

other vaccines due to practical considerations related to manufacturing and cost. Moreover, the schedule of vaccines subject to NCVIA is not static and is updated regularly. The Agency therefore will consider a vaccine manufacturer's request for an exemption to the linear bar code requirement for any of its other licensed vaccines in addition to childhood vaccines.

Note that, as FDA stated in the preamble to the final rule, the Agency continues to emphasize that the general exemption provision in § 201.25(d)(1)(ii) is intended to be used in rare cases (69 FR 9120 at 9131). FDA believes that its revised response to Q12 is consistent with that view because it is narrowly tailored. Further, as alternative technologies continue to advance, the Agency intends to assess these technologies in relation to current bar coding practices and other FDA initiatives, such as efforts to further enhance the security of the drug supply chain through use of a standardized numerical identifier for uniquely identifying prescription drug packages, and the establishment of a unique device identification system for medical devices.

In the **Federal Register** of September 7, 2010 (75 FR 54347), FDA announced the availability of a draft guidance entitled "Guidance for Industry: Bar Code Label Requirements—Questions and Answers (Question 12 Update)" dated August 2010. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated August 2010 and incorporates a revised response to question 12 into the guidance entitled "Guidance for Industry: Bar Code Label Requirements—Questions and Answers". In addition, editorial changes were made to the guidance to improve clarity.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found in FDA regulations. The collection of information in part 201 has

been approved under OMB control number 0910-0537.

## III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

## IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: August 4, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0324]

#### International Conference on Harmonisation; Guidance on E16 Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "E16 Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions." The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance describes recommendations regarding the context, structure, and format of qualification submissions for clinical and nonclinical genomic biomarkers related to development of drug or biotechnology products, including translational

medicine approaches, pharmacokinetics, pharmacodynamics, and efficacy and safety aspects. The guidance is intended to create a harmonized recommended structure for biomarker qualification applications that will foster consistency of applications across regions and facilitate discussions with and among regulatory authorities.

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

**ADDRESSES:** Submit written requests for single copies of the guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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:

*Regarding the guidance:*

Federico Goodsaid, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2148, Silver Spring, MD 20903-0002, 301-796-1535; or

Jennifer Catalano, Center for Biologics and Evaluation Research (HFM-735), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0706.

*Regarding the ICH:*

Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory

requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of July 30, 2009 (74 FR 38033), FDA published a notice announcing the availability of a draft guidance entitled "E16 Genomic Biomarkers Related to Drug Response: Context, Structure, and Format of Qualification Submissions." The notice gave interested persons an opportunity to submit comments by September 28, 2009.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in September 2010.

The guidance provides recommendations on the context, structure, and format of qualification submissions as follows:

- The proposed context of use of a biomarker corresponds to the data supporting its qualification. The context of use of a biomarker in a biomarker

qualification can be narrow or broad—the biomarker(s) might be useful for only a single drug or biotechnology product, for several drug or biotechnology products in a drug class, or even across several drug classes.

- The structure of the submission should be consistent regardless of the context proposed and flexible enough to deal with the specific attributes of each submission. In addition, use of the recommended structure should facilitate submission and review of future biomarker qualification submissions expanding the use of the biomarker to new contexts, as would be the case if, for example, a nonclinical context of use expands to a clinical context of use.

- The format of the data for qualifying a biomarker can vary significantly depending on the context. The format should support an evaluation of the data and can include reports, tabulations, and raw data (if requested by regulatory authorities according to the relevant practices in place).

The application structure described in this guidance is intended for biomarker qualification submissions after sufficient supporting data have been generated. However, this structure can also be considered for submissions intended to obtain scientific advice from regulatory authorities before or during the generation of the biomarker data intended to support qualification.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency'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. Comments

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## III. Electronic Access

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<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: August 4, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0002]

### Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Cellular, Tissue and Gene Therapies Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on September 22 and 23, 2011, from 8 a.m. to 5 p.m.

*Location:* Hilton Hotel, Washington, DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20977, 301-977-8900. For those unable to attend in person, the meeting will also be available by Web cast. On September 22, 2011, the link for the Web cast is available at <http://fda.yorkcast.com/webcast/Viewer/?peid=637f14248dca4236a5f9a3b622e6501e1d>. On September 23, 2011, the link for the Web cast is available at <http://fda.yorkcast.com/webcast/Viewer/?peid=2e8b3eb7638d42ca9652c328a854efb51d>.

*Contact Person:* Gail Dapolito or Sheryl Clark (HFM-71), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20853, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a