DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0268]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 30, 2015.

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 identify 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–2009–D–0268. 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 comments on information collection issues to the Office of Management and Budget in the following ways:
- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0728. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration—OMB Control Number 0910–0728—Extension

The definition of “food” under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), includes “articles used for food or drink” and thus includes alcoholic beverages. See 21 U.S.C. 321(f). As such, alcoholic beverages are subject to the FD&C Act’s adulteration and misbranding provisions, and implementing regulations, related to food. For example, manufacturers of alcoholic beverages are responsible for adhering to the registration of food facilities requirements in 21 CFR part 1 and to the good manufacturing practice regulations in 21 CFR part 110. There are also certain requirements for nutrition labeling on menus, menu boards, and other written materials for alcohol beverages served in restaurants or similar retail food establishments in 21 CFR part 101 (79 FR 71156 (December 1, 2014)). However, as reflected in a 1987 Memorandum of Understanding (MOU) between FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB), TTB is responsible for the dissemination and enforcement of regulations with respect to the labeling of distilled spirits, certain wines, and malt beverages issued in the Federal Alcohol Administration Act (the FAA Act). In TTB Ruling 2008–3, dated July 7, 2008, TTB clarified that certain beers, which are not made from both malted barley and hops but are instead made from substitutes for malted barley (such as sorghum, rice, or wheat) or are made without hops, do not meet the definition of a “malt beverage” under the FAA Act. Accordingly, TTB stated in its Ruling that such products (other than sake, which is classified as a wine under the FAA Act), are not subject to the labeling, advertising, or other provisions of the TTB regulations issued under the FAA Act.

In cases where an alcoholic beverage is not covered by the labeling provisions of the FAA Act, the product is subject to ingredient and other labeling requirements under the FD&C Act and the implementing regulations that we administer. In addition, as provided for under the Fair Packaging and Labeling Act (FPLA), alcoholic beverages that are not covered by the labeling provisions of the FAA Act are subject to the provisions of the FPLA, which we administer. Furthermore, the beers described in the TTB’s Ruling as not being a “malt beverage” are subject to the labeling requirements under the FD&C Act and FPLA, and our implementing regulations. In general, we require that food products under our jurisdiction be truthfully and informatively labeled in accordance with the FD&C Act, the FPLA, and FDA’s regulations. Consumers will use the information to assist them in making choices concerning their purchase of a food product, including choices related to substances that the consumer must avoid to prevent adverse reactions. This information also enables the consumer to determine the role of the food product in a healthful diet. Additionally, FDA intends to use the information to determine whether a manufacturer or other supplier of food products is meeting its statutory and regulatory obligations. Failure of a manufacturer or other supplier of food products to label its products in compliance with section 403 of the FD&C Act and parts 101, 102, 104, and 105 of FDA’s food labeling regulations may result in a product being misbranded under the FD&C Act, subjecting the firm and product to regulatory action. In the Federal Register of August 12, 2015 (80 FR 48322), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Description of Respondents: The respondents to this collection of information are manufacturers of beers that are subject to our labeling laws and regulations.

We estimate the burden of this collection of information as follows:
Our estimate of the number of respondents is based on the number of regulatory submissions to TTAP for beers that do not meet the definition of a “malt beverage” under the FAA Act. Based on its records of submissions received from manufacturers of such products, TTAP estimates the annual number of respondents to be 12 and the annual number of disclosures to be 24. We adopt TTAP’s estimate of 12 annual respondents, and estimate an annual number of 2 disclosures per respondent, as reflected in table 1 above. Our estimate of the average burden per disclosure for each collection provision is based on our experience with food labeling under our jurisdiction. The estimated average burden per disclosure for §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 in table 1 are equal to, and based upon, the estimated average burden per disclosure approved by OMB in OMB control number 0910–0381. We further estimate that the labeling burden of section 403(w)(1) of the FD&C Act, which specifies requirements for the declaration of food allergens, will be 1 hour based upon the similarity of the requirements to that of § 101.4. Finally, FDA estimates that a respondent will spend 1 hour reading the guidance document.

Thus, we estimate that 12 respondents will each label 2 products annually, for a total of 24 labels. We estimate that the manufacturers will spend 7.25 hours (0.5 hours + 1 hour + 0.25 hour + 4 hours + 0.5 hour + 1 hour = 7.25 hours) on each label to comply with our labeling regulations and the requirements of section 403(w)(1) of the FD&C Act, for a total of 174 hours (24 labels × 7.25 hours = 174 hours). In addition, 12 respondents will each spend 0.5 hour reading the guidance document, for a total of 12 hours. Thus, we estimate the total hour burden of the proposed collection of information to be 186 hours (174 hours + 12 hours = 186 hours). The guidance also refers to previously approved collections of information found in our regulations. The collections of information in §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 have been approved under OMB control number 0910–0381. Allergen labeling of these beers under section 403(w)(1) of the FD&C Act (21 U.S.C. 343(w)(1)), which was added by the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), has been approved under OMB control number 0910–0792.

Dated: October 26, 2015.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2015–27556 Filed 10–28–15; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2014–N–2033]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Survey on Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Survey on Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, PRASTaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On June 25, 2015, the Agency submitted a proposed collection of information entitled “Survey on Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types” to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0799. The approval expires on December 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at http://www.reginfo.gov/public/do/PRAMain.

Dated: October 23, 2015.
Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2015–27556 Filed 10–28–15; 8:45 am]
BILLING CODE 4164–01–P

### Table 1—Estimated Annual Third Party Disclosure Burden

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<tr>
<th>Reference</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Avg. burden per disclosure</th>
<th>Total hours</th>
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<td>2</td>
<td>24</td>
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<td>Guidance document entitled “Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration”</td>
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<td>1</td>
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<tr>
<td>Total</td>
<td></td>
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1 There are no capital costs or operating and maintenance costs associated with this collection of information.