TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS[1]—Continued

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	Total hours
312.57, Sponsor recordkeeping showing the receipt, shipment, or other disposition of the investigational drug, and any financial interests.	335	2.70	904	100	90,400
312.62(a), Investigator recordkeeping of the disposition of drugs.	453	1	453	40	18,120
312.62(b), Investigator recordkeeping of case histories of individuals.	453	1	453	40	18,120
312.160(a)(3), Records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests.	111	1.40	155	0.50 (30 minutes).	78
312.160(c), Shipper records of alternative disposition of unused drugs.	111	1.40	155	0.50 (30 minutes).	78
Total					127,006

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

Dated: October 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26304 Filed 11–4–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1119]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA or we) is correcting a notice that appeared in the **Federal Register** of August 14, 2014. The notice announced that a proposed collection of information had been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. In this document, we correct some errors that appeared in the notice.

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: In FR Doc. 2014–19241, appearing on page 47642 in the **Federal Register** of August 14, 2014 (79 FR 47642), we make the following corrections:

1. On page 47643, in the second column, in the Response to Comment 3, delete the sentence starting with ''The scope of the voluntary submission . . . and the product label.''

2. On page 47643, in the second column, in the Response to Comment 3, in the sentence starting with ''Consequently, we have proposed . . .,'' delete ''institute the voluntary consultation process discussed in this document'' and replace it with ''provide for the voluntary registration and Form FDA 2541e submission process''.

3. On page 47643, in the second and third columns, in the Response to Comment 3, delete the sentences starting with ''The ability to submit a voluntary submission . . . of part 114'' and the remaining sentences in the response and replace them with ''FDA has authority to implement the voluntary submission process under sections 402 and 404 of the FD&C Act.''

4. On page 47643, in the third column, in the Response to Comment 4, replace the response with the following: ''A voluntary process filing submission will not result in part 114 applying to products that are not acidified foods as defined in 21 CFR 114.3(b). Further, the voluntary process filing submission process will not result in any changes to part 114.''

5. On pages 47643 to 47644, in the third column on page 47643 and in the first column on page 47644, in the Response to Comment 5, replace the response with the following: ''Our inspectors will not expect all manufacturers to submit voluntary submissions.''

6. On page 47644, in the first column, in the Response to Comment 7, replace the response with the following: ''As discussed in the response to Comment 4, if a product is not an acidified food, the product is not subject to the good manufacturing practice requirements in part 114 and will not become subject to those regulations as a result of a voluntary submission.''

7. On page 47644, in the first and second columns, in the Response to Comment 8, replace the response with the following: ''The draft guidance did address the issue of what constitutes a fermented food. We expect that the acidified foods guidance, when finalized, will provide guidance on what constitutes a fermented food.''

8. On page 47644, in the second column, in the Response to Comment 9, replace the response with the following: ''Manufacturers are free to decide whether to make a voluntary submission, and we believe that some manufacturers may choose to do so. For FDA, the voluntary submission results in increased efficiency.''

9. On page 47644, in the second and third columns, in the Response to Comment 10, delete the first paragraph of the response and delete the second sentence in the second paragraph of the response.

10. On page 47645, in the first column, in the Response to Comment 13, in the second sentence in the second paragraph of the response, delete ''to prevent the detention of product''.

11. On page 47645, in the third column, in the Response to Comment 20, in the first sentence of the response, replace ''and provides'' with ''and, when finalized, will provide''.

12. On page 47646, in the first column, in the Response to Comment 21, in the first sentence of the response, delete ''from the coverage of part 114'' and, at the end of the first sentence of the response, insert ''or that do not otherwise meet the definitions of acidified food.''

13. On page 47646, in the first column, in the Response to Comment 22, replace the response with the following: ''FDA does not agree that the 'Food Product Group' categories in any way indicates FDA's thinking as to whether all fruit and vegetable juices are acidified foods and are therefore subject to the acidified foods regulations in parts 108 and 114. Rather, the 'Food Product Group' categories are designed to help FDA understand the nature of products. For more information on what constitutes an acidified food, we recommend manufacturers consult the definition of acidified foods in § 114.3(b).''

14. On page 47646, in the second column, in the Response to Comment 24, replace the second paragraph of the response with the following: ''When optional information about the 'Food Product Group' category is provided, we will use it to help us understand the nature of the products and to help us prioritize which facilities to inspect.''

Dated: October 30, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26238 Filed 11–4–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Oncologic Drugs 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: Pediatric Oncology Subcommittee of the Oncologic Drugs 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 December 11, 2014, from 8 a.m. to 3:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 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.

Contact Person: Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *ODAC@fda.hhs.gov,* 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: Information will be presented to gauge investigator interest in exploring potential pediatric development plans for three products in various stages of development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of these products for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The products under consideration are: (1) GANETESPIB, application submitted by Synta Pharmaceuticals Corp. (2) Etirinotecan, application submitted by Nektar Therapeutics, and (3) RO5503781, application submitted by Hoffmann-La Roche, Inc.

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 December 3, 2014. Oral presentations from the public will be scheduled between approximately 8:55 a.m. to 9:15 a.m., 11:10 a.m. to 11:30 a.m., and 2:10 p.m. to 2:30 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 November 25, 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 open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 26, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caleb Briggs at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).