

(3) The labeling must include the following:

(i) Patient and physician labeling must include instructions for use, including images that demonstrate how to interact with the device;

(ii) Patient and physician labeling must list the minimum operating system and general purpose computing requirements that support the software of the device;

(iii) Patient and physician labeling must include a warning that the digital therapy device is not intended for use as a stand-alone therapeutic device;

(iv) Patient and physician labeling must include a warning that the digital therapy device does not represent a substitution for the patient's medication; and

(v) Physician labeling must include a summary of the clinical performance testing conducted with the device.

Dated: January 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-00497 Filed 1-12-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 5

[Docket No. TTB-2021-0008; T.D. TTB-187; Re: Notice No. 205]

RIN 1513-AC61

Addition of Singani to the Standards of Identity for Distilled Spirits

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

ACTION: Final rule; Treasury decision.

SUMMARY: This final rule amends the Alcohol and Tobacco Tax and Trade Bureau regulations that set forth the standards of identity for distilled spirits to include "Singani" as a type of brandy that is a distinctive product of Bolivia. This amendment follows a joint petition submitted by the Plurinational State of Bolivia and Singani 63, Inc., and subsequent discussions with the Office of the United States Trade Representative.

DATES: This final rule is effective February 13, 2023.

FOR FURTHER INFORMATION CONTACT: Trevar D. Kolodny, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; telephone 202-453-2226.

SUPPLEMENTARY INFORMATION:

Background

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), codified in the United States Code at 27 U.S.C. 205(e), authorizes the Secretary of the Treasury (the Secretary) to prescribe regulations relating to the labeling of containers of alcohol beverages that will prohibit consumer deception and provide the consumer with adequate information as to the identity and quality of the product contained therein.

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, as codified at 6 U.S.C. 531(d). In addition, the Secretary has delegated certain administrative and enforcement authorities to TTB through Treasury Department Order 120-01.

The TTB regulations in 27 CFR part 5 implement those provisions of section 105(e) of the FAA Act as they pertain to distilled spirits.

Certificates of Label Approval

TTB's regulations at 27 CFR 5.24 prohibit the release of bottled distilled spirits from customs custody for consumption unless the person removing the distilled spirits has obtained and is in possession of a Certificate of Label Approval (COLA) covering the product. The bottles must bear labels identical to the labels appearing on the face of the certificate, or labels with changes authorized by TTB. The TTB regulations at 27 CFR 5.22 also generally prohibit the bottling or removal of distilled spirits from a distilled spirits plant unless the proprietor possesses a COLA covering the labels on the bottle.

Classes and Types of Spirits

The TTB regulations establish standards of identity for distilled spirits products and categorize these products according to various classes and types. See 27 CFR part 5, subpart I. As defined in 27 CFR 5.141(a), the term "class" refers to a general category of spirits. Subpart I sets out the various classes of distilled spirits, such as whisky, rum, gin, and brandy. As used in § 5.141(a), the term "type" refers to a subcategory within a class of spirits. For example, "Cognac" and "Pisco" are types of brandy, and "Cachaça" is a type of rum.

The TTB labeling regulations at 27 CFR 5.63(a)(2) require that the class, type, or other appropriate designation appear on the distilled spirits labels. If a class or type does not appear on the

label, 27 CFR 5.156 and 5.166 require that such products be designated in accordance with trade and consumer understanding thereof, or, if no such understanding exists, with a distinctive or fanciful name appearing in the same field of vision as a statement of composition.

Classification of Singani

"Singani" is a term recognized by the Plurinational State of Bolivia (Bolivia) as a designation for an alcohol beverage product that is distilled from grape wine or grape pomace and produced in certain delimited parts of Bolivia. Under current TTB distilled spirits labeling regulations, Singani products are generally classified as brandies. TTB's regulations at 27 CFR 5.145(a) provide that "brandy" is a spirit distilled from the fermented juice, mash, or wine of fruit, or from the residue thereof. For this purpose, brandy must be distilled at less than 95 percent alcohol by volume (190° proof) and be bottled at not less than 40 percent alcohol by volume (80° proof). Under § 5.145(b), brandies generally must be labeled with their applicable type name as specified in the regulations, or, if the brandy does not conform to a specified type, must be labeled as "brandy" followed immediately by a truthful and adequate statement of composition.

Section 5.145(c) sets out the specific types of brandy and the standards for each type. As described by petitioners Singani 63, Inc. (Singani 63) and Bolivia, Singani may meet the criteria of several of these types of brandy, such as "fruit brandy" under § 5.145(c)(1) or "pomace brandy" (including "grappa brandy") under § 5.145(c)(9), depending on the amount of pomace used.

Section 5.145(c)(1) states that fruit brandy derived solely from grapes and stored for at least 2 years in oak containers must be designated as "grape brandy" or "brandy." That regulation also generally requires that such grape brandy must be labeled as "immature grape brandy" or "immature brandy" if it has been stored in oak barrels for fewer than two years. However, this labeling requirement does not apply to other types of brandy derived from grapes specified in § 5.145(c). The Bolivian standards submitted by petitioners contain no minimum aging requirements, and petitioners' submissions suggest that, unlike many grape brandies, Singani is generally not aged in wood. Under current TTB regulations, a Singani product classified as a grape brandy under paragraph (c)(1) would need to be labeled as an immature brandy unless it was aged in oak barrels for at least two years.

According to information submitted by the petitioners, under the standards set forth by Bolivia, certain categories of Singani may have a minimum alcohol content by volume of as low as 35 percent (70° proof). However, under § 5.145(a), all brandy must be bottled at not less than 40 percent alcohol by volume (80° proof). Thus, under TTB's current regulations, only Singani products bottled at a minimum of 40 percent alcohol by volume (80° proof) may be labeled as any type of brandy specifically defined under the standard of identity in § 5.145(c). A Singani product bottled at less than 40 percent alcohol by volume (80° proof) could be labeled as a "diluted" brandy in accordance with Ruling 75–32 of the Bureau of Alcohol, Tobacco and Firearms (TTB's predecessor agency), or as a distilled spirits specialty product bearing a statement of composition and fanciful name as required under §§ 5.156 and 5.166. Possible statements of composition for such a specialty product could include "spirits distilled from grapes" or "grape spirits."

Singani Petitions and Letters

Petitions and Related Letters

TTB received a petition from Singani 63, a distilled spirits importer, dated November 18, 2014, proposing that TTB amend its regulations to recognize Singani as a type of brandy that is a distinctive product of Bolivia. In support of this petition, Bolivia submitted letters to TTB in December 2015 and January 2017. Singani 63 also submitted a letter to TTB in June 2017 that provided additional information related to the petition.

In the petition, Singani 63 stated that TTB's recognition of Singani as a distinctive product would benefit consumers by informing them that the product was produced and labeled in compliance with Bolivia's laws. It also asserted that Singani is a product that is distinct from other types of brandy. Furthermore, both Singani 63 and Bolivia indicated that Bolivia had established a legal standard for Singani as an exclusively Bolivian product.

In response to these submissions, TTB issued letters in February and October 2017, in which TTB addressed the petitioner's request for rulemaking and identified several deficiencies in the petition and its supporting documents. Accordingly, TTB did not undertake rulemaking at that time to amend its regulations as proposed in Singani 63's petition.

TTB subsequently received a joint petition from Singani 63 and Bolivia in November 2018, again proposing that

TTB recognize Singani as a type of brandy that is a distinctive product of Bolivia. The 2018 joint petition contained additional information in support of its regulatory proposal, including official translations of Bolivian laws and decrees governing the production of Singani.

2020 U.S.-Bolivia Exchange of Letters on Unique Distilled Spirits

Following discussions between officials of Bolivia and the Office of the U.S. Trade Representative (USTR), and after consultations between USTR and TTB, USTR and Bolivia's Ministry of Foreign Affairs exchanged letters on January 6, 2020. The exchange of letters agreed upon a procedure that could potentially lead each party to recognize as distinctive certain distilled spirits products produced in the other party's territory.

The exchange of letters provides that the United States shall endeavor to publish a Notice of Proposed Rulemaking to promulgate a regulation that would provide that Singani is a type of brandy that is a distinctive product of Bolivia. The exchange of letters further provides that if, following this proposed rule, the United States publishes a final rule announcing the promulgation of a regulation establishing Singani as a type of brandy that is a distinctive product of Bolivia, then Bolivia shall, within thirty (30) days thereafter, recognize Bourbon Whiskey and Tennessee Whiskey as distinctive products of the United States. Following such recognition, Bolivia shall prohibit the sale within Bolivia of any product as Bourbon Whiskey, or Tennessee Whiskey, if it has not been manufactured in the United States in accordance with the laws and regulations of the United States governing the manufacture of Bourbon Whiskey and Tennessee Whiskey. These protections also apply to products spelled as "Bourbon Whisky" or "Tennessee Whisky." The publication of this final rule activates Bolivia's obligations under the exchange of letters agreement.

Singani Production

The Bolivian decrees and regulations submitted with the 2018 joint petition establish that Bolivia defines "Singani" as a brandy product of Bolivia. Of the Bolivian decrees and regulations submitted, Bolivian Standard NB 324001 contains the most specific standards for Singani. Among other requirements, NB 324001 requires that Singani be obtained exclusively by distillation of wines made of *Vitis vinifera* grapes produced at a minimum

altitude of 1,600 meters above sea level, prepared, distilled, and bottled in traditional "zones of origin" at a minimum altitude of 1,600 meters above sea level. NB 324001 lists several different categories of Singani, some of which have more specific requirements, such as requiring the product to be made from Muscat of Alexandria grapes specifically. NB 324001 classifies Singani in the group "Brandies and liquors."

In a prior rulemaking, TTB distinguished Singani from Pisco, which is a type of grape brandy manufactured in Peru or Chile in accordance with the laws and regulations of those countries. In 2013, TTB updated its labeling regulations to add Pisco as a type of brandy that is manufactured only in Peru and Chile. In regard to brandy produced in Bolivia, TTB determined that it would not recognize Pisco as a type of brandy produced in that country. See T.D. TTB–113 (78 FR 28739, May 16, 2013). TTB stated that Bolivia maintains standards for Singani but not for Pisco, and cited other evidence suggesting that Pisco and Singani are different products.

Notice of Proposed Rulemaking

On August 25, 2021, TTB published Notice No. 205 in the **Federal Register**, proposing to amend the regulations setting forth the standards of identity for distilled spirits (86 FR 47429). Specifically, TTB proposed amending § 5.22(d), now § 5.145, which lays out the standard of identity for brandy, to include Singani as a type of brandy that is a distinctive product of Bolivia. TTB also asserted that evidence suggests that the generally recognized geographical limits of the Singani-producing areas do not extend beyond certain delimited "zones of production" located exclusively in Bolivia.

Since the publication of Notice No. 205, TTB has published T.D. TTB–176, Modernization of the Labeling and Advertising Regulations for Distilled Spirits and Malt Beverages (see the **Federal Register**, February 9, 2022, 87 FR 7526). In T.D. TTB–176, TTB finalized a reorganization of 27 CFR part 5, including amendments to improve clarity and readability, incorporate current policy into the current regulations, and adopt certain liberalizing changes. Where necessary, TTB has updated regulatory citations and text in this document to reflect the changes in T.D. TTB–176.

In Notice No. 205, TTB proposed to recognize Singani as a type of brandy derived from grapes that is manufactured in Bolivia in compliance with the laws and regulations of Bolivia

governing the manufacture of Singani for consumption in that country. Under the proposed rule, the product could simply be labeled as “Singani” without the term “brandy” appearing on the label, in the same way that products with the type designations “Cognac” or “Pisco” are not required to bear the broader class designation “brandy.”

TTB noted that the Bolivian standard allows products designated as Singani to have an alcohol content ranging from 35 to 45 percent alcohol by volume (70° to 90° proof), while TTB’s standard of identity for brandy requires all brandy products to have a minimum alcohol content of 40 percent by volume (80° proof). TTB therefore proposed to exempt Singani from the general minimum bottling proof requirement for brandy (now in § 5.145(a)) to allow Singani to be bottled at not less than 35 percent alcohol by volume (70° proof) in accordance with the laws and regulations of Bolivia.

In addition, TTB proposed to exempt Singani from the requirement that grape brandies (as currently defined in § 5.145(c)(1)) be labeled with the word “immature” if they have been stored in oak containers for less than two years. TTB noted that Bolivian standards do not require that Singani be aged and explained that the same exemption applies to other types of brandy derived from grapes (specifically neutral brandy, pomace brandy, marc brandy, grappa brandy, Pisco, Pisco Perú, and Pisco Chileno).

Effect on Currently Approved Labels

In Notice No. 205, TTB stated that the proposed change to the regulations would revoke by operation of regulation any COLAs that specify “Singani” as the brand name or fanciful name, or as part of the brand name or fanciful name, of distilled spirits products that are not products of Bolivia. However, TTB also noted that it had searched its COLA database, and that the results of the search did not show any approved labels that used the term “Singani” as the brand name or fanciful name, or as part of the brand name or fanciful name, for distilled spirits produced outside Bolivia.

Comments Received and TTB Response

TTB received nine comments in response to Notice No. 205. All comments appear on “*Regulations.gov*,” the Federal Rulemaking portal, at <http://www.regulations.gov>, in Docket No. TTB–2021–0008. The nine comments came from on-premise retailers (2), members of the general public (2), trade associations (2), one anonymous commenter, the Embassy of Bolivia, and

Singani 63. All nine commenters supported TTB’s proposal to recognize Singani as a distinctive product of Bolivia in the United States.

Based on a review of the comments, TTB has determined that it will finalize the proposal to recognize Singani as a distinctive product of Bolivia. As discussed further below, TTB is modifying one aspect of its proposal as it pertains to the minimum bottling proof for Singani.

General Comments Concerning TTB’s Proposal To Recognize Singani as a Distinctive Product of Bolivia

The two on-premise retailers (Ivy Mix and Alex Day) both stated that the distinctive product designation would help consumers and bartenders understand Singani in relation to other brandy products, and they each submitted published books they wrote, “Cocktail Codex” (Day, Fauchald, Kaplan and Darby, 2018) and “Spirits of Latin America” (Mix and Carpenter, 2020), both of which described Singani in detail.

A comment from a member of the public located in Bolivia (Carlos Paz) and the comment from the anonymous commenter similarly agreed that the designation would help U.S. consumers understand this distilled spirit and its distinctiveness compared to other brandy products. The anonymous commenter also included a 109-page document purporting to be a list of individuals who supported recognition of Singani as its own category as part of an online petition. The other member of the public (Dominick O’Neal) agreed that the Bolivian standards for brandy production are unique, and also mentioned that the reciprocal nature of the exchange of letters agreement would allow this rulemaking to benefit distilled spirits in the United States as well.

Petitioners Singani 63 and the Embassy of Bolivia also submitted comments in support of the proposal. Singani 63 summarized the elements that make Singani distinctive among distilled spirits products, and the Embassy of Bolivia highlighted the extent to which Singani is part of Bolivia’s cultural heritage.

Both trade associations that commented, the National Association of Beverage Importers (NABI) and the Distilled Spirits Council of the United States (DISCUS), also lent their support to the proposal to add Singani as a type of brandy that is a distinctive product of Bolivia, although DISCUS’s support came with certain reservations regarding the proposed minimum bottling proof requirement for Singani, as discussed

below. DISCUS confirmed that neither DISCUS nor its member companies are aware of any Singani production outside Bolivia.

TTB did not receive any comments alerting us to any COLAs that would be revoked by operation of regulation if the proposed rule were to be adopted as a final rule.

Comments Concerning TTB’s Proposal To Authorize a 70° Minimum Bottling Proof for Singani

Three commenters responded to TTB’s specific invitation for comments on the proposal to authorize a minimum bottling proof of 35 percent alcohol by volume (70° proof) for Singani, which is lower than the minimum bottling proof of 40 percent alcohol by volume (80° proof) required for brandy generally.

Two of these commenters (NABI and Dominick O’Neal) supported TTB’s proposal to authorize a lower minimum bottling proof for Singani, arguing that the lower bottling proof requirement reinforces the uniqueness of Singani as a category. NABI also asserted that allowing Singani imports with a bottling proof standard that complied with the Bolivian legal standard, even while falling below TTB’s minimum requirement for brandy generally, would benefit consumers by ensuring that they receive a product that is “fully true to its heritage in the country of origin[.]”

NABI also argued that aligning the U.S. and Bolivian minimum bottling proof standards for Singani would reduce the regulatory burden on importers, who would no longer have to manage inventory controls to prevent lower proof Singani from reaching the U.S. market. NABI also expressed its concern that requiring Singani bottled at an alcohol by volume content less than 40 percent (80° proof) to be labeled as “diluted” is inconsistent with the standard in the country of origin. Finally, while acknowledging that other distilled spirits products fall outside the scope of the proposed rulemaking, NABI opined that other distinctive distilled spirits products would benefit from similar treatment, including Tequila.

In contrast, DISCUS disagreed with TTB’s proposal to allow Singani products to have a lower bottling proof than other brandy products. DISCUS argued that this proposal was inconsistent with TTB’s general minimum bottling proof for brandies. DISCUS also noted that TTB’s labeling regulations require other geographically distinctive products, such as Tequila, Cachaça, Mezcal, Pisco Peru, and Pisco Chileno, to be bottled at a minimum of 40 percent alcohol by volume (80° proof).

TTB Response to Comments Concerning the Proposal to Authorize a 70° Minimum Bottling Proof for Singani

Based on a review of the comments, TTB has decided that it will not proceed with the proposal to authorize a minimum bottling proof of 35 percent alcohol by volume (70° proof) for Singani at this time. Instead, TTB will authorize a minimum bottling proof of 40 percent alcohol by volume (80° proof), which is consistent with the minimum bottling proof requirements for brandy generally and for other geographically distinctive products currently recognized under TTB regulations, such as Tequila, Cachaça, Mezcal, Pisco Peru, and Pisco Chileno.

TTB recognizes that exempting Singani from the minimum bottling proof requirements for brandy would promote consistency with Bolivian rules that allow a lower minimum bottling proof for certain categories of Singani. However, authorizing such an exception for Singani would not be consistent with the minimum bottling proof rules that apply to all other brandies under the TTB regulations. In addition, as referenced in Notice No. 205 and in comments from NABI and DISCUS, the TTB regulations have not previously authorized bottling proofs for other types of products that are below the minimum bottling proof prescribed for the product's class designation, even when a foreign standard permits a lower proof. Accordingly, TTB will consider whether to address exceptions to minimum bottling proofs for Singani and other distinctive products in a possible future rulemaking.

TTB Finding

After careful review of the comments discussed above and consideration of the terms of the 2020 exchange of letters between the United States and Bolivia, TTB has determined that it is appropriate to adopt the regulatory amendments proposed in Notice No. 205, with necessary technical changes to reflect the subsequent amendments to TTB's distilled spirits labeling regulations published in T.D. TTB-176, and with changes to the proposed minimum bottling proof requirement as discussed above. This final rule therefore amends the standards of identity in § 5.145(c) to add Singani as a specific type of brandy derived from grapes that is manufactured in Bolivia in compliance with the laws and regulations of Bolivia governing the manufacture of Singani for consumption in that country. For this purpose, Singani only includes products bottled at not less than 40 percent alcohol by

volume (80° proof), which is the minimum bottling proof required for brandies in general. Singani bottled at less than 40 percent alcohol by volume (80° proof) would need to be labeled as "Diluted" Singani, or as a distilled spirits specialty product bearing a statement of composition and fanciful name. Because Bolivian standards do not require Singani to be aged, this final rule does not require Singani to be labeled as "immature" or to be labeled with any age statement.

Effect on Existing Labels

This amendment to the TTB regulations revokes by operation of regulation any COLA that uses the term "Singani" as a designation for a distilled spirits product that was not manufactured in Bolivia in accordance with the laws and regulations of Bolivia governing the manufacture of Singani for consumption in that country. TTB has searched its COLA database and does not believe that this rulemaking will affect any existing labels. TTB also solicited comments on whether this rulemaking would affect any existing labels, and TTB did not receive any comments indicating any adverse impact.

TTB will continue to allow the use of the terms "Singani" as additional information on labels of products that are currently designated as "brandy" as long as the products in question meet the new regulatory standards for designation as "Singani." Once the final rule goes into effect, future labels of such products may be designated as Singani without the use of the designation "brandy" on the label.

Regulatory Analysis and Notices

Regulatory Flexibility Act

Pursuant to the requirements of the Regulatory Flexibility Act (5 U.S.C. chapter 6), TTB certifies that this final rule will not have a significant economic impact on a substantial number of small entities. The final rule amends the standards of identity for brandy in TTB's regulations at 27 CFR 5.145(c) and makes conforming edits in other sections of part 5. It does not impose or otherwise cause any new reporting, recordkeeping, or other administrative requirements. TTB does not believe this rulemaking will affect any existing labels for distilled spirits products, and TTB did not receive any comments indicating that this rulemaking would affect any existing labels. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

This final rule is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required.

Drafting Information

Trevar D. Kolodny of the Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, drafted this final rule.

List of Subjects in 27 CFR Part 5

Advertising, Alcohol and alcoholic beverages, Consumer protection, Customs duties and inspection, Imports, Labeling, Liquors, Packaging and containers, and Reporting and recordkeeping requirements.

Amendments to the Regulations

For the reasons discussed in the preamble, TTB amends 27 CFR part 5 as follows:

PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS

- 1. The authority citation for part 5 continues to read as follows:

Authority: 26 U.S.C. 5301, 7805, 27 U.S.C. 205 and 207.

Subpart C—Alteration of Labels, Relabeling, and Adding Information to Containers

- 2. Section 5.74 is amended by:
 - a. In paragraph (c), by revising the first sentence; and
 - b. By revising paragraph (f)(1)(ii).

The revisions read as follows:

§ 5.74 Statements of age, storage, and percentage.

* * * * *

(c) * * * A statement of age on labels of rums, brandies, and agave spirits is optional, except that, in the case of brandy (other than immature brandies, fruit brandies, marc brandy, pomace brandy, Pisco brandy, Singani brandy, and grappa brandy, which are not customarily stored in oak barrels) not stored in oak barrels for a period of at least two years, a statement of age must appear on the label. * * *

* * * * *

(f) * * *

(1) * * *

(ii) Labels of whiskies and brandies (other than immature brandies, pomace brandy, marc brandy, Pisco brandy, Singani brandy, and grappa brandy) not required to bear a statement of age, and rum and agave spirits aged for not less than four years, may contain general inconspicuous age, maturity or similar

representations without the label having to bear an age statement.

* * * * *

Subpart I—Standards of Identity for Distilled Spirits

■ 3. Section 5.145 is amended by:

- a. In paragraph (b), removing the words “(c)(1) through (12)” and adding, in their place, the words “(c)(1) through (13);
- b. Revising paragraph (c) introductory text;
- c. Redesignating paragraphs (c)(7) through (12) as (c)(8) through (13); and
- d. Adding new paragraph (c)(7).

The revisions and addition read as follows:

§ 5.145 Brandy.

* * * * *

(c) *Types.* Paragraphs (c)(1) through (13) of this section set out the types of brandy and the standards for each type.

Type	Standards
* * * * *	* * * * *
(7) Singani	Brandy derived from grape/s that is manufactured in Bolivia in accordance with the laws and regulations of Bolivia governing the manufacture of Singani for consumption in that country.
* * * * *	* * * * *

Subpart N—Advertising of Distilled Spirits

■ 4. In § 5.235(c), revise the third sentence to read as follows:

§ 5.235 Prohibited practices.

* * * * *

(c) * * * An advertisement for any whisky or brandy (except immature brandies, pomace brandy, marc brandy, Pisco brandy, Singani brandy, and grappa brandy) which is not required to bear a statement of age on the label or an advertisement for any rum or agave spirits, which has been aged for not less than 4 years may, however, contain inconspicuous, general representations as to age, maturity or other similar representations even though a specific age statement does not appear on the label of the advertised product and in the advertisement itself.

* * * * *

Signed: December 20, 2022.

Mary G. Ryan,
Administrator.

Approved: December 20, 2022.

Thomas C. West, Jr.
Deputy Assistant Secretary (Tax Policy).

[FR Doc. 2022-28374 Filed 1-12-23; 8:45 am]

BILLING CODE 4810-31-P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 16

[Docket No. TTB-2023-0001; Notice No. 220]

Civil Monetary Penalty Inflation Adjustment—Alcoholic Beverage Labeling Act

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

ACTION: Notification of civil monetary penalty adjustment.

SUMMARY: This document informs the public that the maximum penalty for violations of the Alcoholic Beverage Labeling Act (ABLA) is being adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended. Prior to the publication of this document, any person who violated the provisions of the ABLA was subject to a civil penalty of not more than \$22,979, with each day constituting a separate offense. This document announces that this maximum penalty is being increased to \$24,759.

DATES: The new maximum civil penalty for violations of the ABLA takes effect on January 13, 2023, and applies to penalties that are assessed after that date.

FOR FURTHER INFORMATION CONTACT: Vonzella C. Johnson, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; (202) 508-0413.

SUPPLEMENTARY INFORMATION:

Background

Statutory Authority for Federal Civil Monetary Penalty Inflation Adjustments

The Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act), Public Law 101-410, 104 Stat. 890, 28 U.S.C. 2461 note, as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114-74, section 701, 129 Stat. 584, requires the regular adjustment and evaluation of civil monetary penalties to maintain their deterrent effect and helps to ensure that penalty amounts imposed by the Federal Government are properly accounted for and collected. A “civil

monetary penalty” is defined in the Inflation Adjustment Act as any penalty, fine, or other such sanction that is: (1) For a specific monetary amount as provided by Federal law, or has a maximum amount provided for by Federal law; (2) assessed or enforced by an agency pursuant to Federal law; and (3) assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts.

The Inflation Adjustment Act, as amended, requires agencies to adjust civil monetary penalties by the inflation adjustment described in section 5 of the Inflation Adjustment Act. The amended Inflation Adjustment Act also provides that any increase in a civil monetary penalty shall apply only to civil monetary penalties, including those whose associated violation predated such an increase, which are assessed after the date the increase takes effect.

The Inflation Adjustment Act, as amended, provides that the inflation adjustment does not apply to civil monetary penalties under the Internal Revenue Code of 1986 or the Tariff Act of 1930.

Alcoholic Beverage Labeling Act

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the Federal Alcohol Administration Act (FAA Act) pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). In addition, the Secretary of the Treasury has delegated certain administrative and enforcement authorities to TTB through Treasury Order 120-01.

The FAA Act contains the Alcoholic Beverage Labeling Act (ABLA) of 1988, Public Law 100-690, 27 U.S.C. 213-219a, which was enacted on November 18, 1988. Section 204 of the ABLA, codified in 27 U.S.C. 215, requires that a health warning statement appear on the labels of all containers of alcoholic