

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2006-D-0031]

**Draft Informed Consent Information Sheet: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; 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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “Informed Consent Information Sheet: Guidance for IRBs, Clinical Investigators, and Sponsors.” The draft guidance announced in this notice is intended to assist institutional review boards (IRBs), clinical investigators, and sponsors involved in clinical investigations of FDA-regulated products in carrying out their responsibilities related to informed consent. The draft guidance provides the Agency’s recommendations and requirements for informed consent to assure the protection of the rights and welfare of human subjects in clinical investigations.

**DATES:** Although comments on any guidance can be submitted at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers a comment on this draft guidance before it begins work on the final version of the guidance, electronic or written comments on the draft guidance should be submitted by September 15, 2014.

**ADDRESSES:** Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201,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 (1-888-463-6332 or 301-796-3400); or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002 (1-800-835-4709 or 240-402-7800); or the Division of Industry and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4622, Silver Spring, MD 20993 (1-800-638-2041 or 301-796-7100). Send one self-addressed adhesive label to assist the office in processing your requests.

Submit electronic comments on the draft guidance to 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.

**FOR FURTHER INFORMATION CONTACT:** Marsha Melvin, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave, Building 32, Silver Spring, MD 20993, [marsha.melvin@fda.hhs.gov](mailto:marsha.melvin@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

FDA is announcing the availability of a draft guidance entitled: “Informed Consent Information Sheet: Guidance for IRBs, Clinical Investigators, and Sponsors.” This draft guidance is intended to assist IRBs, clinical investigators, and sponsors involved in clinical investigations of FDA-regulated products in carrying out their responsibilities related to informed consent under 21 CFR part 50 by providing recommendations regarding the informed consent process, the elements of informed consent, and the documentation of informed consent to assure the protection of the rights and welfare of human subjects in clinical investigations. When finalized, this guidance will supersede the following Information Sheets: “A Guide to Informed Consent” and “Frequently Asked Questions” (only the sections entitled “Informed Consent Process” and “Informed Consent Document Content”) (September 1998, Office of Health Affairs, Food and Drug Administration). To enhance human subject protection and reduce regulatory burden, the Department of Health and Human Services (HHS), Office for Human Research Protections (OHRP) and FDA have been actively working to harmonize the Agencies’ regulatory requirements and guidance for human subject research. This draft guidance document was developed as a part of these efforts.

In addition, FDA acknowledges that HHS announced in 2011 that the Federal Government is contemplating various ways of enhancing the regulations overseeing research on human subjects. Before developing proposed changes to the regulations—which have been in place since 1991 and are often referred to as the Common Rule—the Government issued an Advance Notice of Proposed Rulemaking (ANPRM) seeking the public’s input on an array of issues related to the ethics, safety, and oversight of human research. The changes under consideration can be found in the July 26, 2011, issue of the

**Federal Register** in an ANPRM entitled “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators” (available at [www.hhs.gov/ohrp/human\\_subjects/anprm2011page.html](http://www.hhs.gov/ohrp/human_subjects/anprm2011page.html)). FDA issues this draft guidance while the Agencies continue to explore potential changes to the Common Rule. To the extent that issues presented in this draft guidance intersect with the Common Rule, FDA plans to coordinate with other relevant Federal Agencies to facilitate consistency across policies.

FDA is issuing this as a draft guidance because the Information Sheet entitled: “A Guide to Informed Consent” has been substantially revised due to changes in regulation/regulatory policy and in response to numerous questions about informed consent from subjects, subject advocates, and the research community. For example, the draft guidance includes a more detailed discussion of informed consent for non-English speaking subjects. In addition, new sections address the new element of informed consent for applicable clinical trials and discuss informed consent issues related to consent capacity, children as subjects, review of patient records, subjects with low literacy or numeracy, subjects participating in more than one clinical trial, and study suspension/termination. The draft guidance also explains the responsibilities of the IRB, investigator, sponsor, and FDA related to the development and review of informed consent documents.

The draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA’s current thinking on this topic. 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. The Paperwork Reduction Act of 1995**

This draft guidance includes information collections provisions that 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 referenced in this guidance that are related to IRB recordkeeping requirements under 21 CFR 56.115, which include the requirements for records related to informed consent, have been approved under OMB control number 0910–0130;

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.*

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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](mailto: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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