

phrases that appear in a number of health claims that are authorized by regulation, as well as in some QHCs for which the Agency has issued a letter of enforcement discretion. Results of the study will not be used to develop population estimates.

In the **Federal Register** of January 27, 2012 (77 FR 4329), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received one comment that dealt with topics outside the scope of the proposed collection of

information described in the 60-day notice. Therefore, the comment is not addressed here.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener	350	1	350	0.083 (5 minutes)	29
Cognitive interview	9	1	9	1 hour	9
Pretest invitation	1,700	1	1,700	0.033 (2 minutes)	56
Pretest	60	1	60	0.167 (10 minutes)	10
Survey invitation	45,000	1	45,000	0.033 (2 minutes)	1,485
Survey	1,200	1	1,200	0.167 (10 minutes)	200
Total					1,789

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

This burden estimate is 94 hours lower than the estimate published in the 60-day notice and includes 23 more hours for the cognitive interview screener, 48 more hours for the pretest invitation, and 165 fewer hours for the survey invitation. These estimates were adjusted to better reflect the anticipated effort required to recruit, conduct cognitive interviews, pretest, and survey participants with the desired characteristics. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

III. 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, and are available electronically at <http://www.regulations.gov>. (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. U.S. Food and Drug Administration, "Guidance for Industry: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Foods and Human Dietary Supplements," 2003, available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053832.htm>.

2. U.S. Food and Drug Administration, "Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims," 2009, available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm072780.htm>.

RegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm.

3. U.S. Food and Drug Administration, "Selenium and Certain Cancers (Qualified Health Claim: Final Decision Letter) (Docket No. 02P-0457)," 2003, available at <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072780.htm>.

4. U.S. Food and Drug Administration, "Selenium and a Reduced Risk of Site-Specific Cancers (FDA-2008-Q-04323)," 2009, available at <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm168527.htm>.

5. U.S. Food and Drug Administration, "Settlement Reached for Qualified Health Claims Relating Selenium to Reduced Risk of Prostate, Colon, Rectal, Bladder, and Thyroid Cancers," 2011, available at <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm256940.htm>.

6. Derby, B.M. and A.S. Levy, "Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims," 2005, available at <http://www.fda.gov/OHRMS/dockets/dockets/03N0496/03N-0496-rpt0001.pdf>.

7. Choinière, C. and L. Verrill, "Experimental Study of Qualified Health Claims: Consumer Inferences About Monounsaturated Fatty Acids From Olive Oil, EPA and DHA Omega-3 Fatty Acids, and Green Tea," 2009, available at <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm207549.htm>.

8. Hooker, N.H. and R. Teratanavat, "Dissecting Qualified Health Claims: Evidence From Experimental Studies," *Critical Reviews in Food Science and Nutrition*, vol. 48, pp. 160-176, 2008.

9. Kapsak, W.R., D. Schmidt, N.M. Childs, et al., "Consumer Perceptions of Graded, Graphic and Text Label Presentations for Qualified Health Claims," *Critical Reviews in Food Science and Nutrition*, vol. 48, pp. 248-256, 2008.

10. National Cancer Institute, "Health Information National Trends Survey," 2007, available at <http://hints.cancer.gov/>.

11. Bailey, R.L., J.J. Gahche, C.V. Lentino, et al., "Dietary Supplement Use in the United States, 2003-2006," *Journal of Nutrition*, vol. 141, pp. 261-266, 2011.

12. Radimer, K., B. Bindewald, J. Hughes, et al., "Dietary Supplement Use by US Adults: Data From the National Health and Nutrition Examination Survey, 1999-2000," *American Journal of Epidemiology*, vol. 160, pp. 339-349, 2004.

Dated: September 7, 2012.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2012-22795 Filed 9-14-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0881]

Draft Guidance for Industry on Self-Identification of Generic Drug Facilities, Sites, and Organizations; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Monday, August 27, 2012 (77 FR 51811). The document announced a draft guidance for industry entitled "Self-Identification of Generic Drug Facilities, Sites, and Organizations." The document was published with an incorrect docket

number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT:

Joyce Strong, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 32, Rm. 3208, Silver Spring, MD 20993-0002, 301-796-9148.

SUPPLEMENTARY INFORMATION: In FR Doc. 2012-20946, appearing on page 51811 in the **Federal Register** of Monday, August 27, 2012, the following correction is made:

1. On page 51811, in the third column, the docket number is corrected to read "FDA-2012-D-0881".

Dated: August 30, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-22784 Filed 9-14-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Pediatric Oncology Subcommittee of the 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 4, 2012, from 8 a.m. to 5:30 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: Minh Doan, 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), to find out further information regarding FDA advisory committee information. 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: The subcommittee will receive a presentation on pediatric provisions mandated by the Food and Drug Administration Safety and Innovation Act. This will be an awareness presentation and there will not be a formal Committee discussion or recommendation. In addition, information will be presented regarding pediatric development plans for four products that are in development for an adult oncology indication. The subcommittee will consider and discuss issues relating to the development of each product for pediatric use and provide guidance to facilitate the formulation of written requests for pediatric studies, if appropriate. The four products under consideration are: (1) Trametinib, application submitted by GlaxoSmithKline, LLC; (2) TH-302, application submitted by Threshold Pharmaceuticals, Inc.; (3) volasertib (BI 6727), application submitted by Boehringer Ingelheim Pharmaceuticals, Inc.; and (4) blinatumomab (MT 103), application submitted by Amgen 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 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 November 19, 2012. Oral presentations from the public will be scheduled between approximately 9:15 a.m. to 9:30 a.m., 11:15 a.m. to 11:30 a.m., 2:05 p.m. to 2:20 p.m., and 4:10 p.m. to 4:25 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 8, 2012. 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 9, 2012.

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 Minh Doan 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/ucm11462.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).

Dated: September 11, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012-22794 Filed 9-14-12; 8:45 am]

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