

Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, email: [CTPRegulations@fda.hhs.gov](mailto:CTPRegulations@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (Tobacco Control Act) was signed into law, amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) and giving FDA authority to regulate tobacco product manufacturing, distribution, and marketing. The new provisions include, among other things, the authority to issue regulations related to tobacco product manufacturing practice in order to protect the public health and to assure that tobacco products are in compliance with the FD&C Act. Specifically, section 906(e) of the FD&C Act (21 U.S.C. 387f(e)) provides that in applying manufacturing restrictions to tobacco, the Secretary shall prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology.

On May 10, 2016, FDA published a final rule entitled "Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (81 FR 28974) (the deeming rule) that became effective on August 8, 2016. Under the deeming rule, newly deemed tobacco products, including ENDS, are now subject to the provisions of the Tobacco Control Act that apply automatically to all products that meet the statutory definition of a tobacco product in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)).

On January 10, 2012, industry stakeholders submitted recommendations for good manufacturing practice requirements (and a draft preamble) for tobacco products that were immediately subject to FDA's jurisdiction when the Tobacco Control Act went into effect. This January 10, 2012, letter was posted to

this Docket No. FDA-2013-N-0227 on March 12, 2013, as part of a request for comments on the recommendations contained in the letter. On June 7, 2017, a group of 13 tobacco companies submitted to FDA: (1) Recommendations for good manufacturing practice requirements for ENDS and (2) an attachment letter with a meeting request (Ref. 1). The tobacco companies' ENDS recommendations are intended to supplement an earlier letter dated January 10, 2012. According to the June 7, 2017, letter, the tobacco companies' ENDS recommendations seek to account for the differences in manufacturing ENDS.

FDA is providing an opportunity for all interested parties to comment only on the tobacco companies' ENDS recommendations submitted on June 7, 2017.

##### II. References

The following reference has been placed on display in the Dockets Management Staff (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday and is available electronically at <https://www.regulations.gov>.

1. Proposed Good Manufacturing Practices Regulation to Account for FDA's Deeming Regulation and Request for Meeting, submitted to FDA, June 7, 2017.

Dated: November 16, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2017-N-6330]

##### **Bone, Reproductive and Urologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA

is establishing a docket for public comment on this document.

**DATES:** The public meeting will be held on January 9, 2018, from 8 a.m. to 5 p.m.

**ADDRESSES:** College Park Marriott Hotel and Conference Center, Chesapeake Ballroom, 3501 University Blvd. East, Hyattsville, MD 20783. The conference center's telephone number is 301-985-7300. Answers to commonly asked questions about FDA Advisory Committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2017-N-6330. The docket will close on January 8, 2018. Submit either electronic or written comments on this public meeting by January 8, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 8, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of January 8, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before December 22, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

You may submit comments 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-2017-N-6330 for “Bone, Reproductive and Urologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://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 <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.

#### FOR FURTHER INFORMATION CONTACT:

Kalyani Bhatt, 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: [BRUDAC@fda.hhs.gov](mailto:BRUDAC@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 <https://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.

#### SUPPLEMENTARY INFORMATION:

*Agenda:* The committee will discuss new drug application (NDA) 206089, oral testosterone undecanoate capsules, submitted by Clarus Therapeutics, for the proposed indication of testosterone replacement in males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired).

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 <https://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. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before December 22, 2017, will be provided to the committee. 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 December 14, 2017. 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 December 15, 2017.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

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 Kalyani Bhatt 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 <https://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: November 17, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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