Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

OMB Control No. 0910-0728

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Alcohol and Tobacco Tax and Trade Bureau (TTB) is responsible for the promulgation and enforcement of regulations with respect to the labeling of distilled spirits, wines, and malt beverages pursuant to the Federal Alcohol Administration Act (FAA Act).[1] In 2008, TTB issued a ruling (TTB Ruling 2008-3, dated July 7, 2008) clarifying that certain beers do not meet the definition of a "malt beverage" under the FAA Act. TTB has 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. 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, and other provisions of the TTB regulations promulgated under the FAA Act. Because these beers are not subject to the labeling provisions of the FAA Act, they are subject to the labeling provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA).[2]

FDA's food labeling regulations under parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) were issued under the authority of sections 4, 5, and 6 of the FPLA (15 U.S.C. 1453, 1454, and 1455) and under sections 201, 301, 402, 403, 409, 411, 701, and 721 of the FD&C Act (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of these regulations derive from section 403 of the FD&C Act, which provides that a food product shall be deemed to be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the food product, is false or misleading in any particular, or bears certain types of unauthorized claims. The disclosure requirements and other collections of information in the regulations in parts 101, 102, 104, and 105 are necessary to ensure that food products produced or sold in the United States are in compliance with the labeling provisions of the FD&C Act and the FPLA.

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[1] *See* the 1987 Memorandum of Understanding between FDA and TTB's predecessor agency, the ATF (available at *http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116370.htm*).

[2] However, as explained in the TTB ruling, some TTB labeling requirements such as the Government Health Warning Statement under the Alcoholic Beverage Labeling Act and certain marking requirements under the Internal Revenue Code continue to apply to these products.

In the Federal Register of December 23, 2014 (79 FR 77013), FDA announced the availability of a guidance entitled, "*Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration*." The guidance is intended to assist manufacturers in labeling beers that are subject to FDA's labeling laws and regulations. All labeling regulations discussed in this guidance have been previously approved by OMB in accordance with the Paperwork Reduction Act of 1995 under OMB Control No. 0910-0381. The regulations approved under OMB Control No. 0910-0381 include §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105. This information collection added manufacturers of certain beers that do not meet the definition of a "malt beverage" under the FAA Act as new respondents to these labeling regulations. This information collection includes OMB approval of 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). FDA, in the guidance, also reminds manufacturers that the labeling of wine beverages containing less than 7 percent alcohol by volume, such as wine coolers, diluted wine beverages, dealcoholized or partially dealcoholized wine and ciders, is also subject to FDA labeling requirements.

FDA is requesting approval of the information collection provisions in the guidance entitled, "*Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration*."

2. Purpose and Use of the Information Collection

The primary user of the information to be disclosed on the label or labeling of food products is the consumer that purchases the food product. Consumers may 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 uses 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, and the firm and the product subject to regulatory action.

Section 101.3 of FDA's food labeling regulations requires that the label of a food product in packaged form bear a statement of identity, (i.e., the name of the product), including as appropriate, the form of the food or the name of the food imitated. Section 101.4 prescribes the requirements for the declaration of ingredients on the label or labeling of food products in packaged form, including using the common or usual name of each ingredient. Section 101.5 requires that the label of a food product in packaged form specify the name and place of business of the manufacturer, packer, or distributor and, if the food producer is not the manufacturer of the food product, its connection with the food product. Section 101.9 requires that nutrition information be provided for all food products intended for human consumption and offered for sale, unless an exemption in § 101.9(j) applies to the product. Section 101.22 contains labeling requirements for the disclosure of spices, flavorings, colorings, and chemical preservatives (101.22(j)) in food products. Section 101.105 specifies requirements for the declaration of the net quantity of contents on the label of a food in packaged form.

Under the FD&C Act, as amended by the FALCPA, the food source name of any "major food allergen" present must be declared (section 403(w)(1) of the FD&C Act, 21 U.S.C. 343(w)(1)). Section 201(qq) of the FD&C Act, (21 U.S.C. 321(qq)), defines "major food allergen" as milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of them, with the exception of highly refined oils.

Description of respondents: The respondents to this collection of information are manufacturers of beers that are subject to FDA's labeling laws and regulations. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

The regulations in parts 101, 102, 104, and 105 do not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies are free to use whatever forms of information technology may best assist them in meeting labeling requirements for food. FDA has developed a web-based data entry system so small businesses may electronically claim exemption from the requirements for nutrition labeling (available at: *https://info1.cfsan.fda.gov/nle/client/login.cfm*). The agency estimates that one hundred percent (100%) of firms will use information technology (electronic means) to assist them in meeting labeling requirements.

4. Efforts to Identify Duplication and Use of Similar Information

No duplication of Federal regulations concerning the requirements for the labeling of food products is likely because of the clear Congressional authorization that FDA promulgate regulations pertaining to the labeling of foods, as opposed to the jurisdiction of the U.S. Department of Agriculture (meats and poultry) and the Federal Trade Commission (advertising). In addition, as noted above, FDA and TTB's predecessor agency, the ATF, signed a Memorandum of Understanding in 1987 clarifying that TTB is responsible for the promulgation and enforcement of regulations with respect to the labeling of distilled spirits, wines, and malt beverages pursuant to the FAA Act.

5. Impact on Small Businesses or Other Small Entities

FDA estimates that fifty percent (50%) of respondents are small businesses. The requirements are the minimum requirements for complying with the provisions of the FD&C Act. In most cases, the information that is required to be disclosed or submitted to the Agency is information that is available to a firm, including a small business, as a normal course of its doing business. Small businesses may claim exemption from the requirements for nutrition labeling under the provisions of 21 CFR 101.9(j)(18) and 101.36(h)(2). FDA aids small businesses in complying with its requirements through the Agency's Regional Small Business Representatives and through the scientific and administrative staffs within the Agency. FDA has provided a Small Business Guide on the Agency's website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. There are no consequences to Federal program or policy activities if the information is collected less frequently. As noted above, failure of a firm to comply with the requirements for disclosure of the information on the labels or labeling of its food products may result in those products being misbranded under section 403 of the FD&C Act, and the products and the firm subject to regulatory action.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of August 12, 2015 (80 FR 48322). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Information submitted to FDA under the food labeling regulations may contain trade secret and commercial confidential information. Only information that is releasable under the Agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by Section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

11. Justification for Sensitive Questions

This collection of information does not contain questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Third Party Disclosure Burden[1]					
Citation	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
21 CFR 101.3 and 101.22	12	2	24	.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 Federal Food, Drug, and Cosmetic Act	12	2	24	1	24
Guidance Document, "Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration"	12	1	12	1	12
Total					186

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents in Table 1 is based on the number of regulatory submissions submitted 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 number of respondents to be 12 and the number of disclosures annually to be 24. Thus, FDA adopts TTB's estimate of 12 respondents, and an annual number of disclosures per respondent of 2, in Table 1 of this document.

FDA's estimate of the average burden per disclosure for each regulation is based on FDA's experience with food labeling under the Agency's 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 No. 0910-0381. FDA further estimates 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 one hour based upon the similarity of the requirements to that of § 101.4. Finally, FDA estimates that a respondent will spend one hour reading the guidance document.

Thus, FDA estimates that 12 respondents will each label two products annually, for a total of 24 labels. FDA estimates 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 FDA's labeling regulations and the requirements of section 403(w)(1) of the FD&C Act, for a total of 174 hours (24 labels x 7.25 hours = 174 hours). In addition, 12 respondents will each spend one hour reading the guidance document, for a total of 12 hours. Thus, FDA calculates the total hour burden of this 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 FDA 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 No. 0910-0381.

12 a. Annualized Cost Burden Estimate

It is estimated that the burden of this information collection results in a total of 186 hours annually, and that a line worker will be responsible for all information collections. At a wage of $46.27 per hour, including overhead (Bureau of Labor Statistics), the maximum cost of meeting this information collection is $46.27 x 186 = $8,606.22 per year.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

In the ICR for 0910-0381, FDA estimated a cost to the Federal Government of approximately $2,646,000 per year and that an additional one person per year at an estimated cost of $180,000 would be required to respond to violations involving conventional foods. FDA adopts this estimate for this collection and estimates that an additional one person per year at an estimated cost of $180,000 would be required to respond to violations involving beer labeling.

15. Explanation for Program Changes or Adjustments

The burden estimate remains unchanged.

16. Plans for Tabulation and Publication and Project Time Schedule

These information collection requirements will not be published, tabulated, or manipulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Approval to not display the expiration date of OMB approval is not being sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.