

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.*

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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:

**Date and Time:** The meeting will be held on September 20, 2011, from 1 p.m. to approximately 4 p.m.

**Location:** National Institutes of Health (NIH), 9000 Rockville Pike, Building 29B, Conference Room C, Bethesda, MD 20892. The public is welcome to attend the meeting at the specified location where a speakerphone will be provided. Public participation in the meeting is limited to the use of the speakerphone in the conference room. Important information about transportation and directions to the NIH campus, parking, and security procedures is available on the Internet at <http://www.nih.gov/about/visitor/index.htm>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) Visitors must show two forms of identification, one of which must be a government-issued photo identification such as a Federal employee badge, driver's license, passport, green card, etc. Detailed information about security procedures is located at <http://www.nih.gov/about/visitorsecurity.htm>. Due to the limited available parking visitors are encouraged to use public transportation.

**Agenda:** On September 20, 2011, the committee will meet in open session to hear updates of the research programs in the Laboratory of Enteric and Sexually Transmitted Diseases, Division of Bacterial, Parasitic, and Allergenic Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA.

**Procedure:** On September 20, 2011, from 1 p.m. to approximately 3:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be

made to the contact person on or before September 13, 2011. Oral presentations from the public will be scheduled between approximately 2:30 p.m. and 3:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 9, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 10, 2011.

**Closed Committee Deliberations:** On September 20, 2011, from approximately 3:30 p.m. to approximately 4 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the report of the intramural research programs and make recommendations regarding personnel staffing decisions.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: August 18, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011-21535 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-0332]

#### Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability; Correction

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

**ACTION:** Notice of availability; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice of availability that appeared in the **Federal Register** of August 4, 2011 (76 FR 47211). The Agency is required to report annually in the **Federal Register** on the status of postmarketing requirements and commitments required of, or agreed upon by, holders of approved drug and biological products. The August 4, 2011, notice is the Agency's report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct. The document was published with an error. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Joyce A. Strong, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3208, Silver Spring, MD 20993-0002, 301-796-9148.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2011-19806, appearing on page 47211 in the **Federal Register** of August 4, 2011, the following correction is made:

On page 47214, table 1 is corrected to read as follows:

TABLE 1—SUMMARY OF POSTMARKETING REQUIREMENTS AND COMMITMENTS  
[Numbers as of September 30, 2010]

	NDA/ANDA (% of Total PMR or % of total PMC)	BLA (% of Total PMR or % of total PMC) <sup>1</sup>
Number of open PMRs .....	526	149.
On-schedule open PMRs (see table 2 of this document) .....	477 (91%)	131 (88%).
Off-schedule open PMRs (see table 3 of this document) .....	49 (9%)	18 (12%).
Number of open PMCs <sup>2</sup> .....	473	307.
On-schedule open PMCs (see table 4 of this document) .....	399 (84%)	236 (77%).
Off-schedule open PMCs (see table 5 of this document) .....	74 (16%)	71 (23%).

<sup>1</sup> On October 1, 2003, FDA completed a consolidation of certain therapeutic products formerly regulated by CBER into CDER. Consequently, CDER now reviews many BLAs. Fiscal year statistics for postmarketing requirements and commitments for BLAs reviewed by CDER are included in BLA totals in this table.

<sup>2</sup> The number of PMCs reported as open as of September 30, 2009, in the "Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments" notice published in the **Federal Register** on November 9, 2010 (75 FR 68802), inadvertently also included open PMRs. That error has been corrected for the current reporting period.