (Tax, Trade, and Tariff Policy).

[FR Doc. 2016-14358 Filed 6-20-16; 8:45 am]

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