II. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses but is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

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7. Yang, S., M.G. Leff, D. McTague, *et al.,* ''Multistate Surveillance for Food-Handling, Preparation, and Consumption Behaviors Associated With Foodborne Diseases: 1995 and 1996 Behavioral Risk Factor Surveillance Systems Food-Safety Questions,'' *Morbidity and Mortality Weekly Report,* 47(SS–4):33–54, September 11, 1998, (*http://www.cdc.gov/mmwr/preview/mmwrhtml/00054714.htm*).

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Dated: August 18, 2011.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2011–21485 Filed 8–22–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0386]

International Conference on Harmonisation; Guidance on E2F Development Safety Update Report; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''E2F Development Safety Update Report.'' 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 the format, content, and timing of a development safety update report (DSUR) for an investigational drug. The DSUR will serve as a common standard for periodic reporting on drugs under development (including marketed drugs that are under further study) among the ICH regions. The DSUR can be submitted in the United States in place of an annual report for an investigational new drug application (IND). The harmonized DSUR is intended to promote a consistent approach to annual clinical safety reporting among the ICH regions and enhance efficiency by reducing the number of reports generated for submission to the 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, 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, 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 the Center for Biologics Evaluation and Research 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:* Ellis F. Unger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4208, Silver Spring, MD 20993–0002, 301–796–2270; or Peter F. Bross, Center for Biologics Evaluation and Research (HFM–755), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5102.

Regarding the ICH: Michelle Limoli, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 3506, Silver Spring, MD 20993, 301–796–8377.

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 August 5, 2008 (73 FR 45462), FDA published a notice announcing the availability of a draft guidance entitled ''E2F Development Safety Update Report.'' The notice gave interested persons an opportunity to submit comments by November 3, 2008.

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 August 2010.

The guidance describes the format, content, and timing of a DSUR for an investigational drug. The DSUR will serve as a common standard for periodic reporting on drugs under development (including marketed drugs that are under further study) among the ICH regions. The DSUR is patterned after the periodic safety update report (used for safety reporting in the postmarketing environment) and can be submitted in the United States in place of an annual report for an IND. The harmonized DSUR is intended to promote a consistent approach to annual clinical safety reporting among the ICH regions and enhance efficiency by reducing the number of reports generated for submission to the regulatory authorities.

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

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.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov, http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

Dated: August 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21447 Filed 8–22–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Vaccines and Related Biological Products Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Vaccines and Related Biological Products Advisory Committee. This meeting was announced in the **Federal Register** of July 22, 2011 (76 FR 44016). The amendment is being made to reflect a change in the *Date and Time, Location, Agenda, Procedure,* and *Closed Committee Deliberations* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Donald W. Jehn or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 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.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 22, 2011, FDA announced that a meeting of the Vaccines and Related Biological Products Advisory Committee would be held on September 20, 2011. On page 44016, in the 2nd and 3rd column and on page 44017, in the 1st column, the *Date and Time, Location, Agenda, Procedure,* and *Closed Committee Deliberations* portions of the document are changed to read as follows: