Dated: January 22, 2007.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 07–393 Filed 1–29–07; 8:45 am]

BILLING CODE 4150–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Chronic Care Workgroup Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the 13th meeting of the American Health Information Community Chronic Care Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. No. 92–463, 5 U.S.C.; App.)

DATES: February 15, 2007, from 1 p.m. to 4 p.m.

ADDRESSES: Mary C. Switzer Building (330 C Street, SW., Washington, DC 20201), Conference Room 4090 (please bring photo ID for entry to a Federal building).

FOR FURTHER INFORMATION: *http://www.hhs.gov/healthit/ahic/chroniccare/.*

SUPPLEMENTARY INFORMATION: The Workgroup will continue to discuss possible Recommendations to the American Health Information Community, and medical/legal issues and challenges facing the use of remote monitoring and secure messaging technologies.

The meeting will be available via Internet access. For additional information, go to *http://www.hhs.gov/healthit/ahic/chroniccare/cc_instruct.html.*

Dated: January 24, 2007.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 07–394 Filed 1–29–07; 8:45 am]

BILLING CODE 4150–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; American Health Information Community Population CARE and Clinical Care Connections Workgroup Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the 13th meeting of the American Health Information Community Population Care and Clinical Care Connections Workgroup [formerly Biosurveillance Workgroup] in accordance with the Federal Advisory Committee Act (Pub. L. No. 92–463, 5 U.S.C., App.)

DATES: February 2, 2007, from 10 a.m. to 3 p.m.

ADDRESSES: Mary C. Switzer Building (330 C Street, SW., Washington, DC 20201), Conference Room 4090 (please bring photo ID for entry to a Federal building)

FOR FURTHER INFORMATION CONTACT: *http:/www.hhs.gov/healthit/ahic/biosurveillance/.*

SUPPLEMENTARY INFORMATION: The Workgroup will discuss the priority areas of Adverse Events and Response Management.

The meeting will be available via Internet access. For additional information, go to *http://www.hhs.gov/healthit/ahic/biosurveillance/bio_instruct.html.*

Dated: January 22, 2007.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 07–395 Filed 1–29–07; 8:45 am]

BILLING CODE 4150–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC): Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee.

Name: Healthcare Infection Control Practices Advisory Committee (HICPAC).

Times and Dates:

8:30 a.m.–5 p.m., February 15, 2007.

8:30 a.m.–4 p.m., February 16, 2007.

Place: Centers for Disease Control and Prevention (CDC) Roybal Campus, Bldg 19, Auditorium B3, 1600 Clifton Road, Atlanta, GA 30333.

Status: Open to the public, limited only by the space available.

Purpose: The Committee is charged with providing advice and guidance to the Secretary, the Assistant Secretary for Health, the Director, CDC, and the Director, National Center for Infectious Diseases (NCID), regarding (1) the practice of hospital infection control; (2) strategies for surveillance, prevention, and control of infections (e.g., nosocomial infections), antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters to Be Discussed: Agenda items will include: Information Technology Standards Update; National Quality Forum Update and Prevention Epidemiology Centers Update.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Harriette Lynch, Committee Management Specialist, HICPAC, Division of Healthcare Quality Promotion, NCID, CDC, 1600 Clifton Road, NE, M/S A–07, Atlanta, Georgia 30333, telephone 404–639–4035.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 23, 2007.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7–1393 Filed 1–29–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0421]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biological Products: Reporting of Biological Product Deviations in Manufacturing; Forms FDA 3486 and 3486A

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of

information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 1, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Biological Products: Reporting of Biological Product Deviations in Manufacturing; Forms FDA 3486 and 3486A (OMB Control Number 0910–0458)—Extension

Under section 351 of the Public Health Service Act (42 U.S.C. 262), all biological products, including human blood and blood components, offered for sale in interstate commerce must be licensed and meet standards designed to ensure the continued safety, purity, and potency of such products. In addition, the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351) provides that drugs and devices (including human blood and blood components) are adulterated if they do not conform with Current Good Manufacturing Practice (CGMP) assuring that they meet the requirements of the act. All establishments manufacturing biological products including human blood and blood components must comply with the applicable CGMP regulations (parts 211, 606, and 820 (21 CFR parts 211, 606, and 820)). Transfusion services are required under 42 CFR 493.1271 to comply with 21 CFR parts 606 and 640 as they pertain to the performance of manufacturing activities. FDA regards biological product deviation (BPD) reporting to be an essential tool in its directive to protect public health by establishing and maintaining surveillance programs that provide timely and useful information.

Section 600.14 requires the manufacturer who holds the biological product license, for other than human blood and blood components, and who had control over the product when the deviation occurred, to report to the Center for Biologics Evaluation and Research (CBER) or to the Center for Drugs Evaluation and Research (CDER) as soon as possible but not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Section 606.171 requires a licensed manufacturer of human blood and blood components, including Source Plasma; an unlicensed registered blood establishment; or a transfusion service who had control over the product when the deviation occurred, to report to CBER as soon as possible but not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. The BPD reporting under 21 CFR 1271.350(b) for human cells, tissues, and cellular and tissue-based products is approved under OMB control number 0910–0559 (expires November 30, 2007). Form FDA 3486 is used to submit BPDs under these regulations.

Respondents to this collection of information are the licensed manufacturers of biological products other than human blood and blood components, licensed manufacturers of blood and blood components including Source Plasma, unlicensed registered blood establishments, and transfusion services. Based on information from FDA's database, there are an estimated 147 licensed manufacturers of biological products other than human blood and blood components, 194 licensed manufacturers of human blood and blood components, including Source Plasma, and 1,230 unlicensed registered blood establishments. Based on the Center for Medicare and Medicaid Services records, there are an estimated 4,980 transfusion services. The number of licensed manufacturers and total annual responses under § 600.14 include the estimates for both CBER and CDER. The number of total annual responses is based on the number of BPD reports FDA received in fiscal year 2005. The rate of submission is not expected to change significantly in the next few years. Based on information from industry, the estimated average time to complete a deviation report is 2 hours. The availability of the standardized report form, Form FDA 3486, and the ability to submit this report electronically to CBER (CDER does not currently accept electronic filings) further streamlines the report submission process.

CBER is developing an addendum to Form FDA 3486. The web-based addendum (Form FDA 3486A) would request additional information when a BPD report has been reviewed by FDA and evaluated as a possible recall. The additional information requested would include information not contained in the Form FDA 3486 such as: (1) Distribution pattern, (2) method of consignee notification, (3) consignee(s) of products for further manufacture, (4) additional product information, and (5) updated product disposition. This information would be requested by CBER through e-mail notification to the submitter of the BPD report. This information would be used by CBER for purposes of recall classification. We plan to use Form FDA 3486A for only biological products regulated by CBER. We do not plan to use this form for biological products regulated by CDER because they receive very few BPD reports and do not accept electronic filings. CBER estimates that 5 percent of the total BPD reports submitted to CBER would need additional information submitted in the addendum. CBER estimates it would take between 15 to 45 minutes to complete the addendum. For calculation purposes, CBER is using one-half hour.

Activities such as investigating, changing standard operating procedures or processes, and followup are currently required under part 211 (approved under OMB control no. 0910–0139, expires September 30, 2008); part 606 (approved under OMB control no. 0910–0116, expires December 31, 2008); and part 820 (approved under OMB control no. 0910–0073, expires September 30, 2007) and, therefore, are not included in the burden calculation for the separate requirement of submitting a BPD report to FDA.

In the **Federal Register** of October 31, 2006, (71 FR 63772), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Responses	Total Hours
600.14	3486	147	2.73	401	2.0	802
606.171 [2]	3486	194	169.89	32,958	2.0	65,916
606.171 [3]	3486	6,210	1.50	9,311	2.0	18,622
	3486A [4]	6,551	0.33	2,133	0.5	1,067
Total						86,407

[1] There are no capital costs or maintenance costs associated with this collection of information.
[2] Licensed manufacturers of human blood and blood components, including Source Plasma.
[3] Unlicensed registered blood establishments and transfusion services (1,230 + 4,980 = 6,210).
[4] Five percent of the total annual responses to CBER (42,653 x 0.05 = 2,133).

Dated: January 24, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–1415 Filed 1–29–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0105]

James T. Kimball; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Mr. James T. Kimball's request for a hearing and is issuing a final order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. James T. Kimball from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Kimball was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the act. In addition, Mr. Kimball has failed to file with the agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is effective January 30, 2007.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On May 24, 2000, a jury found Mr. Kimball guilty of one count of conspiring to commit offenses against the United States and the Florida Department of Health, a Federal felony offense under 18 U.S.C. 371; six counts of distributing a misbranded drug into interstate commerce, a Federal felony offense under 21 U.S.C. 331(a); and one count of making a false statement in a matter within the jurisdiction of a Federal agency, a Federal felony offense under 18 U.S.C. 1001. On October 19, 2000, the U.S. District Court for the Middle District of Florida entered judgment and sentenced Mr. Kimball for these offenses.

The bases for these convictions were Mr. Kimball's knowing and willful participation, including conspiring, to violate Federal laws in connection with the distribution of a misbranded drug, deprenyl, into interstate commerce, and false statements he made to the U.S. Customs Service about shipments of deprenyl for export. The drug deprenyl was misbranded because it contained selegiline, the active ingredient of a prescription drug Eldepryl, but was dispensed without a prescription issued by a licensed practitioner.

As a result of these convictions, FDA served Mr. Kimball by certified letter on April 25, 2005,[1] a proposal to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The notice also offered Mr. Kimball an opportunity to request a hearing on the debarment proposal. The debarment proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that Mr. Kimball was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the act.

The certified letter also informed Mr. Kimball that his request for a hearing could not rest upon mere allegations or denials, but must present specific facts showing that there was a genuine and substantial issue of fact requiring a hearing. The letter also informed Mr. Kimball that the only material issue of fact was whether he was convicted as alleged in the letter, and that the facts underlying his conviction are not at issue in this proceeding. Finally, the letter informed Mr. Kimball that if it conclusively appeared from the face of the information and factual analyses in his request for a hearing that there was no genuine and substantial issue of fact that precluded the order of debarment, FDA would enter summary judgment against him and deny his request for a hearing.

In a letter dated May 16, 2005, Mr. Kimball responded to the certified letter by requesting a hearing.

II. Denial of Hearing

In his May 16, 2005, request for a hearing, Mr. Kimball does not present any arguments or information to show why he should not be debarred. Mr. Kimball merely states that: (1) He ''was not convicted pursuant to the statements set forth in FDA's alleged notice'', (2) the allegations of his convictions are incorrect, and (3) his conviction does not mandate his debarment. Such statements do not create a basis for a hearing because hearings will not be granted on mere allegations, denials, or general

[1] The certified letter was mailed to the prison facility where records indicated that Mr. Kimball was incarcerated, and the return receipt was signed on April 25, 2005, by an employee at the facility. In his request for hearing, Mr. Kimball stated that he received the letter on May 5, 2005. The delivery dates do not alter the nature of Mr. Kimball's request for a hearing or our application of summary judgement in this matter.