the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report Form; *Use:* Providers of services participating in the Medicare program are required under sections 1815(a), 1833(e) and 1861(v)(1)(A) of the Social Security Act (42 U.S.C. 1395g) to submit annual information to achieve settlement of costs for health care services rendered to Medicare beneficiaries. In addition, regulations at 42 CFR 413.20 and 413.24 require adequate cost data and cost reports from providers on an annual basis. The Form CMS–2540–10 cost report is needed to determine a provider's reasonable cost incurred in furnishing medical services to Medicare beneficiaries and reimbursement due to or from a provider. The revisions made to the SNF cost report are in accordance with the statutory requirement for hospice payment reform in § 3132 of the Patient Protection and Affordable Care Act (ACA). *Form Number:* CMS–2540–10 (OMB control number 0938–0463); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 14,398; *Total Annual Responses:* 14,398; *Total Annual Hours:* 2,908,396. (For policy questions regarding this collection contact Amelia Citerone at 410–786–8008).

Dated: August 7, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–19837 Filed 8–11–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0268]

Agency Information Collection Activities; Proposed Collection; 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 or we) is announcing an opportunity for public comment on our proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments on the information collection provisions of the recommended labeling of certain beers subject to our labeling jurisdiction.

DATES: Submit either electronic or written comments on the collection of information by October 13, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 section 201(f) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) See 21 U.S.C. 321(f), includes ''articles used for food or drink'' and thus includes alcoholic beverages. 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 between FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB), TTB is responsible for the promulgation and enforcement of regulations with respect to the labeling of distilled spirits, certain wines, and malt beverages pursuant to the Federal Alcohol Administration Act (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 promulgated 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.

Therefore, 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. Furthermore, 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), we announced the availability of a guidance entitled, ''Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration''. Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/FoodGuidances.* This guidance is intended to assist manufacturers on how to label bottled or otherwise packaged beers that are subject to our labeling laws and regulations.

Our 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.

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 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.

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:

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 (30 minutes)	12
21 CFR 101.4	12	2	24	1	24
21 CFR 101.5	12	2	24	0.25 (15 minutes)	6
21 CFR 101.9	12	2	24	4	96
21 CFR 101.105	12	2	24	0.5 (30 minutes)	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.

Our 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, we adopt TTB's estimate of 12 respondents, and an annual number of disclosures per respondent of 2, in table 1 of this document.

Our estimates of the average burden per disclosure for each regulation are based on our 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. 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, which was added by the Food Allergen Labeling and Consumer Protection Act of 2004, has been approved under OMB control number 0910–0792.

Dated: August 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–19741 Filed 8–11–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1399]

Guidance for Entities Considering Whether To Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance entitled ''Guidance for Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' This guidance is intended to inform entities that are considering registering as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as added by the Drug Quality and Security Act (DQSA), of the regulatory implications of registration as an outsourcing facility.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Guidance for Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' On November 27, 2013, President Obama signed the DQSA (Pub. L. 113–54) into law. The DQSA added a new section 503B to the FD&C Act that created a category of entities called ''outsourcing facilities.'' Section 503B(d)(4) of the FD&C Act (21 U.S.C. 353b(d)(4)) defines an outsourcing facility, in part, as a facility that complies with all of the requirements of section 503B, including registering with FDA as an outsourcing facility and paying associated fees. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

FDA has received questions about whether entities engaged in various types of activities (*e.g.,* a facility that is compounding only non-sterile drugs or only repackaging biological products) should register as an outsourcing facility. Because entities that register as outsourcing facilities must pay a registration fee and FDA has determined that fees paid pursuant to sections 503B and 744K of the FD&C Act will not be refunded, FDA is issuing this guidance to answer some of these questions and to provide potential registrants additional information about the regulatory impact of registering as an outsourcing facility.

In the **Federal Register** of February 19, 2015 (80 FR 8871), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on May 20, 2015. FDA received eleven comments on the draft guidance. Some of the comments raised issues that were not directly pertinent to the topics addressed in this guidance. FDA intends to consider those comments as they relate to issues being addressed in other policy documents being developed by the Agency.

In response to received comments or on its own initiative, FDA made the following changes as it finalized this guidance: (1) Removed the reference to a separate guidance document that explains how outsourcing facilities should report the products they compound to FDA because that guidance is not directly related to the issue of entities considering whether to register as outsourcing facilities; (2) noted that FDA has issued separate guidance documents addressing some of the conditions of section 503B and that it intends to publish additional guidance addressing other conditions; (3) added a reference to FDA's draft guidance regarding compounding animal drug products from bulk drug substances, which addresses outsourcing facilities engaging in this activity; and (4) made grammatical and other minor editorial changes for clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on registering as an outsourcing facility under section 503B of the FD&C Act. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division