TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN FOR TOBACCO PRODUCTS [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.40(a) and (c)	5,832	1	5,832	80	466,560

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

The Estimated Annual Reporting Burden for Human Foods is no longer a part of this information collection. The burden has now been incorporated into OMB control number 0910–0541.

Our estimated burden for the information collection reflects an overall increase of 453,834 hours (currently approved 231,224) and a corresponding increase of 7,108 annual responses (currently approved 15,527). The new estimated totals are 685,058 hours and 22,635 annual responses. We attribute this adjustment to an increase in the number of EA submissions we received since the last extension.

Dated: June 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12221 Filed 6–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1860]

Advisory Committee; Pulmonary-Allergy Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Pulmonary-Allergy Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Pulmonary-Allergy Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until May 30, 2020.

DATES: Authority for the Pulmonary-Allergy Drugs Advisory Committee will expire on May 30, 2020, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Cindy Chee, 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, email: *PADAC@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Pulmonary-Allergy Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pulmonary medicine, allergy, clinical immunology, and epidemiology or statistics. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmonary-AllergyDrugsAdvisoryCommittee/ucm107567.htm* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check *https://www.fda.gov/AdvisoryCommittees/default.htm*.

Dated: June 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12219 Filed 6–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0478]

Sebela Ireland, Ltd. et al.; Withdrawal of Approval of 24 Abbreviated New Drug Applications; 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** on February 23, 2018. The notice announced the voluntary withdrawal of approval of 24 abbreviated new drug applications (ANDAs) from multiple applicants, effective March 26, 2018. The notice indicated that FDA was withdrawing approval of the following ANDA after receiving a withdrawal request from Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc. (Sun Pharmaceutical), 2 Independence Way, Princeton, NJ 08540: ANDA 077483, Benazepril Hydrochloride and Hydrochlorothiazide Tablets, 5 milligrams (mg)/6.25 mg, 10 mg/12.5 mg, 20 mg/12.5 mg, and 20 mg/25 mg. Before withdrawal of this ANDA became effective, however, Sun

Pharmaceutical informed FDA that it did not want approval of the ANDA withdrawn. Because Sun Pharmaceutical timely requested that approval of this ANDA not be withdrawn, the approval of ANDA 077483 is still in effect.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, February 23, 2018 (83 FR 8089), appearing on page 8089 in FR Doc. 2018–03700, the following correction is made:

1. On page 8090, the entry for ANDA 077483 in the table is removed.

Dated: June 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12220 Filed 6–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1774]

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Draft Guidance for Industry and Food and Drug Administration Staff.'' This draft guidance document provides an overview of the mechanisms available to applicants through which they can request feedback from or a meeting with FDA regarding potential or planned medical device investigational device exemption (IDE) applications, premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, evaluation of automatic class III designations (de novo requests), premarket notification (510(k)) submissions, Clinical Laboratory Improvement Amendments (CLIA) Waiver by Application, Accessory Classification Requests, and certain investigational new drug (IND) applications and biologics license applications (BLAs). This draft guidance, when finalized, is intended to supersede the document entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' issued on September 29, 2017. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by August 6, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made 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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2018–D–1774 for ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program; Draft Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for