draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated March 2015.

## II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ensuring safety of animal feed maintained and fed on-farm. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## III. Paperwork Reduction Act of 1995

FDA concludes that there are no collections of information under the Paperwork Reduction Act of 1995.

## IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: March 2, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–05222 Filed 3–8–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA 2016–N–0001]**

### Tenth Annual Drug Information Association/Food and Drug Administration Statistics Forum—2016; Public Conference

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

**ACTION:** Notice of public conference.

**SUMMARY:** The Food and Drug Administration (FDA), in co-sponsorship with the Drug Information Association (DIA), is announcing a public conference entitled ''Tenth Annual DIA/Food and Drug Administration Statistics Forum—2016.'' This public conference is intended to be an open forum for the timely discussion of topics of mutual theoretical and practical interest to statisticians and clinical trialists who develop and review new drugs and biologics. A primary focus for this public conference will be to establish an ongoing dialogue between industry and regulatory Agencies—emphasizing the regulatory and statistical challenges associated with innovative approaches to the design and analysis of clinical trials and measuring the progress being made in designing and implementing innovative solutions.

**DATES:** The main meeting will be held over 3 days: April 25, 2016, from 1 p.m. to 5:30 p.m.; April 26, 2016, from 8:30 a.m. to 5 p.m.; and April 27, 2016, from 8:30 a.m. to 3:30 p.m. On April 25, there will also be pre-meeting tutorials from 8:30 a.m. to 12 p.m. and a scientific working group session from 5:40 p.m. to 7 p.m.

**ADDRESSES:** The meeting will be held at the Marriott Bethesda North Hotel and Conference Center, 5701 Marinelli Rd., North Bethesda, MD 20852, 301–822–9200.

**FOR FURTHER INFORMATION CONTACT:** Meredith Kaganovskiy, DIA, 800 Enterprise Rd., Horsham, PA 19044, 215–442–6117, *Meredith.Kaganovskiy@DIAglobal.orgM*; or Stephen Wilson, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3630, Silver Spring, MD 20993–0002, 301–796–0579, *Stephen.Wilson@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA and DIA will sponsor an open public discussion between industry, academia, contract research organizations, regulatory scientists, and other parties on topics related to the innovative statistical methodologies and quantitative approaches used by sponsors to provide evidence for the approval of new therapies.

The forum will provide a unique opportunity for all of the relevant stakeholders to collaboratively describe the issues and discuss appropriate solutions. It is important that all of the stakeholders examine their roles in making the necessary changes and improvements in the framework used to develop evidence for the regulatory decisions and work to foster a mutual understanding of relevant scientific issues and challenges.

The conference will benefit FDA by enhancing communication with the broader statistical community.

The goals of the program are as follows:

- Explore and implement innovative statistical solutions to important issues associated with the quantitative evidence needed for the regulatory review of therapeutic drugs and biologics
- Describe the application of statistical methodologies and thinking regarding the development of new therapeutic biologics and drugs
- Assess the impact of regulations and guidance on statistical practice
- Discuss ideas for improving the communication between industry statisticians and regulatory reviewers

A description of the planned activities of the working groups can be found at *http://www.diaglobal.org/en/conference-listing/meetings/2016/04/dia-fda-statistics-2016-forum.*

## II. Registration and Accommodations

### *A. Registration*

There is a registration fee to attend this meeting. The registration fee is to help defray the costs of the event; including meeting facilities, program materials, refreshments, staff time and administrative overhead, and costs involved in getting speakers to the events; and will not result in any profits. Seats are limited, and registration will be on a first-come, first-served basis. On-site registration will be available to the extent that space is available on the day of the conference. **Please note:** Registration will open at 7:30 a.m. each day.

To register, please complete registration online at *http://www.diaglobal.org/en/conference-listing/meetings/2016/04/dia-fda-statistics-2016-forum/register.* (FDA has verified the Web address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) The costs of registration for the different categories of attendees are as follows:

| Category | Cost |
|---|---|
| Industry Representatives | $1,350 |
| Charitable Nonprofit/Academic (Full time) | 675 |
| Government (Full time) | 405 |
| Tutorial Fees | 405 |

All registrants will be required to pay the applicable fee, with the exception of a limited number of speakers/organizers who will have a complimentary registration.

### *B. Accommodations*

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the Bethesda North Marriot Hotel and Conference Center, 5701 Marinelli Rd., North Bethesda, MD 20852 are eligible for a reduced rate of $199, not including applicable taxes.

The Marriott Bethesda North Hotel and Conference Center has a limited

number of rooms available at the discounted rate of $199 per night until April 1, 2016, or until the block is filled. To receive the reduced rate, hotel reservations must be made with onPeak, *https://compass.onpeak.com/e/72FOR16,* and not directly with the hotel. If you need special accommodations due to a disability, please contact *Stephanie.Ritter@DIAglobal.org* at least 7 days in advance.

Dated: March 3, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–05219 Filed 3–8–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–D–0349]**

### Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled ''Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR part 1271; Guidance for Industry.'' The guidance document provides establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/Ps) for which no premarket submissions are required because they are not also regulated as drugs, devices, and/or biological products, with recommendations for complying with the requirements for investigating and reporting adverse reactions involving communicable disease in recipients of these HCT/Ps. The guidance also provides updated information specific to reporting adverse reactions related to HCT/Ps to supplement the general instructions accompanying the MedWatch mandatory reporting form, Form FDA 3500A. The guidance supplements section XXII of FDA's guidance entitled ''Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' dated December 2011 and supersedes the guidance entitled ''Guidance for Industry: MedWatch Form FDA 3500A: Mandatory Reporting of Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)'' dated November 2005. The guidance announced in this notice finalizes the draft guidance of the same title dated February 2015.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**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–D–0349 for ''Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely under Section 361 of the Public Health Service Act and 21 CFR part 1271; Guidance for Industry.'' 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.

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128,