to FDA abbreviated new drug applications (ANDAs) and related submissions (i.e., prior approval supplements) for which the applicant is seeking approval of a new strength of the drug product. The draft guidance highlights deficiencies about impurity information that may cause FDA to refuse to receive an ANDA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 17, 2014.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 75, Rm. 1670, Silver Spring, MD 20993–0002, 240–402–7930.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''ANDA Submissions—Refuse to Receive Lack of Proper Justification of Impurity Limits.'' This draft guidance is intended to assist applicants preparing to submit to FDA ANDAs, and prior approval supplements to ANDAs, for which the applicant is seeking approval of a new strength of the drug product. The draft guidance highlights serious deficiencies in impurity information that may cause FDA to refuse to receive an ANDA. Specifically, these deficiencies include: (1) Failing to justify proposed limits for specified identified impurities in drug substances and drug products that are above qualification thresholds; (2) failing to justify proposed limits for specified unidentified impurities that are above identification thresholds; and (3) proposing limits for unspecified impurities (e.g., any unknown impurity) above identification thresholds.

Under the provisions of the Generic Drug User Fee Amendments of 2012, the Office of Generic Drugs (OGD) is tasked with a number of activities, including the development of ''enhanced refusal to receive standards for ANDAs and other related submissions by the end of year 1 of the program. . . .'' Recent data underscore the need for improvement in the quality of original ANDA submissions. Between 2009 and 2012, OGD refused to receive 497 ANDAs, primarily because the submissions contained serious deficiencies. FDA evaluates each incoming ANDA individually to determine whether its format and content meet threshold criteria to permit a substantive review and thus can be received by FDA. The Agency cannot receive an ANDA unless it contains the information required under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) and related regulations (e.g., 21 CFR 314.101(b)(1)). FDA issued the draft guidance for industry ''ANDA Submissions—Refuse-to-Receive Standards'' to explain in some detail the kind of omissions that can lead to a refuse-to-receive determination. This guidance is being issued concurrently with the final version of the guidance for industry, ''ANDA Submissions—Refuse to Receive Standards.'' FDA intends to develop additional guidance documents further clarifying the enhanced refusal to receive standards.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''ANDA Submissions—Refuse to Receive for Lack of Proper Justification for Impurity Limits.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314.94 have been approved under 0910–0001.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22110 Filed 9–16–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Cardiovascular and Renal 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: Cardiovascular and Renal 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 October 30, 2014, 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: Kristina Toliver, 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, *CRDAC@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 new drug application (NDA) 206316, edoxaban tablets, submitted by Daiichi Sankyo, Inc., for the prevention of stroke and systemic embolism (blood clots other than in the head) in patients with nonvalvular atrial fibrillation (A Fib; abnormally rapid and chaotic contractions of the atria, the upper chambers of the heart).

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 October 16, 2014. 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 October 7, 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 October 8, 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 Kristina Toliver 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: September 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22071 Filed 9–16–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Electronic Cigarettes and the Public Health; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Tobacco Products, is announcing a public workshop to obtain information on electronic cigarettes and the public health. The workshop will include presentations and panel discussions about the current state of the science, and will focus on product science, packaging, constituent labeling, and environmental impacts. FDA intends to follow this workshop with two additional electronic cigarette workshops, with one on individual health effects and one on population health effects.

Dates and Times: The public workshop will be held on December 10, 2014, from 8 a.m. to 5 p.m. and on December 11, 2014, from 8:30 a.m. to 3:30 p.m. Individuals who wish to attend the public workshop must register by November 25, 2014.

Location: The public workshop will be held at the FDA White Oak Conference Center, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking, transportation, security, and information regarding special accommodations due to a disability, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: *workshop.CTPOS@fda.hhs.gov.*

Registration to Attend the Workshop: If you wish to attend the workshop in person or by Webcast, you must register by submitting either an electronic or written request no later than November 25, 2014. Please submit electronic requests at *https://www.surveymonkey.com/s/CTP-December-Workshop.* Persons without Internet access may send written requests for registration to Caryn Cohen (see *Contact Person*). Requests for registration must include the prospective attendee's name, title, affiliation, address, email address if available, and telephone number. Registration is free and you may register to either attend in-person or view the live Webcast. Both seating and viewership are limited, so early registration is recommended. FDA may limit the number of registrants from a single organization, as well as the total number of participants, if registration reaches full capacity. For those registrants with Internet access, confirmation of registration will be emailed to you no later than November 26, 2014. Onsite registration may be allowed if space is available. If registration reaches maximum capacity,