C. Impairment of hearing as described under the criteria in 102.10 or 102.11.

111.10 [Reserved]

111.11 [Reserved]

111.12 *Myasthenia gravis,* characterized by A or B despite adherence to prescribed treatment for at least 3 months (see 111.00C):

A. Disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Bulbar and neuromuscular dysfunction (see 111.00E), resulting in:

1. One myasthenic crisis requiring mechanical ventilation; or

2. Need for supplemental enteral nutrition via a gastrostomy or parenteral nutrition via a central venous catheter.

111.13 *Muscular dystrophy,* characterized by disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities.

111.14 *Peripheral neuropathy,* characterized by disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities.

111.15 [Reserved]

111.16 [Reserved]

111.17 *Neurodegenerative disorders of the central nervous system, such as Juvenile-onset Huntington's disease and Friedreich's ataxia,* characterized by disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities.

111.18 *Traumatic brain injury,* characterized by disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities, persisting for at least 3 consecutive months after the injury.

111.19 [Reserved]

111.20 *Coma or persistent vegetative state,* persisting for at least 1 month.

111.21 *Multiple sclerosis,* characterized by disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities.

111.22 *Motor neuron disorders,* characterized by A or B:

A. Disorganization of motor function in two extremities (see 111.00D1), resulting in an extreme limitation (see 111.00D2) in the ability to stand up from a seated position, balance while standing or walking, or use the upper extremities; or

B. Bulbar and neuromuscular dysfunction (see 111.00E), resulting in:

1. Acute respiratory failure requiring invasive mechanical ventilation; or

2. Need for supplemental enteral nutrition via a gastrostomy or parenteral nutrition via a central venous catheter.

[FR Doc. 2016–15306 Filed 6–30–16; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2015–D–1839]

The Food and Drug Administration's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is announcing the availability of a guidance for industry entitled ''FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels: Guidance for Industry.'' The guidance explains 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.

DATES: The guidance is available on July 1, 2016. Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–1839. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of

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*, 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