

TABLE 1—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN<sup>1</sup>

Reference	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Avg. burden per disclosure	Total hours
21 CFR 101.3 and 101.22 .....	12	2	24	0.5	12
21 CFR 101.4 .....	12	2	24	1	24
21 CFR 101.5 .....	12	2	24	0.25	6
21 CFR 101.9 .....	12	2	24	4	96
21 CFR 101.105 .....	12	2	24	0.5	12
Section 403(w)(1) of the FD&C Act .....	12	2	24	1	24
Guidance document entitled "Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration" .....	12	1	12	1	12
<b>Total</b> .....					<b>186</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate of the number of respondents is based on the number of regulatory submissions to TTB 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, TTB estimates the annual number of respondents to be 12 and the annual number of disclosures to be 24. We adopt TTB'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 1 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.*

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## 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](mailto: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.*

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