may find a total coliform positive
sample about three times per year in
finished product testing, for a total of 23
hours of record testing. 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.

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
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/Advisory
Committees/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: February 17, 2016.

Jill Hartzler Warner,
Associate Commissioner for Special Medical Programs.

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Food and Drug Administration

[Notice Docket No. FDA–2016–N–0001]

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
or written comments and ask for a redetermination by April 22, 2016. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 22, 2016. See “Petitions” in the SUPPLEMENTARY INFORMATION section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions
Submit electronic comments in the following way:
• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
• If you want to submit a comment with confidential information that you do not wish to be made publicly available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:
• Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2014–E–2346 for “Determination of Regulatory Review Period for Purposes of Patent Extension; BREO ELLIPTA.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.
• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:
Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–7600.

SUPPLEMENTARY INFORMATION:
I. Background
The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product BREO ELLIPTA (vilanterol trifenate; fluticasone furoate). BREO ELLIPTA is indicated for long-term, once-daily maintenance treatment of airflow obstruction and for reducing exacerbations in patients with chronic obstructive pulmonary disease. Subsequent to this approval, the USPTO received a patent term restoration application for BREO ELLIPTA (U.S. Patent No. 7,439,393) from Glaxo Group Limited, and the USPTO requested FDA’s assistance in determining this patent’s eligibility for patent term restoration. In a letter dated March 19, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of BREO ELLIPTA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

II. Determination of Regulatory Review Period
FDA has determined that the applicable regulatory review period for BREO ELLIPTA is 1,980 days. Of this time, 1,677 days occurred during the testing phase of the regulatory review period, while 303 days occurred during the approval phase. These periods of
time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective: December 10, 2007. The applicant claims June 26, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 10, 2007, which was 30 days after FDA receipt of the first IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act: July 12, 2012. FDA has verified the applicant’s claim that the new drug application (NDA) for BREO ELLIPTA (NDA 204275) was initially submitted on July 12, 2012.

3. The date the application was approved: May 10, 2013. FDA has verified the applicant’s claim that NDA 204275 was approved on May 10, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 981 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see DATES) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to http://www.regulations.gov at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Petitions that have not been made publicly available on http://www.regulations.gov may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 16, 2016.

Leslie Kux, Associate Commissioner for Policy.