FDA is issuing this guidance as level 1 guidance 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 alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 in this guidance were approved under OMB Control Nos. 0910–0643 and 0910–0645. This guidance also refers to previously approved collections of information found in FDA regulations. The collection of information in 21 CFR 7.46 has been approved under OMB Control No. 0910–0249.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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 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.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/default.htm* or *http://www.regulations.gov*.

Dated: September 3, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21713 Filed 9–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Oncologic Drugs 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 a meeting of the Oncologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of August 25, 2009 (74 FR 42907). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: 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.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 25, 2009, FDA announced that a meeting of the Oncologic Drugs Advisory Committee would be held on October 6, 2009. On page 42907, in the second column, the *Agenda* portion of the document is changed to read as follows:

Agenda: The committee will discuss new drug application (NDA) 021–825, with the proposed trade name FERRIPROX (deferiprone) film-coated tablets, manufactured by ApoPharma Inc. This product is an iron chelating agent, which is a drug that binds with iron in the body and helps to make elimination of iron easier, reducing iron build-up. There are two specific proposed indications (uses) of FERRIPROX: (1) For the treatment of iron overload, or build-up in patients with transfusion-dependent thalassemia, an inherited blood disorder that necessitates frequent transfusion of normal blood which can lead to iron build-up due to the iron content in the blood a patient receives; and (2) for the treatment of iron overload in patients with other transfusion-dependent anemias (other blood disorders that require frequent transfusions) for whom the use of other iron chelating agents has been considered inappropriate.

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: September 2, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21556 Filed 9–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Cellular, Tissue and Gene Therapies 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: Cellular, Tissue and Gene Therapies 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 October 9, 2009, from 8:30 a.m. to approximately 4:30 p.m.

Location: Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD.

Contact Person: Gail Dapolito or Danielle Cubbage, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20853, 301–827–1289, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512389. 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: On October 9, 2009, in open session, the Committee will discuss ISOLAGEN THERAPY, BLA 125348, Isolagen Technologies, Inc., for moderate to severe nasolabial fold wrinkles. Nasolabial fold wrinkles are the two skin folds that run from each side of the nose to the corners of the mouth.

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/AdvisoryCommittees/Calendar/default.htm*. 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 October 2, 2009. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 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 October 1, 2009. 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 October 2, 2009.

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 Gail Dapolito 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.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: September 2, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21557 Filed 9–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[System Number 09–17–0003]

Privacy Act of 1974; Report of an Altered System of Records Medical Staff Credentials and Privileges Records

AGENCY: Department of Health and Human Services (HHS), Indian Health Service (IHS).

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. 09–17–0003, ''Medical Staff Credentials and Privileges Records.'' The amended and altered system of records makes several administrative revisions which includes the deletion of the Social Security Numbers (SSNs) language to comply with the Office of Management and Budget (OMB) Memorandum (M)07–16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information (May 22, 2007); and the HHS Directive Memorandum of October 6, 2008 to all Operating Division Heads to develop and execute a plan to eliminate the unnecessary collection and use of SSNs; and the inclusion of a new routine use to comply with OMB (M)07–16 and the HHS Memorandum dated September 19, 2007 to incorporate Notification of Breach Routine Use language; and the update of the Appendix 1 of the SOR.

DATES: *Effective Dates:* IHS filed an altered system report with the Chair of the House Committee on Oversight and Government Reform, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, OMB on September 9, 2009. To ensure that all parties have adequate time in which to comment, the altered SOR will become effective 40 days from the publication of the notice, or from the date it was submitted to OMB and the Congress, whichever is later, unless IHS receives comments on all portions of this notice.

ADDRESSES: The public should address comments to: Mr. William Tibbitts, IHS Privacy Act Officer, Division of Regulatory Affairs, Office of Management Services, 801 Thompson Avenue, TMP Suite 450, Rockville, MD 20852–1627; call non-toll free (301) 443–1116; send via facsimile to (301) 443–2316, or send your e-mail requests, comments, and return address to: *William.Tibbitts@ihs.qov*.

FOR FURTHER INFORMATION CONTACT: Contact Paul Fowler, D.O., J.D., IRS Risk Management Officer, Office of Clinical and Preventive Services, Suite 331, 801 Thompson Avenue, Rockville, Maryland 20852 or via the Internet at *Paul.Fowler@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 IRS. The purpose of altering System No. 09–17–0003, ''Medical Staff Credentials and Privileges Records,'' is to enable IRS to reflect current program changes, statutory and implementation changes. The exclusion of SSN language; the inclusion of a new routine use and revision or modification of the IHS addresses in Appendix 1 is necessary to this system of records.

Dated: August 28, 2009.

Yvette Roubideaux,

Director of Indian Health Service.

09–17–0003

SYSTEM NAME:

Indian Health Service Medical Staff Credentials and Privileges Records, HHS/IHS/OCPS.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Each IHS Area Office and each IHS Service Unit (*see* Appendix 1). Records may also be located at hospitals and offices of health care providers who are under contract to IHS. A current list of contractor sites is a available by writing to the appropriate System Manager (Area or Service Unit Director) at the address shown in Appendix 1.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Prospective, current and former IHS medical staff members. The term IHS medical staff includes fully licensed individuals permitted by law to provide patient care services independently and without concurrent professional direction or supervision, within the scope of his/her license and in accordance with individually granted clinical privileges. The IHS medical staff includes physicians (M.D. and D.O.) and dentists and may include other health care practitioners such as psychologists, optometrists, podiatrists, audiologists, and, in some States, certified nurse midwives. Types of