DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. FDA–2013–N–0227]

Tobacco Product Manufacturing Practice; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting public input on updated recommendations for regulations on good manufacturing practice for electronic nicotine delivery systems (ENDS) that were submitted to FDA by a group of 13 tobacco companies (tobacco companies’ ENDS recommendations). FDA is providing an opportunity for interested parties to comment on the tobacco companies’ ENDS recommendations.

DATES: Submit electronic or written comments on the tobacco companies’ ENDS recommendations by December 22, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 22, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of December 22, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2013–N–0227 for “Tobacco Product Manufacturing Practice; Establishment of a Public Docket.” 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 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.

FOR FURTHER INFORMATION CONTACT: Matthew Brenner, Center for Tobacco
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 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.


Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2017–25245 Filed 11–21–17; 8:45 am]

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, HHHS.

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.