

comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Office of Nutrition and Food Labeling (HFS-820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Carole Adler, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2371.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

We are announcing the availability of a final guidance for industry entitled "FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels." We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of July 30, 2015, we made available a draft guidance for industry entitled "FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels." The draft guidance would explain to manufacturers of conventional foods and dietary supplements our policy on determining the amount to declare on the nutrition label for certain nutrients and dietary ingredients that are present in a small amount. We gave interested parties an opportunity to submit comments by September 28, 2015, for us to consider before beginning work on the final

version of the guidance. We received a few comments on the draft guidance, yet most pertained to the Nutrition Facts label itself or to specific nutrients rather than our policy on the declaration of small amounts. We only made editorial changes to the guidance, which include updates to the list of nutrients in 21 CFR 101.9(g)(4) and (g)(5) consistent with the final rule entitled, "Food Labeling; Revision of the Nutrition and Supplement Facts Labels" that appeared in the **Federal Register** on May 27, 2016 (81 FR 33742). The guidance announced in this document finalizes the draft guidance dated July 2015.

##### **II. Electronic Access**

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: June 24, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-15477 Filed 6-30-16; 8:45 am]

**BILLING CODE 4164-01-P**

## **DEPARTMENT OF THE TREASURY**

### **Alcohol and Tobacco Tax and Trade Bureau**

#### **27 CFR Part 16**

[Docket No. TTB-2016-0006; T.D. TTB-138]

**RIN 1513-AC28**

#### **Civil Monetary Penalty Inflation Adjustment—Alcoholic Beverage Labeling Act**

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

**ACTION:** Interim final rule (Treasury decision); Request for comments.

**SUMMARY:** This interim final rule implements the provisions of the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996 and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, with respect to the civil penalty provision of the Alcoholic Beverage Labeling Act of 1988 (ABLA). Specifically, this interim final rule increases the maximum civil monetary penalty for violations of the provisions of the ABLA from \$10,000 to \$19,787, in accordance with Federal law.

**DATES:** The effective date of this interim final rule is July 1, 2016. Comments on

this interim final rule must be received by August 30, 2016.

**ADDRESSES:** Please send your comments on the interim final rule to one of the following addresses:

- <http://www.regulations.gov> (via the online comment form for this document as posted within Docket No. TTB-2016-0006 at [Regulations.gov](http://www.regulations.gov), the Federal e-rulemaking portal);

- *U.S. Mail:* Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; or

- *Hand delivery/courier in lieu of mail:* Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 400, Washington, DC 20005.

See the Public Participation section of this document for specific instructions and requirements for submitting comments.

**FOR FURTHER INFORMATION CONTACT:** Andrew L. Malone, Public Guidance Program Manager, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; (202) 453-1039, ext. 188.

#### **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, 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 Debt Collection Improvement Act of 1996 (the Improvement Act of 1996), Public Law 104-134, section 31001(s), 110 Stat. 1321, enacted on April 26, 1996, amended the Inflation Adjustment Act by requiring civil monetary penalties to be adjusted for inflation. Specifically, the Improvement Act of 1996 required, among other things, that the head of each Federal agency adjust each civil monetary penalty provided by law within the jurisdiction of the

respective agency by the inflation adjustment described under section 5 of the Inflation Adjustment Act. The Improvement Act of 1996 required the adjustment of the civil monetary penalty to be done by regulation and published in the **Federal Register**.

Under the Improvement Act of 1996, any increase in a civil monetary penalty made pursuant to the amendment applied only to violations which occur after the date the increase takes effect. The act also provided that the first adjustment of a penalty made pursuant to the amendment may not exceed 10 percent of such penalty.

The Inflation Adjustment Act has been further amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the Improvements Act of 2015), Public Law 114-74, section 701, 129 Stat. 584, enacted on November 2, 2015. The Improvements Act of 2015 changed the method agencies use to calculate inflation adjustments to civil monetary penalties, as well as the method and frequency of future adjustments. The Improvements Act of 2015 also instructed agencies to apply its method of calculating the inflation adjustment to the original statutory penalty, rather than to penalties as they were adjusted under the Improvement Act of 1996. To account for inflation that took place between the enactment of the original penalties and the enactment of the Improvements Act of 2015, agencies must make a "catch-up" first adjustment through an interim final rulemaking that is published no later than July 1, 2016, and takes effect no later than August 1, 2016. Agencies shall adjust civil monetary penalties no later than January 15 of every year thereafter. The Improvements Act of 2015 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.

As amended, the Inflation Adjustment Act 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). The Secretary has delegated various authorities through Treasury Department Order 120-01, dated

December 10, 2013, (superseding Treasury Department Order 120-01, dated January 24, 2003), to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law.

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 beverages manufactured, imported, or bottled for sale or distribution in the United States, as well as on containers of alcoholic beverages that are manufactured, imported, bottled, or labeled for sale, distribution, or shipment to members or units of the U.S. Armed Forces, including those located outside the United States.

The health warning statement requirement applies to containers of alcoholic beverages manufactured, imported, or bottled for sale or distribution in the United States on or after November 18, 1989. The statement reads as follows:

GOVERNMENT WARNING: (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

Section 204 of the ABLA also specifies that the Secretary of the Treasury shall have the power to ensure the enforcement of the provisions of the ABLA and issue regulations to carry out them out. In addition, section 207 of the ABLA, codified in 27 U.S.C. 218, provides that any person who violates the provisions of the ABLA is subject to a civil penalty of not more than \$10,000, with each day constituting a separate offense.

Most of the civil monetary penalties administered by TTB are imposed by the Internal Revenue Code of 1986, and thus are not subject to the inflation adjustment mandated by the Inflation Adjustment Act. The only civil monetary penalty enforced by TTB that is subject to the inflation adjustment is the penalty imposed by the ABLA at 27 U.S.C. 218.

#### *Previous Civil Monetary Penalty Adjustment for Violations of the ABLA*

In accordance with the Improvement Act of 1996, TTB's predecessor agency, the Bureau of Alcohol, Tobacco, and Firearms (ATF), issued a final rule that was published in the **Federal Register** and effective on October 23, 1996 (61 FR 54935, T.D. ATF-385), that adjusted the

civil monetary penalty provision by increasing the maximum penalty for violations of the ABLA from \$10,000 to \$11,000.

The TTB regulations implementing the ABLA are found in 27 CFR part 16, Alcoholic Beverage Health Warning Statement. The 1996 final rule established a new section, 27 CFR 16.33, addressing the penalty provision. Specifically, paragraph (a) of § 16.33 codified the statutory \$10,000 penalty set forth in the ABLA, and paragraph (b) addressed the Improvement Act of 1996 requirement, stating that the penalty provided for in paragraph (a) shall be periodically adjusted in accordance with inflation, with the civil penalty for violations occurring after October 23, 1996, not to exceed \$11,000.

As noted earlier, the Improvements Act of 2015 changed the Inflation Adjustment Act's method of calculating the inflation adjustment and the method and frequency of future adjustments. Accordingly, this interim final rule revises § 16.33 to reflect the amendments to the Inflation Adjustment Act.

#### *Cost-of-Living Adjustment*

As mentioned earlier, the ABLA contains a maximum civil monetary penalty, rather than a range of minimum and maximum civil monetary penalties. For such penalties, the Inflation Adjustment Act, as amended, provides that the first adjustment will be determined by increasing the maximum civil monetary penalty by the cost-of-living adjustment. For the first adjustment after the date of enactment of the Improvements Act of 2015, the cost-of-living adjustment means the percentage (if any) for each civil monetary penalty by which the Consumer Price Index for all-urban consumers (CPI-U) for the month of October, 2015, exceeds the CPI-U for the month of October of the calendar year in which the amount of such civil penalty was last established or adjusted under a provision of law other than the Inflation Adjustment Act. This means that the inflation adjustment must be applied to the original statutory penalty (for the ABLA, \$10,000), and not to any increases promulgated under the Inflation Adjustment Act, as amended by the Improvement Act of 1996. Any increase determined under section 5 of the Inflation Adjustment Act, as amended, must be rounded to the nearest multiple of \$1.

The CPI-U in October 1988, the year in which the ABLA was enacted and its civil monetary penalty was established, was 120.2, and the CPI-U for October 2015 was 237.838. The rate of inflation

for the period between October 1988 and October 2015 is therefore 97.8686 percent. When applied to the original ABLA civil monetary penalty of \$10,000, this rate of inflation yields a raw (unrounded) inflation adjustment of \$9,786.86. Rounded to the nearest dollar, the inflation adjustment is \$9,787, meaning that the new maximum civil monetary penalty for violations of the ABLA will be \$19,787.

The Inflation Adjustment Act, as amended, provides that the amount of increase in the initial adjustment of a civil monetary penalty shall not exceed 150 percent of the amount of that civil monetary penalty on the date of enactment of the Improvements Act of 2015; this penalty adjustment does not exceed the maximum. The Inflation Adjustment Act, as amended, also provides that, for the initial adjustment, an agency may adjust the amount of a civil monetary penalty by less than the otherwise required amount if the agency, after publishing a notice of proposed rulemaking and providing an opportunity for comment, determines that (1) increasing the civil monetary penalty by the otherwise required amount will have a negative economic impact or (2) the social costs of increasing the civil monetary penalty by the otherwise required amount outweigh the benefits. The Office of Management and Budget must concur with such a determination. However, TTB has determined that neither of these circumstances apply to the initial cost-of-living adjustment described above.

#### Notice of Future Increases

After the initial “catch-up” adjustment, section 4 of the Inflation Adjustment Act, as amended, requires heads of agencies to adjust civil monetary penalties and to make the adjustments notwithstanding section 553 of title 5, United States Code. Section 553 of title 5 is the rulemaking provision of the Administrative Procedure Act, which requires notice-and-comment rulemaking for certain agency actions and requires agencies to provide interested parties the right to petition for the issuance, amendment, or repeal of a rule.

Until the Improvements Act of 2015, the Inflation Adjustment Act required agencies to adjust their civil monetary penalties by regulation. For all adjustments after the initial adjustment via interim final rule, the amendments in the Improvements Act of 2015 allow agencies to apply the cost-of-living adjustment formula in the Inflation Adjustment Act and publish the resulting civil monetary penalty without

establishing it by regulation. As the Inflation Adjustment Act, as amended, now requires annual cost-of-living adjustments, to be applied no later than January 15 of every year after 2016, TTB has determined that it is most expedient to publish the new penalty on its Web site, rather than in § 16.33. TTB will announce future adjustments to the maximum civil monetary penalty in the ABLA through notices published in the **Federal Register** and update its Web site when adjustments are announced.

#### TTB Determination

Accordingly, this interim final rule revises § 16.33 to reflect the changes to the Inflation Adjustment Act made by the Improvements Act of 2015. Paragraph (a) of § 16.33 states that the ABLA provides that any person who violates the provisions of 27 CFR part 16 shall be subject to a civil penalty of not more than \$10,000. However, pursuant to the provisions of the Inflation Adjustment Act, as amended, the civil penalty provided in the ABLA is subject to periodic cost-of-living adjustment. Accordingly, any person who violates the provisions of 27 CFR part 16 shall be subject to a civil penalty of not more than the amount listed at [https://www.ttb.gov/regulation\\_guidance/ablapenalty.html](https://www.ttb.gov/regulation_guidance/ablapenalty.html). Paragraph (a) also states that each day shall constitute a separate offense.

Paragraph (b) of the revised § 16.33 indicates that TTB will provide notice in the **Federal Register** and at the Web site above of cost-of-living adjustments to the civil penalty for violations of 27 CFR part 16.

Paragraph (c) of the revised § 16.33 reflects the changes the Improvements Act of 2015 made with respect to the applicability of adjusted penalties. As mentioned earlier, before the Improvements Act of 2015, an adjusted penalty only applied to violations that occurred after the date the increase took effect; this language had been reflected in the previous § 16.33(b). Consistent with section 6 of the Inflation Adjustment Act, as amended, new paragraph (c) states that any increase in the penalty described in paragraph (a) shall apply only to penalties, including those whose associated violation predated such an increase, which are assessed after the date the increase takes effect. An increase will take effect on the date a notice is published in the **Federal Register** announcing the increase. The effective date of the increase also will be listed at the Web site mentioned above.

#### Public Participation

##### Comments Invited

TTB invites comments from interested members of the public on the cost-of-living adjustment to the ABLA civil monetary penalty.

##### Submitting Comments

You may submit comments on this proposed rule by using one of the following three methods (please note that TTB has a new address for comments submitted by U.S. Mail):

- **Federal e-Rulemaking Portal:** You may send comments via the online comment form posted with this proposed rule within Docket No. TTB–2016–0006 on “[Regulations.gov](http://www.regulations.gov),” the Federal e-rulemaking portal, at <http://www.regulations.gov>. A direct link to that docket is available under T.D. TTB–138 on the TTB Web site at <http://www.ttb.gov/rrd/decisions.shtml>. Supplemental files may be attached to comments submitted via [Regulations.gov](http://www.regulations.gov). For complete instructions on how to use [Regulations.gov](http://www.regulations.gov), visit the site and click on the “Help” tab.

- **U.S. Mail:** You may send comments via postal mail to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005.

- **Hand Delivery/Courier:** You may hand-carry your comments or have them hand-carried to the Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 400, Washington, DC 20005.

Please submit your comments by the closing date shown above in this proposed rule. Your comments must reference T.D. TTB–138 and include your name and mailing address. Your comments also must be made in English, be legible, and be written in language acceptable for public disclosure. TTB does not acknowledge receipt of comments, and TTB considers all comments as originals.

In your comment, please clearly indicate if you are commenting on your own behalf or on behalf of an association, business, or other entity. If you are commenting on behalf of an entity, your comment must include the entity’s name, as well as your name and position title. If you comment via [Regulations.gov](http://www.regulations.gov), please enter the entity’s name in the “Organization” blank of the online comment form. If you comment via postal mail or hand delivery/courier, please submit your entity’s comment on letterhead.

You may also write to the Administrator before the comment

closing date to ask for a public hearing. The Administrator reserves the right to determine whether to hold a public hearing.

#### Confidentiality

All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

#### Public Disclosure

TTB will post, and you may view, copies of this interim final rule, selected supporting materials, and any online or mailed comments received about this interim final rule within Docket No. TTB-2016-0006 on the Federal e-rulemaking portal, *Regulations.gov*, at <http://www.regulations.gov>. A direct link to that docket is available on the TTB Web site at <http://www.ttb.gov/rrd/decisions.shtml> under T.D. TTB-138. You may also reach the relevant docket through the *Regulations.gov* search page at <http://www.regulations.gov>. For information on how to use *Regulations.gov*, click on the site's "Help" tab.

All posted comments will display the commenter's name, organization (if any), city, and State, and, in the case of mailed comments, all address information, including email addresses. TTB may omit voluminous attachments or material that the Bureau considers unsuitable for posting.

You may also view copies of this interim final rule and any electronic or mailed comments that TTB receives about this interim final rule by appointment at the TTB Information Resource Center, 1310 G Street NW., Washington, DC 20005. 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 an appointment or to request copies of comments or other materials.

#### Administrative Procedure Act

TTB is issuing this interim final rule without prior notice and opportunity for public comment in accordance with provisions of the Improvements Act of 2015, which directs agencies to make the "catch-up" adjustment through interim final rulemaking. In addition, TTB finds good cause under 5 U.S.C. 553(d)(3) to dispense with the effective date limitation in 5 U.S.C. 553(d) because this interim final rule merely implements the provisions of the Inflation Adjustment Act, as amended, and does not change TTB's interpretation of any regulation or the

requirements of any recordkeeping provision.

#### Regulatory Flexibility Act

Because the agency was not required to publish a notice of proposed rulemaking, the provisions of the Regulatory Flexibility Act relating to an initial and final regulatory analysis (5 U.S.C. 603, 604) are not applicable to this interim final rule. Accordingly, a regulatory flexibility analysis is not required.

#### Executive Order 12866

It has been determined that this interim final rule is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required.

#### Drafting Information

Andrew L. Malone of the Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, drafted this document.

#### List of Subjects in 27 CFR Part 16

Alcohol and alcoholic beverages, Consumer protection, Health, Labeling, Penalties.

#### Amendment to the Regulations

For the reasons set forth in the preamble, TTB is amending 27 CFR, chapter I, part 16 as follows:

#### PART 16—Alcoholic Beverage Health Warning Statement

- 1. The authority citation for part 16 continues to read as follows:

**Authority:** 27 U.S.C. 205, 215, 218; 28 U.S.C. 2461 note.

- 2. Section 16.33 is revised to read as follows:

#### § 16.33 Civil penalties; adjustments.

(a) *General.* The Act provides that any person who violates the provisions of this part shall be subject to a civil penalty of not more than \$10,000. However, pursuant to the provisions of the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended, this civil penalty is subject to periodic cost-of-living adjustment. Accordingly, any person who violates the provisions of this part shall be subject to a civil penalty of not more than the amount listed at <https://www.ttb.gov/regulation-guidance/ablapenalty.html>. Each day shall constitute a separate offense.

(b) *Notice of cost-of-living adjustment.* TTB will provide notice in the **Federal Register** and at the Web site referenced in paragraph (a) of this section of cost-of-living adjustments to the civil penalty for violations of this part.

(c) *Applicability of increases in penalty.* Any increase in the penalty described in paragraph (a) of this section shall apply only to penalties, including those whose associated violation predated such an increase, which are assessed after the date the increase takes effect. An increase will take effect on the date a notice is published in the **Federal Register** announcing the increase. The effective date of the increase also will be listed at the Web site in paragraph (a) of this section.

Dated: May 16, 2016.

**Mary G. Ryan,**

*Acting Administrator.*

Approved: May 27, 2016.

**Timothy E. Skud,**

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

[FR Doc. 2016-15636 Filed 6-30-16; 8:45 am]

**BILLING CODE 4810-31-P**

## DEPARTMENT OF JUSTICE

### Office of the Attorney General

#### 28 CFR Part 0

[AG Order No. 3691-2016]

#### Office for Access to Justice

**AGENCY:** Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** This rule amends the Code of Federal Regulations to reflect the establishment of the Office for Access to Justice as a distinct component of the Department of Justice. The Office for Access to Justice was created by the Attorney General to address the access-to-justice crisis in the criminal and civil justice systems. The office's mission is to help ensure that the justice system is efficient, fair, and accessible to all, irrespective of an individual's wealth and status. This rule sets forth the Office's organization, mission and functions.

**DATES:** This rule is effective July 1, 2016.

**FOR FURTHER INFORMATION CONTACT:** Lisa Foster, Director, Office for Access to Justice, U.S. Department of Justice, RFK Main Justice Building, Room 3340, 950 Pennsylvania Avenue NW., Washington, DC 20530. Telephone: (202) 514-5312.

#### SUPPLEMENTARY INFORMATION:

##### Background

In 2010, the Attorney General established the Office for Access to Justice to address the access-to-justice crisis in the criminal and civil justice