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Dated: February 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-03542 Filed 2-19-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-3655]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water

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.

DATES: Fax written comments on the collection of information by March 23, 2016.

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 0910-0658. Also include the FDA 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, PRASStaff@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.

Recordkeeping Requirements for Microbiological Testing and Corrective Measures for Bottled Water—21 CFR 129.35(a)(3)(i), 129.80(g), and 129.80(h)—OMB Control Number 0910-0658—Extension

The bottled water regulations in parts 129 and 165 (21 CFR parts 129 and 165) require that if any coliform organisms are detected in weekly total coliform testing of finished bottled water, followup testing must be conducted to determine whether any of the coliform organisms are *Escherichia coli*. The adulteration provision of the bottled water standard (§ 165.110(d)) provides that a finished product that tests positive for *E. coli* will be deemed

adulterated under section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)). In addition, the current good manufacturing practice (CGMP) regulations for bottled water in part 129 require that source water from other than a public water system (PWS) be tested at least weekly for total coliform. If any coliform organisms are detected in the source water, the bottled water manufacturers are required to determine whether any of the coliform organisms are *E. coli*. Source water found to contain *E. coli* is not considered water of a safe, sanitary quality and would be unsuitable for bottled water production. Before a bottler may use source water from a source that has tested positive for *E. coli*, a bottler must take appropriate measures to rectify or otherwise eliminate the cause of the contamination. A source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected over a 24-hour period from the same sampling site are tested and found to be *E. coli* negative.

Description of Respondents: The respondents to this information collection are domestic and foreign bottled water manufacturers that sell bottled water in the United States.

In the **Federal Register** of October 19, 2015 (80 FR 63228) 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 BURDEN¹

| 21 CFR Section; Activity | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|--|-------------------------|------------------------------------|----------------------|----------------------------------|-------------|
| § 129.35(a)(3)(i), § 129.80(h); Bottlers subject to source water and finished product testing. | 319 | 6 | 1,914 | 0.08 (5 minutes) | 153 |
| § 129.80(g), § 129.80(h); Bottlers testing finished product only | 95 | 3 | 285 | 0.08 (5 minutes) | 23 |
| § 129.35(a)(3)(i), § 129.80(h); Bottlers conducting secondary testing of source water. | 3 | 5 | 15 | 0.08 (5 minutes) | 1 |
| § 129.35(a)(3)(i), § 129.80(h); Bottlers rectifying contamination | 3 | 3 | 9 | 0.25 (15 minutes) | 2 |
| Total Annual Burden | | | | | 179 |

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

The current CGMP regulations already reflect the time and associated recordkeeping costs for those bottlers that are required to conduct microbiological testing of their source water, as well as total coliform testing of their finished bottled water products. We therefore conclude that any additional burden and costs in

recordkeeping based on followup testing that is required if any coliform organisms detected in the source water test positive for *E. coli* are negligible. We estimate that the labor burden of keeping records of each test is about 5 minutes per test. We also require followup testing of source water and finished bottled water products for *E.*

coli when total coliform positives occur. We expect that 319 bottlers that use sources other than PWSs may find a total coliform positive sample about three times per year in source testing and about three times in finished product testing, for a total of 153 hours of recordkeeping. In addition to the 319 bottlers, about 95 bottlers that use PWSs

may find a total coliform positive sample about three times per year in finished product testing, for a total of 23 hours of recordkeeping. Upon finding a total coliform sample, bottlers will then have to conduct a followup test for *E. coli*.

We expect that recordkeeping for the followup test for *E. coli* will also take about 5 minutes per test. As shown in table 1 of this document, we expect that three bottlers per year will have to carry out the additional *E. coli* testing, with a burden of 1 hour. These bottlers will also have to keep records about rectifying the source contamination, for a burden of 2 hours. For all expected total coliform testing, *E. coli* testing, and source rectification, we estimate a total burden of 179 hours. We base our estimate on our experience with the current CGMP regulations.

Dated: February 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-03549 Filed 2-19-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Nonprescription 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: Nonprescription 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 April 15, 2016, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

Contact Person: Moon Hee V. Choi, 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, NDAC@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: The committee will discuss data submitted by Galderma Laboratories, L.P. to support supplemental new drug application (sNDA) 20-380, for over-the-counter (OTC) marketing of adapalene gel 0.1%. The proposed OTC use is for the treatment of acne and to clear up acne pimples and acne blemishes. The applicant proposes to label the product for 12 years and older. The committee will be asked to consider whether data support an acceptable risk/benefit profile for the nonprescription use of adapalene gel 0.1% by OTC consumers.

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 April 1, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 March 24, 2016. 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 March 25, 2016.

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 disabilities. If you require accommodations due to a disability, please contact Moon Hee V. Choi 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).

Dated: February 17, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016-03573 Filed 2-19-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-E-2346]

Determination of Regulatory Review Period for Purposes of Patent Extension; BREO ELLIPTA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for BREO ELLIPTA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic