Dated: October 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24126 Filed 11–2–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2018–D–1459]

Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed at One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics.'' The draft guidance, when finalized, will provide questions and answers on topics related primarily to implementing two final rules, one entitled ''Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments,'' and the other entitled ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels.'' This draft guidance also discusses formatting issues for dual-column labeling, products that have limited space for nutrition labeling, and additional issues dealing with compliance.

DATES: Submit either electronic or written comments on the draft guidance by January 4, 2019 to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2018–D–1459 for ''Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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.'' We will review this copy, including the claimed confidential information, in our 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., 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 draft guidance.

FOR FURTHER INFORMATION CONTACT: Jillonne Kevala, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1450.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance for industry entitled ''Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-

Column Labeling, and Miscellaneous Topics.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 alternate approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

The draft guidance, when finalized, will provide questions and answers on topics related primarily to implementing two final rules: (1) ''Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments'' (81 FR 34000 (May 27, 2016)) and (2) ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels'' (81 FR 33742 (May 27, 2016)). This draft guidance also discusses formatting issues for dual-column labeling, products that have limited space for nutrition labeling, and additional issues dealing with compliance.

II. The Paperwork Reduction Act

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 101 have been approved under OMB control number 0910–0381.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: October 30, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24124 Filed 11–2–18; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–114540–18]

RIN 1545–BO88

Amount Determined Under Section 956 for Corporate United States Shareholders

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that reduce the amount determined under section 956 of the Internal Revenue Code with respect to certain domestic corporations. The proposed regulations affect certain domestic corporations that own (or are treated as owning) stock in foreign corporations.

DATES: Written or electronic comments and requests for a public hearing must be received by December 5, 2018.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–114540–18), Internal Revenue Service, Room 5203, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–114540–18), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–114540–18).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Rose E. Jenkins, (202) 317–6934; concerning submissions of comments or requests for a public hearing, Regina Johnson, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

I. Section 956

The Revenue Act of 1962 (the ''1962 Act''), Pub. L. 87–834, sec. 12, 76 Stat. at 1006, enacted sections 951 and 956 as part of subpart F of part III, subchapter N, chapter 1 of the 1954 Internal Revenue Code (''subpart F''), as amended. Subpart F was enacted in order to limit the use of low-tax jurisdictions for the purposes of obtaining indefinite deferral of U.S. tax on certain earnings that would otherwise be subject to U.S. federal income tax. H.R. Rep. No. 1447 at 57 (1962). Congress enacted subpart F in part to address taxpayers who had ''taken advantage of the multiplicity of foreign tax systems to avoid taxation by the United States on what could ordinarily be expected to be U.S. source income.'' *Id.* at 58.

Before the 1962 Act, United States shareholders (as defined in section 951(b)) (''U.S. shareholders'') of controlled foreign corporations (as defined in section 957) (''CFCs'') were not subject to U.S. tax on earnings of the foreign corporations unless and until earnings of the foreign corporations were distributed to the shareholders as a dividend. S. Rep. No. 1881 at 78 (1962). The subpart F regime eliminated deferral for certain—generally passive or highly mobile—earnings of CFCs by subjecting those earnings to immediate U.S. taxation regardless of whether there was an actual distribution. *Id.* at 80. Earnings that were not subject to immediate U.S. taxation under the subpart F regime were generally taxable only upon repatriation, as those earnings did not present the same concerns regarding indefinite tax deferral compared to earnings subject to subpart F.

Section 956 was enacted alongside the subpart F regime in the 1962 Act to ensure that a CFC's earnings not subject to immediate tax when earned (under the subpart F regime) would be taxed when repatriated, either through a dividend or an effective repatriation. Recognizing that repatriation of foreign earnings was possible through means other than a taxable distribution, Congress enacted section 956 ''to prevent the repatriation of income to the United States in a manner which does not subject it to U.S. taxation.'' H.R. Rep. No. 1447 at 58. Congress determined that the investment by a CFC of its earnings in United States property, including obligations of a U.S. person, ''is substantially the equivalent of a dividend.'' *See* S. Rep. No. 1881 at 88 (1962). *See also* S. Rep. No. 94–938 at 226 (1976) (''[S]ince the investment . . . in the stock or debt obligations of a related U.S. person or its domestic affiliates makes funds available for use by the U.S. shareholders, it constitutes an effective repatriation of earnings which should be taxed.''). Accordingly, Congress enacted section 956 as an anti-abuse measure to tax a CFC's investment of earnings in United States property in the same manner as if it had distributed those earnings to the United States. *See* JCS–10–87 at 1081–82 (1987) (''In general, two kinds of transactions are repatriations that end deferral and trigger tax. First, an actual dividend payment ends deferral. . . . Second, in