the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On January 11, 2008, West-Ward Pharmaceutical Corp., on behalf of Hikma Farmacêutica of Portugal, submitted a citizen petition (Docket No. FDA–2008–P–0029) to FDA under 21 CFR 10.30. The petition requests that the agency determine whether NUBAIN (nalbuphine hydrochloride) injection, 10 and 20 mg/ml (NDA 18–024), manufactured by Endo Pharmaceuticals (Endo), was withdrawn from sale for reasons of safety or effectiveness. NUBAIN was approved on May 15, 1979. NUBAIN is an analgesic drug product used for the relief of moderate to severe pain. NUBAIN may be used as a supplement to balanced anesthesia, for preoperative and postoperative analgesia, and for obstetrical analgesia during labor and delivery. Manufacture of NUBAIN was discontinued in 2003, and the drug product was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book.

FDA has reviewed its records and, under § 314.161, has determined that NUBAIN (nalbuphine hydrochloride) injection, 10 and 20 mg/ml, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that NUBAIN (nalbuphine hydrochloride) injection, 10 and 20 mg/ml, was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list NUBAIN (nalbuphine hydrochloride) injection, 10 and 20 mg/ml, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List''delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to NUBAIN (nalbuphine hydrochloride) injection, 10 and 20 mg/ml, may be approved by the agency if all other legal and regulatory requirementsfor the approval of ANDAs are met. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: November 14, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–27714 Filed 11–20–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Oncologic Drugs 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: Oncologic Drugs 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 December 16, 2008, from 8 a.m. to 4 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy, Gaithersburg, MD. The hotel phone number is 301–977–8900.

Contact Person: Nicole Vesely, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6793, fax: 301–827–6776, e-mail: *nicole.vesely@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. 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 previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss biologics license application (BLA) 125084, trade name ERBITUX (cetuximab), ImClone Systems, Inc., and BLA 125147, trade name VECTIBIX (panitumumab), Amgen, Inc., in the context of K-ras as a predictive and/or prognostic biomarker in oncology drug development.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: 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 December 2, 2008. Oral presentations from the public will be scheduled between approximately 11:30 a.m. to 12:30 p.m. Those desiring to make 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 November 24, 2008. 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 November 25, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 17, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–27713 Filed 11–20–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Privacy Act of 1974; Report of Amended or Altered System; Medical, Health and Billing Records System

AGENCY: Indian Health Service (IHS), HHS.

ACTION: Amendment of One Altered Privacy Act System of Records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4), the IHS has amended and is publishing the proposed alteration of a system of records, System No. 09–17–0001, ''Medical, Health and Billing Records.'' The amended and altered system of records makes only administrative edits and revisions as necessary.

DATES: The amended and altered system, which incorporates the comments received following the initial publication, shall become effective November 21, 2008.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia Gowan, IHS Lead Health Information Management (HIM) Consultant and Area HIM Consultant, Office of Health Programs, Phoenix Area Office, Two Renaissance Square, Suite 606, 40 North Central Avenue, Phoenix, AZ 85004–4450, Telephone (602) 364–5172 or via the Internet at *Patricia.Gowan@ihs.gov.*

SUPPLEMENTARY INFORMATION: As required by the Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4), this document sets forth the amendment of the proposed alteration of a system of records maintained by the IHS, in response to comments received following the initial publication in the **Federal Register** at 73 FR 50038 on August 25, 2008. IHS is altering System No. 09–17–0001, ''Health, Medical and Billing Records,'' for a few reasons. First, the changes will enable IHS to disclose controlled substance prescription data to a centralized database administered by an authorized State public health entity, such as State prescription drug monitoring programs (PMP). Second, the changes will enable IHS to disclose data from the National Patient Information Reporting System (NPIRS)/National Data Warehouse (NDW) to the various Epidemiology Centers established and funded under 25 U.S.C. 1621m. During the comment period, IHS received several responses from the public. Only one comment recommended any changes to the proposed alteration.

Comment: One commenter suggested adding a new routine use to allow the disclosure of IHS records to Epidemiology Centers under a Business Associate Agreement (BAA).

Response: After a careful review of this comment, IHS disagrees with the suggested change therefore has not revised the notice. The proposed revision to Routine Use number 10 is sufficient to enable IHS to share information with Epidemiology Centers established and funded under 25 U.S.C. 1621m. The BAA would only be sufficient for sharing information with Epidemiology Centers that perform functions involving the use or disclosure of individually identifiable health information on behalf of IHS. The Epidemiology Centers are funded through cooperative agreements. They engage in many authorized activities that do not involve the use or disclosure of individually identifiable health information or are otherwise not carried out on behalf of IHS.

This Notice meets the requirement to notify the public that the IHS is amending the proposed changes in the IHS system of records by incorporating the administrative changes following the initial publication at 73 FR 50038, August 25, 2008. With this notification, this system of records is effective November 21, 2008.

Dated: November 14, 2008.

Robert G. McSwain,

Director, Indian Health Service.

09–17–0001

SYSTEM NAME:

Medical, Health, and Billing Records Systems, Health and Human Services/Indian Health Service/Office of Clinical and Preventive Services (HHS/IHS/OCPS).

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

IHS hospitals, health centers, school health centers, health stations, field clinics, Service Units, IHS Area Offices (Appendix 1), and Federal Archives and Records Centers (Appendix 2). Automated, electronic and computerized records, including Patient Care Component (PCC) records, are stored at the Information Technology Support Center (ITSC), IHS, located in Albuquerque, New Mexico (Appendix 1). Records may also be located at contractor sites. A current list of contractor sites is available by writing to the appropriate System Manager (Area or Service Unit Director/Chief Executive Officer) at the address shown in Appendix 1.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals, including both IHS beneficiaries and non-beneficiaries, who are examined/treated on an inpatient and/or outpatient basis by IHS staff and/or contract health care providers (including Tribal contractors).

CATEGORIES OF RECORDS IN THE SYSTEM:

Note: Records relating to claims by and against the HHS are maintained in the Administrative Claims System, 09–90–0062, HHS/Office of the Secretary/Office of the General Counsel (HHS/OS/OGC). Such claims include those arising under the Federal Torts Claims Act, Military Personnel and Civilian Employees Claims Act, Federal Claims Collection Act, Federal Medical Care Recovery Act, and Act for Waiver of Overpayment of Pay.

1. Health and medical records containing examination, diagnostic and treatment data, proof of IHS eligibility, social data (such as name, address, date of birth, Social Security Number (SSN), Tribe), laboratory test results, and dental, social service, domestic violence, sexual abuse and/or assault, mental health, and nursing information.

2. Follow-up registers of individuals with a specific health condition or a