assistance to blood and plasma establishments in the reporting of any event associated with the manufacturing, to include testing, processing, packing, labeling, or storage, or with the holding or distribution, of blood or blood components that may effect the safety, purity, or potency of a distributed product as required under §§ 600.14 and 606.171 (21 CFR 600.14 and 606.171). The guidance provides additional information regarding the regulations in § 606.171 by describing who must report, what must be included in the report, when the establishment must report, and how to report either electronically or by mail using Form FDA–3486, a standardized reporting format. Examples of reportable and non-reportable events concerning donor suitability, product collection, component preparation, testing, labeling, quality control and distribution are discussed. The guidance also contains a Biological Product Deviation Reporting Flow Chart to aid the blood or plasma establishment in determining if an event is reportable.

In the **Federal Register** of August 13, 2001 (66 FR 42546) FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated August 2001.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information under § 606.171 and 21 CFR 606.100 were approved under OMB control number 0910–0116. The collection of information under § 600.14 was approved under OMB control number 0910–0139. The collections of information under 21 CFR 820.90 and 820.100 were approved under OMB control number 0910–0458. The collections of information under 21 CFR 211.192 and 211.198 were approved under OMB control number 0910–0139.

III. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination 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/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–17378 Filed 10–18–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0221 (Formally Docket No. 01D–0221)]

Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components,'' dated October 2006. The guidance document provides licensed manufacturers of biological products other than blood and blood components with the FDA's current thinking related to the biological product deviation reporting requirements. The guidance document will assist the licensed manufacturers of biological products other than blood and blood components in determining when a report is required, who submits the report, what information to submit in the report, the timeframe for reporting, and how to submit the report. This guidance finalizes the draft guidance document of the same title dated August 2001.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, 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 written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Jr., Center for Biologics Evaluation and Research (HFM–17), 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 document entitled ''Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components,'' dated October 2006. The guidance is intended to provide assistance to licensed manufacturers of biological products other than blood and blood components in the reporting of any event associated with the manufacturing, to include testing, processing, packing, labeling, or storage, or with the holding or distribution of a licensed biological product which may affect the safety, purity, or potency of a distributed licensed product as required under § 600.14 (21 CFR 600.14). The guidance provides additional information regarding the regulations in § 600.14, which describe who must report, what must be included in the report, when the licensed manufacturer must report, and provides that the licensed

manufacturer must report either electronically or by mail using Form FDA–3486, a standardized reporting format. Examples of reportable and nonreportable events concerning the incoming material specifications, process controls, product specifications, product testing, product labeling, quality control procedures, and product distribution are discussed. These examples may not apply to all establishments because they include deviations and unexpected events related to standard operating procedures implemented at individual establishments and may not be an industry standard or a procedure at your facility. The guidance also contains a Biological Product Deviation Reporting Flowchart to aid in determining if an event is reportable.

In the **Federal Register** of August 13, 2001 (66 FR 42547), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated August 2001.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information under § 600.14 was approved under OMB control number 0910–0458. The collections of information under 21 CFR 606.100 and 606.171 were approved under OMB control number 0910–0116. The collections of information under 21 CFR 820.90 and 820.100 were approved under OMB control number 0910–0139, and the collections of information under 21 CFR 211.192 and 211.198 were approved under OMB control number 0910–0073.

III. Comments

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination 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/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 10, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–17374 Filed 10–18–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel, Resources and Training Review Teleconference.

Date: November 8, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892.

Contact Person: Keith McKenney, PhD, Scientific Review Administrator, NHGRI, 5635 Fishers Lane, Suite 4076, Bethesda, MD 20814. 301–594–4280, mckenneyk@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: October 10, 2006.

Linda Payne,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–8777 Filed 10–18–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Conference Grants Review.

Date: October 20, 2006.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Atul Sahai, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 908, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–2242, *sahaia@niddk.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)