DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Parts 24

[CBP Dec. 22–26; Docket No. USCBP–2018–0033]

RIN 1515–AE39

Refund of Alcohol Excise Tax

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Interim final rule; request for comments.

SUMMARY: This document amends U.S. Customs and Border Protection regulations to implement certain changes made by the Taxpayer Certainty and Disaster Tax Relief Act of 2020, which amended the Craft Beverage Modernization Act provisions of the Tax Cuts and Jobs Act of 2017. Pursuant to these changes, the responsibility for administering refunds, reduced tax rates, and tax credits on imported alcohol is moving from U.S. Customs and Border Protection (CBP) to the U.S. Department of the Treasury, effective January 1, 2023.

DATES: This interim final rule is effective January 1, 2023; comments must be received by March 2, 2023.

ADDRESSES: You may submit comments, identified by docket number Docket No. USCBP–2018–0033, by one of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Due to COVID–19-related restrictions, CBP has temporarily suspended its ability to receive public comments by mail.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the 'Public Participation' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Due to the relevant COVID–19-related restrictions, CBP has temporarily suspended on-site public inspection of the public comments.

FOR FURTHER INFORMATION CONTACT: Kellee Gross, Branch Chief, Trade Processes Branch, Office of Trade, 202–815–1699, *kellee.m.gross@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views or arguments on all aspects of the interim rule. See **ADDRESSES** above for information on how to submit comments. U.S. Customs and Border Protection (CBP) also invites comments that relate to the effects that might result from this interim rule. Comments that will provide the most assistance to CBP will reference a specific portion of the interim rule, explain the reason for any recommended change, and include data, information, or authority that supports such recommended change.

II. Background

Sections 13801–13808 of the Tax Cuts and Jobs Act of 2017 (Pub. L. 115–97), signed December 22, 2017, commonly referred to as the Craft Beverage Modernization Act (CBMA), amended the Internal Revenue Code for two calendar years with respect to the tax treatment of alcoholic beverages, including beer, wine, and distilled spirits. The CBMA authorized reduced tax rates and tax credits for alcoholic beverages. On August 16, 2018, CBP published an interim final rule, CBP Dec. 18–09, in the **Federal Register** (83 FR 40675), updating the language of title 19 of the Code of Federal Regulations (CFR) to implement the CBMA and make other technical changes to 19 CFR part 24. Specifically, the interim final rule amended 19 CFR 24.36 to encompass CBP's authority to refund the difference between the full excise tax rate paid by an importer to CBP at the time of entry summary filing and the CBMA's lower effective tax rate. CBP solicited comments on this interim final rule. No comments were received. On December 19, 2019, the Further Consolidated Appropriations Act was signed, which extended the relevant provisions of the CBMA through calendar year 2020. *See* Public Law 116–94.

On December 27, 2020, the Taxpayer Certainty and Disaster Tax Relief Act of 2020 (Tax Relief Act) was enacted. *See* Public Law 116–260, Division EE, sections 106–110. The Tax Relief Act amended and made permanent the CBMA. Section 107(e) of the Tax Relief Act directed that the Secretary of the Treasury (or the Secretary's delegate within the Department of the Treasury (Treasury)) shall implement and administer the new statutory provisions in coordination with CBP. In June 2021, Treasury informed Congress that it intended to delegate administration of the CBMA import refund program, formerly administered by CBP under 19 CFR 24.36(d)(10), to the Alcohol and Tobacco Tax and Trade Bureau (TTB) in the ''Report to Congress on Administration of Craft Beverage Modernization Act Refund Claims for Imported Alcohol.'' [1] The authority subsequently was delegated to TTB.

On September 23, 2022, TTB published a temporary rule in the **Federal Register** (87 FR 58021) to implement regulations for the administration of the CBMA. Concurrent with the temporary rule, TTB published a Notice of Proposed Rulemaking in the **Federal Register** (87 FR 58043) proposing to make the temporary regulations final and soliciting comments.

Likewise, CBP is publishing this interim final rule to update the regulations issued in CBP Dec. 18–09 to reflect the transfer of authority for administration of the CBMA import refund program to TTB beginning on January 1, 2023, and to direct the public to the relevant TTB regulations regarding refunds administered by TTB. CBP is accepting comments on these changes to the regulations.

III. Discussion of Changes to § 24.36

Section 24.36 deals with refunds of excessive duties, taxes, fees, or interest. CBP is amending the introductory text to paragraph (d) to clarify the basis for TTB's authority to administer refunds arising under the CBMA beginning on January 1, 2023. CBP is amending paragraph (d)(10) to state that it applies to goods entered or withdrawn from warehouse on or before December 31, 2022, because after that date TTB will handle the refunds covered by the paragraph. CBP is also amending paragraph (d)(10) to reflect that the statutory authorities, giving CBP the authority to administer claims pertaining to these goods entered or withdrawn from warehouse on or before December 31, 2022, reauthorized the CBMA twice.[2] CBP is also amending

[1] ''Report to Congress on Administration of Craft Beverage Modernization Act Refund Claims for Imported Alcohol,'' June 2021, available at *https://www.ttb.gov/images/pdfs/treasury-cbma-import-claims-report-june-2021.pdf.*

[2] The Further Consolidated Appropriations Act, Public Law 116–94 (December 20, 2019), reauthorized the CBMA for 2020. The Taxpayer Certainty and Disaster Tax Relief Act of 2020,

paragraph (e) by removing the entirety of the existing paragraph and replacing it with revised paragraphs (e)(1) and (e)(2) to clearly direct the public to the relevant TTB regulations. Paragraph (e)(1) directs the public to the TTB regulations governing refunds for overpayment of alcohol and tobacco excise taxes. Paragraph (e)(2) directs the public to the TTB regulations governing refunds for alcohol excise taxes on or after January 1, 2023, based on assignment of a reduced tax rate or tax credits to an importer by a foreign producer. The refunds described in paragraph (e) are administered by TTB.

IV. Statutory and Regulatory Requirements

A. Inapplicability of Notice and Delayed Effective Date

The Administrative Procedure Act (APA) requirements in 5 U.S.C. 553 govern agency rulemaking procedures. Section 553(b) of the APA generally requires notice and public comment before issuance of a final rule. In addition, section 553(d) of the APA requires that a final rule have a 30-day delayed effective date. The APA, however, provides exceptions from the prior notice and the public comment and the delayed effective date requirements, when an agency for good cause finds that such procedures are ''impracticable, unnecessary, or contrary to the public interest.'' *See* 5 U.S.C. 553(b)(3)(B), (d)(3). Treasury and CBP find that prior notice and comment are unnecessary, and that good cause exists to issue these regulations effective on January 1, 2023. Prior notice and comment are unnecessary, as required in 5 U.S.C. 553(b)(3)(B), because the rule does not substantively alter the underlying rights or interests of importers or filers, but instead corrects the regulations to clarify that the authority to administer CBMA refund claims is being transferred from CBP to TTB on January 1, 2023, by statute. For the same reason, CBP finds that good cause exists for dispensing with the requirement for a delayed effective date as required in 5 U.S.C. 553(d)(3).

B. Executive Orders 13563 and 12866

Executive Orders 13563 and 12866 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This interim final rule is not a ''significant regulatory action,'' under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has not reviewed this regulation.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions) when the agency is required to publish a general notice of proposed rulemaking for a rule. Since a general notice of proposed rulemaking is not necessary for this rule, CBP is not required to prepare a regulatory flexibility analysis for this rule.

D. Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule, because this final rule does not trigger any new or revised recordkeeping or reporting.

E. Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1) pertaining to the Secretary of the Treasury's authority (or that of his/her delegate) to approve regulations related to customs revenue functions.

Troy A. Miller, the Acting Commissioner of CBP, having reviewed and approved this document, has delegated the authority to electronically sign this document to Robert F. Altneu, who is the Director of the Regulations and Disclosure Law Division for CBP, for purposes of publication in the **Federal Register**.

List of Subjects

19 CFR Part 24

Accounting, Claims, Harbors, Reporting and recordkeeping requirements, Taxes.

Amendments to the Regulations

For the reasons stated above, part 24 of Title 19 of the Code of Federal Regulations is amended as set forth below:

PART 24—CUSTOMS FINANCIAL AND ACCOUNTING PROCEDURE

■ 1. The general and specific authority citations for Part 24 are revised to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58a–58c, 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1505, 1520, 1624; 26 U.S.C. 4461, 4462; 31 U.S.C. 3717, 9701; Pub. L. 107–296, 116 Stat. 2135 (6 U.S.C. 1 *et seq.*).

* * * * *

Section 24.36 also issued under 26 U.S.C. 5001(c)(4), 5041(c)(7), 5051(a)(6), 6423; Pub. L. 115–97; Pub. L. 116–260; 134 Stat. 3046.

* * * * *

■ 2. Amend § 24.36 by revising paragraph (d) introductory text, and paragraphs (d)(10) and (e) to read as follows:

§ 24.36 Refunds of excessive duties, taxes, etc.

* * * * *

(d) The authority of CBP to make refunds pursuant to paragraphs (a), (b), and (c) of this section of excessive deposits of alcohol or tobacco taxes, as defined in section 6423(d)(1), Internal Revenue Code of 1986, as amended (26 U.S.C. 6423(d)(1)), is confined to cases of the types which are excepted from the application of section 6423, Internal Revenue Code of 1986, as amended (26 U.S.C. 6423), and which are not administered by the Department of the Treasury under section 107(e) of Public Law 116–260, div. EE, title I (December 27, 2020). The excepted types of cases and, therefore, the types in which CBP is authorized to make refunds of such taxes are those in which:

* * * * *

(10) For alcohol excise taxes imposed under the Internal Revenue Code for goods entered or withdrawn from warehouse for consumption on or before December 31, 2022, the refund of tax is claimed pursuant to the assignment of a reduced tax rate or tax credit to an importer by a foreign producer in accordance with CBP implementation of sections 13801–13808 of Public Law 115–97 (December 22, 2017), as amended. For goods entered or withdrawn from warehouse for consumption after December 31, 2022, see the procedures provided in paragraph (e)(2) of this section.

(e) In any instance in which a refund of an alcohol or tobacco tax is not of a type covered by paragraph (d) of this section the following procedures will apply:

(1) Except as provided in paragraph (e)(2), a claim for refund of any overpayment of internal revenue tax on an entry must be filed with the Alcohol

Public Law 116–260 (December 27, 2020), made the CBMA permanent and gave CBP the authority to administer CBMA claims through December 31, 2022.

and Tobacco Tax and Trade Bureau (TTB), in accordance with TTB regulations found in Part 70 of Title 27 of the Code of Federal Regulations.

(2) A claim for refund of alcohol excise taxes based on the assignment of a reduced tax rate or tax credit to an importer by a foreign good producer for goods entered or withdrawn from warehouse for consumption on or after January 1, 2023, and submitted pursuant to 26 U.S.C. 5001(c)(4), 5041(c)(7), and 5051(a)(6), must be filed with TTB, in accordance with TTB regulations found in Part 27, subpart P, of Title 27 of the Code of Federal Regulations.

Robert F. Altneu,

Director, Regulations & Disclosure Law Division, Regulations & Rulings, Office of Trade, U.S. Customs and Border Protection.

Approved:

Thomas C. West Jr.,

Deputy Assistant Secretary of the Treasury for Tax Policy.

[FR Doc. 2022–28375 Filed 12–29–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA–2022–N–3188]

Medical Devices; Neurological Devices; Classification of the Pediatric Autism Spectrum Disorder Diagnosis Aid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the pediatric Autism Spectrum Disorder (ASD) diagnosis aid into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the pediatric Autism Spectrum Disorder diagnosis aid's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 30, 2022. The classification was applicable on June 2, 2021.

FOR FURTHER INFORMATION CONTACT: Mohua Choudhury, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4102, Silver Spring, MD 20993–0002, 240–402–3095, *Mohua.Choudhury@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the pediatric Autism Spectrum Disorder diagnosis aid as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On November 3, 2020, FDA received Cognoa, Inc.'s request for De Novo classification of the Cognoa ASD Diagnosis Aid. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.