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In the **Federal Register** of October 14, 2010 (75 FR 63189), we published a notice announcing the availability of a draft guidance entitled ''Guidance for Industry: Investigational New Drug Applications (INDs)—Determining whether Human Research Studies can be Conducted without an IND'' (''the draft guidance'').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]

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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@*

fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a Study Data Technical Conformance Guide (the Guide) and an update to the Study Data Standards Catalog, which will be revised and renamed the Data Standards Catalog (the Catalog). The Guide supplements the guidance for industry, ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data,'' (eStudy Data guidance) (available at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*), and provides technical recommendations to sponsors for the electronic submission of standardized animal and human study data and related information contained in certain submissions to new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologic license applications (BLAs), and investigational new drug applications (INDs). The eStudy Data guidance, when finalized, will implement the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act with respect to standardized study data contained in NDA, ANDA, BLA, and IND submissions.

The Guide integrates and updates the Study Data Specifications and the CDER Common Data Standards Issues document and is available on FDA's Study Data Standards Resources Web page at *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.* The Guide is intended to complement and promote interactions between sponsors and FDA review divisions. It is not intended to replace the need for sponsors to communicate directly with review divisions regarding data standards implementation approaches or issues. The Guide, when finalized, will supersede the Study Data Specifications (Versions 1.0–2.0) and the CDER Study Data Common Issues Document (Versions 1.0–1.1). The Guide is organized as follows:

Section 1: Introduction—provides information on regulatory policy and guidance background, purpose, and document control.

Section 2: Planning and Providing Standardized Study Data—recommends and provides details on preparing an overall study data standardization plan and a study data reviewer's guide.

Section 3: Exchange Format—Electronic Submissions—presents the specifications, considerations, and recommendations for the file formats currently supported by FDA.

Section 4: Study Data Submission Format: Clinical and Non-Clinical—presents general considerations and specifications for sponsors using, for example, the following standards for the submission of study data: Clinical Data Interchange Standards Consortium, Study Data Tabulation Model, Analysis Data Model, and Standard for Exchange of Nonclinical Data.

Section 5: Therapeutic Area Standards—presents supplemental considerations and specific recommendations when sponsors submit study data using FDA supported TA standards.

Section 6: Terminology—presents general considerations and specific recommendations when using controlled terminologies/vocabularies for clinical trial data.

Section 7: General Electronic Submission Format—provides specifications and recommendations on submitting study data using the electronic Common Technical Document format.

Section 8: Data Fitness—provides general recommendations on standards compliance, data traceability expectations, legacy data conversion, versioning, and data validation rules.

II. 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.*

III. Electronic Access

Persons with access to the Internet may obtain the Guide and the Catalog at either *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm* or *http://www.regulations.gov.*

Dated: January 31, 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–N–0001]

Advancing the Development of Pediatric Therapeutics: Pediatric Bone Health; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Pediatric and Maternal Health Staff in the Center for Drug Evaluation and Research and the Office of Pediatric Therapeutics are announcing a 1-day public workshop entitled ''Advancing the Development of Pediatric Therapeutics (ADEPT): Pediatric Bone Health.'' The purpose of this initial workshop is to provide a forum to consider issues related to advancing pediatric regulatory science in the evaluation of bone health in pediatric patients.

Date and Time: The public workshop will be held on March 4, 2014, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held in the Pooks Hill Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814. The hotel's telephone number is 301–897–9400.

Contact: Denise Pica-Branco, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1732, Fax: 301–796–9858, email: *denise.picabranco@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA has engaged experts in pediatrics to address challenging issues related to the evaluation of effects on bone health for products used to treat pediatric patients. Identification of signals in animal studies and adult clinical trials that warrant further clinical investigation and identification of biomarkers that may be predictive of bone health in children will be discussed. Additionally, strategies and methods to address the challenges of assessing long-term bone health for products used to treat pediatric patients will be discussed.

I. Participation in the Public Workshop

There is no fee to attend the public workshop, but attendees should register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at *PediatricBoneHealth@fda.hhs.gov* before February 28, 2014.