DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0503]

Guidance for Clinical Investigators, Sponsors, and Institutional Review Boards on Investigational New Drug Applications—Determining Whether Human Research Studies Can Be Conducted Without an Investigational New Drug Application; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the final guidance for clinical investigators, sponsors, and institutional review boards (IRBs) entitled ''Investigational New Drug Applications (INDs)—Determining whether Human Research Studies can be Conducted without an IND,'' published in the **Federal Register** of September 10, 2013 (78 FR 55262). We are reopening the comment period only with respect to those subsections of the final guidance that address the applicability of the IND regulations to clinical research studies involving cosmetics and foods (including dietary supplements).

DATES: Submit either electronic or written comments by April 7, 2014.

ADDRESSES: Submit electronic comments on the final 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: Paul L. Ferrari, Center for Food Safety and Applied Nutrition (HFS–024), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1722.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 14, 2010 (75 FR 63189), we published a notice announcing the availability of a draft guidance entitled ''Guidance for Industry: Investigational New Drug Applications (INDs)—Determining whether Human Research Studies can be Conducted without an IND'' (''the draft guidance''). In the **Federal Register** of September 10, 2013 (78 FR 55262), we published a notice announcing the availability of the final version of the guidance, entitled ''Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs)—Determining whether Human Research Studies can be Conducted without an IND'' (''the final guidance''). We are reopening the comment period only with respect to those subsections of the final guidance that address the applicability of the IND regulations to clinical research studies involving cosmetics and foods (including dietary supplements), in response to requests from interested persons.

II. Request for Comments

Following publication of the September 10, 2013, **Federal Register** notice of availability of the final guidance, we received correspondence asking us to provide for further opportunity to comment on subsections C (''Cosmetics'') and D (''Foods'') of section VI (''Specific Issues Concerning the Application of the IND Regulations'') of the final guidance. The correspondence explained that more time was needed to review the guidance and consider its effect on researchers and health care providers, among others. In response to these requests, we have decided to reopen the comment period with respect to the foods and cosmetics subsections of the final guidance for 60 days. Accordingly, we invite comment on subsections VI.C and VI.D by April 7, 2014.

III. How To Submit Comments

Interested persons may submit either electronic comments regarding subsections VI.C and VI.D of the final guidance 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.*

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02550 Filed 2–5–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0092]

Study Data Technical Conformance Guide and Data Standards Catalog; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a Study Data Technical Conformance Guide and an update to the Data Standards Catalog (formerly the Study Data Standards Catalog). The Study Data Technical Conformance Guide supplements the revised draft guidance for industry ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' and provides specifications, recommendations, and general considerations on submitting standardized study data using FDA supported data standards specified in the Data Standards Catalog.

DATES: Although you can comment on these documents at any time, to ensure that the Agency considers your comments, please submit either electronic or written comments by May 7, 2014.

ADDRESSES: Submit written requests for a copy of the Study Data Technical Conformance Guide and the Data Standards Catalog to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments on the Study Data Technical Conformance Guide and the Data Standards Catalog 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: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1160, Silver Spring, MD 20993–0002, *CDERDataStandards@*