4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2015-N-5106]**

# Clinical Outcome Assessment Compendium

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

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

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the establishment of a docket to receive suggestions, recommendations, and comments from interested parties (including academic institutions, regulated industry, and patient groups) on our pilot "Clinical Outcome Assessment Compendium" (COA Compendium). FDA has developed a Web site that describes the purpose of the pilot COA Compendium and provides background information. Comments received on the pilot COA Compendium during its pilot phase will help FDA determine its utility, and may assist FDA in developing future iterations of the COA Compendium and identifying best methods for conveying COA Compendium information on FDA's Web site.

**DATES:** Submit either electronic or written comments by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://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 http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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-2015-N-5106 for "Clinical Outcome Assessment Compendium." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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:

http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Nikunj B. Patel, Clinical Outcome Assessments Staff (formerly Study Endpoints and Labeling Development (SEALD)), Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6369, Silver Spring, MD 20993-0002, 240-402-6502, email: COACompendium@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Capturing outcomes that are important to patients in clinical trials is a high priority for FDA. The pilot COA Compendium is part of FDA's efforts to foster patient-focused drug development.[1] The COA Compendium is intended to facilitate communication and to provide clarity and transparency to drug developers and the research community by collating and

[1] The term drug, as used in this notice, refers to human drugs including biological products.

summarizing clinical outcome assessment information for many different diseases and conditions into a single resource. It can be used as a starting point when considering how certain clinical outcome assessments might be utilized in clinical trials and will likely be most informative in early drug development. The public is referred to the following FDA Web site for additional background information, along with the pilot COA Compendium: http://www.fda.gov/COACompendium.

## II. Establishment of a Docket and Request for Comments

To help FDA determine the utility of the COA Compendium, develop future iterations of the COA Compendium, and identify best methods for conveying COA Compendium information on FDA's Web site, FDA is launching the pilot COA Compendium and soliciting public suggestions, recommendations, and comments for each aspect of the COA Compendium mentioned on the following FDA Web site: http://www.fda.gov/COACompendium. Specifically, FDA welcomes your comments concerning: (1) The utility of the COA Compendium; (2) the best approach for developing future iterations of it, including any suggested expansions of its scope; and (3) COA Compendium-related questions you would like FDA to address in its future communications. FDA will consider all comments submitted but will generally not respond directly to the person or organization submitting the comment.

Dated: January 7, 2016.

**Leslie Kux**,

*Associate Commissioner for Policy*.

[FR Doc. 2016-529 Filed: 1/12/2016 8:45 am; Publication Date:  1/13/2016]