DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Intellectual and Developmental Disabilities; Agency Information Collection Activities; Proposed Collection; Comment Request; Financial Status Reporting Form for State Councils on Developmental Disabilities

AGENCY: Administration for Community Living, Administration on Intellectual and Developmental Disabilities, HHS.

ACTION: Notice.

SUMMARY: For the program of the State Councils on Developmental Disabilities, funds are awarded to State agencies contingent on fiscal requirements in subtitle B of the Developmental Disabilities Assistance and Bill of rights Act. The SF–425, ordinarily mandated in the revised OMB Circular A–102, provides no accounting breakouts necessary for proper stewardship. Consequently, the proposed streamlined form will substitute for the SF–425 and will allow compliance monitoring and proactive compliance maintenance and technical assistance.

DATES: Submit written or electronic comments on the collection of information by August 23, 2012.

ADDRESSES: Submit electronic comments on the collection of information to: *Carla.Thomas@acf.hhs.gov.* Submit written comments on the collection of information to Carla Thomas, Administration on Intellectual and Developmental Disabilities, Administration on Community Living, Washington, DC 20447 or by fax at (202) 205–8037.

FOR FURTHER INFORMATION CONTACT: Jennifer Johnson at (202) 690–5982 or *Carla.Thomas@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 42 U.S.C. 1500 *et seq.* (the DD Act), ACL/AIDD has submitted the following proposed collection of information to OMB for review and clearance.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Financial Status Reporting Form for State Councils on Developmental Disabilities Program	55	3	5.10	841.5

Estimated Total Annual Burden Hours: 841.5.

Dated: July 19, 2012.

Kathy Greenlee,

Administrator & Assistant Secretary for Aging.

[FR Doc. 2012–18019 Filed 7–23–12; 8:45 am]

BILLING CODE 4154–01–P

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.

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 (the PRA).

DATES: Fax written comments on the collection of information by August 23, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–New and title ''Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@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–New)

I. Background

In the **Federal Register** of August 17, 2009 (74 FR 41438) (the August 17, 2009, notice), FDA published a notice of availability of the draft guidance document entitled ''Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration'' (the draft guidance). Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/FoodGuidances.* This guidance, when finalized, will provide industry with information on how to label beers that are subject to FDA's labeling laws and regulations. This draft guidance was issued in light of the ruling by the Alcohol and Tobacco Tax and Trade Bureau (TTB) (formerly The Bureau of Alcohol, Tobacco, and Firearms (ATF)) clarifying that certain beers do not meet the definition of a ''malt beverage'' under the Federal Alcohol Administration Act (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 (the FD&C Act) and the Fair Packaging and Labeling Act (FPLA). FDA, in the draft 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.

As reflected in the 1987 Memorandum of Understanding between FDA and TTB's predecessor Agency, the ATF (Ref. 1), TTB is responsible for the issuance and enforcement of regulations with respect

to the labeling of distilled spirits, wines, and malt beverages under the FAA Act.

The 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. (See TTB Ruling 2008–3.) (Ref. 2). 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 issued under the FAA Act. Therefore, these beers are subject to the labeling requirements under FDA's regulations. 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.

The guidance is intended to assist manufacturers in labeling beers that are subject to FDA's labeling laws and regulations. In general, FDA requires that food products under its labeling jurisdiction be truthfully and informatively labeled in accordance with the FD&C Act and the FPLA, and FDA's implementing regulations. These FDA labeling requirements are explained in the guidance document.

In the August 17, 2009, notice, FDA published a request for public comment on the proposed collection of information. FDA received one letter in response to the notice, containing multiple comments. Several comments in this letter were generally supportive of FDA's information collection provisions in the guidance. Additional comments were outside the scope of the four collection of information topics on which the notice solicits comments and will not be discussed in this document.

(Comment 1) One comment stated that FDA should require alcohol content labeling for the beers discussed in the guidance, including the percent alcohol by volume (%ABV); the amount of alcohol (in fluid ounces (oz) or grams) per serving; the definition of a ''standard drink'' (i.e., 12 fluid oz of regular beer, 5 fluid oz of wine, or 1.5 fluid oz of 80-proof distilled spirits); the number of standard drinks per container; and, the advice on moderate drinking, such as ''The Dietary Guidelines for Americans recommends no more than one drink per day for women, two drinks per day for men.'' The comment stated that when a consumer sees a beverage such as ''sorghum beer'' or ''wheat beer'' labeled the same way that all other FDA regulated beverages are labeled, the consumer may not know that it is an alcoholic beverage.

(Response) FDA appreciates the concerns discussed in the comment. As explained in the guidance, certain TTB labeling requirements apply to these products. For example, these non-malt beers, like all alcohol beverages, are required to bear the health warning statement under the Alcoholic Beverage Labeling Act (27 U.S.C. 213–215). FDA's guidance documents do not establish legally enforceable requirements, and therefore cannot include mandatory language such as ''shall, must, required, or requirement'' unless specific regulatory or statutory requirements are cited. To the extent that the comment requests FDA to engage in rulemaking, the comment is outside the scope of the comment request on the four collection of information topics as they relate to the provisions of the draft guidance document.

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 PRA under OMB control number 0910–0381. The regulations approved under OMB control number 0910–0381 include §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 (21 CFR 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105). The proposed information collection seeks to add 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. The proposed information collection also seeks 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).

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). 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.

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

TABLE 1—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN [1]

Citation	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average 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

TABLE 1—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN [1]—Continued

Citation	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
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
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 are 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 number 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 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, FDA estimates that 12 respondents will each label 2 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 × 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, FDA estimates the total hour burden of the proposed collection of information to be 186 hours (174 hours + 12 hours = 186 hours).

The draft 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 number 0910–0381.

II. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Memorandum of Understanding 225–88–2000 between FDA and Bureau of Alcohol, Tobacco and Firearms, available at *http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116370.htm.*

2. TTB Ruling 2008–3 dated July 7, 2008, available at *http://www.ttb.gov/rulings/2008-3.pdf.*

Dated: July 16, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18028 Filed 7–23–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–1975–N–0336 (Formerly 75N–0184), FDA–1975–N–0355 (Formerly 75N–0185), FDA–1976–N–0272 (Formerly 76N–0056), FDA–1976–N–0344 (Formerly 76N–0057), FDA–1978–N–0701 (Formerly 78N–0070), FDA–1979–N–0224 (Formerly 79N–0169), FDA–1983–N–0297 (Formerly 83N–0030), and FDA–1988–N–0004 (Formerly 88N–0242); DESI 597, 1626, 3265, 10837, 12283, and 50213, and Hydrocortisone Acetate and Pramoxine Hydrochloride]

Drugs for Human Use; Drug Efficacy Study Implementation; Certain Prescription Drugs Offered for Various Indications; Opportunity To Affirm Outstanding Hearing Request

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is offering an opportunity to affirm outstanding hearing requests pertaining to several dockets. FDA will assume that companies with outstanding hearing requests that do not respond to this notice are no longer interested in pursuing their requests, and will deem the requests withdrawn.

DATES: *Effective Date:* This notice is effective August 23, 2012.

Hearing Requests: Hearing requests must be affirmed by notifying FDA by August 23, 2012. Hearing requests not affirmed within that timeframe will be deemed withdrawn.

ADDRESSES: Requests to affirm or withdraw outstanding hearing requests, as well as all other communications in response to this notice, should be identified with the appropriate docket number, and directed to Pamela Lee, Office of Unapproved Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5173, Silver Spring, MD 20993–0002.