required information and are retained for the required time period.

Section 101 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) amended section 414(a) of the FD&C Act and expanded our access to records. Specifically, FSMA expanded our access to records beyond records relating to the specific suspect article of food to records relating to any other article of food that we reasonably believe is likely to be affected in a similar manner. In addition, we can access records if we believe that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that we reasonably believe is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. To gain access to these records, our officer or employee must present appropriate credentials and a written notice, at reasonable times and within reasonable limits and in a reasonable manner.

On February 23, 2012, we issued an interim final rule in the **Federal Register** (77 FR 10658) (the 2012 IFR) amending § 1.361 to be consistent with the current statutory language in section 414(a) of the FD&C Act, as amended by section 101 of FSMA. In the 2012 IFR, we concluded that the information collection provisions of § 1.361 were exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities (77 FR 10658 at 10661). The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records under § 1.361. Accordingly, we have not included an estimate of burden hours associated with § 1.361 in table 1.

Description of Respondents: Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce.

In the **Federal Register** of April 17, 2014 (79 FR 21767) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1.337, 1.345, and 1.352 (Records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (Learning for new firms)	18,975	1	18,975	4.790	90,890
Total					5,110,890

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

This estimate is based on our estimate of the number of facilities affected by the final rule entitled ''Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,'' published in the **Federal Register** of December 9, 2004 (69 FR 71562 at 71650). With regard to records maintenance, we estimate that approximately 379,493 facilities will spend 13.228 hours collecting, recording, and checking for accuracy of the limited amount of additional information required by the regulations, for a total of 5,020,000 hours annually. In addition, we estimate that new firms entering the affected businesses will incur a burden from learning the regulatory requirements and understanding the records required for compliance. In this regard, the Agency estimates the number of new firms entering the affected businesses to be 5 percent of 379,493, or 18,975 firms. Thus, we estimate that approximately 18,975 facilities will spend 4.790 hours learning about the recordkeeping and records access requirements, for a total of 90,890 hours annually. We estimate that approximately the same number of firms (18,975) will exit the affected businesses in any given year, resulting in no growth in the number of total firms reported on line 1 of table 1. Therefore, the total annual recordkeeping burden is estimated to be 5,110,890 hours.

Dated: June 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14977 Filed 6–25–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0404]

Small Entity Compliance Guide: Gluten-Free Labeling of Foods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled ''Gluten-Free Labeling of Foods—Small Entity Compliance Guide.'' The small entity compliance guide (SECG) is being issued for a final rule published in the **Federal Register** of August 5, 2013, and is intended to set forth in plain language the requirements of the regulation and to help small businesses understand the regulation.

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

ADDRESSES: Submit written requests for single copies of the SECG to the Food Labeling and Standards Staff, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

Submit electronic comments on the SECG 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: Felicia B. Billingslea, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 5, 2013 (78 FR 47154), we issued a final rule that established a regulatory definition of the term ''gluten-free'' for voluntary use in the labeling of foods. The final rule, which is codified at 21 CFR 101.91, became effective on September 4, 2013, but has a compliance date of August 5, 2014.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612) and determined that the final rule could have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121), we are making available this SECG to explain the actions that a small entity must take to comply with the rule.

We are issuing this SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). This SECG represents our current thinking on establishing a regulatory definition of the term ''gluten-free'' for voluntary use in the labeling of foods. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding the guidance 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 of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: June 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14929 Filed 6–25–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 31, 2014, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm*; under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

For those unable to attend in person, the meeting will also be Webcast. The Webcast will be available at the following link: *https://collaboration.fda.gov/bpac714/.*

Contact Person: Bryan Emery, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6132, Silver Spring, MD 20993–0002, 240–402–8054; or Pearline Muckelvene, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6129, Silver Spring, MD 20993–0002, 240–402–8129; or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On the morning of July 31, 2014, the committee will meet in open session to discuss Baxter Healthcare Corporation's biologics license application for HyQvia, Immune Globulin Infusion 10 percent (human) combined with Recombinant Human Hyaluronidase for the treatment of patients with primary immune deficiency disorders. In the afternoon, the Committee will meet in open session to discuss reentry of blood donors deferred on the basis of Chagas disease test results.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 24, 2014. Oral presentations from the public will be scheduled for July 31, 2014, between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 16, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled