the collections of information related to the elements of informed consent under 21 CFR 50.25, the documentation of informed consent under 21 CFR 50.27, IRB written notification to approve or disapprove research under 21 CFR 56.109(e), and IRB continuing review under 21 CFR 56.109(f) have been approved under OMB control number 0910–0755; the collection of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078.

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Persons with access to the Internet may obtain the draft guidance at either *http://www.regulations.gov* or *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm.*

Dated: July 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–16492 Filed 7–14–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0800]

Draft Guidance for Industry on Substantial Equivalence Reports; Manufacturer Requests for Extensions or To Change the Predicate Tobacco Product; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Substantial Equivalence Reports: Manufacturer Requests for Extensions or To Change the Predicate Tobacco Product.'' This draft guidance provides information to tobacco product manufacturers about FDA's policies on manufacturer requests for extensions of time to respond to deficiencies that FDA has identified, and manufacturer requests to change the predicate tobacco product, in substantial equivalence (SE) reports.

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 September 15, 2014.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit electronic comments on the draft 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, 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: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for tobacco product manufacturers entitled ''Substantial Equivalence Reports: Manufacturer Requests for Extensions or To Change the Predicate Tobacco Product.'' During the review of an SE report, the Center for Tobacco Products (CTP) may issue a scientific advice/information letter or preliminary finding letter to a manufacturer highlighting deficiencies of the SE report (deficiency letter). In response to those letters, some manufacturers have requested an extension of time to respond to the deficiencies or have indicated they may change the predicate tobacco product identified in the SE report. In this draft guidance, FDA provides information to tobacco product manufacturers about CTP's policies on manufacturer requests for extensions of time to respond to deficiencies CTP has identified, and manufacturer requests to change the predicate tobacco product.

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 ''Substantial Equivalence Reports: Manufacturer Requests for Extensions or To Change the Predicate Tobacco Product.'' 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. 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 have been approved under OMB control number 0910–0673.

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 guidance at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: July 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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