and falsifying patient data in research supported by National Institute on Aging (NIA), National Institutes of Health (NIH), grant R01 AG18461.

Specifically, Ms. Okoro intentionally and knowingly fabricated and falsified data for six visit dates on one patient data form and falsified and fabricated patient condition information on two additional study subjects by failing to note that each patient had experienced a fall as documented in their medical charts.

ORI has implemented the following administrative actions for a period of three (3) years, beginning July 17, 2006:

(1) Ms. Okoro is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) Any institution that submits an application for PHS support for a research project on which Ms. Okoro's participation is proposed or which uses her services in any capacity on PHS supported research must concurrently submit a plan for supervision of her duties. The supervisory plan must be designed to ensure the scientific integrity of Ms. Okoro's research contribution and must be submitted to ORI by the institution.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

Chris B. Pascal, J.D.,

Director, Office of Research Integrity.

[FR Doc. E6–12857 Filed 8–7–06; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Advisory Board to the National Center for Toxicological Research; 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR).

General Function of the Committee: The Board advises the Director, NCTR, in establishing, implementing, and evaluating the research programs that assist the Commissioner of Food and Drugs in fulfilling his regulatory responsibilities. The Board provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

Date and Time: The meeting will be held on August 29, 2006 from 8:30 a.m. to 4:30 p.m. and on August 30, 2006, from 8 a.m. to 12 noon.

Location: August 29, 2006: NCTR SAB Conference Room B–12, 3900 NCTR Dr., Jefferson, AR 72079. August 30, 2006: University of Arkansas for Medical Sciences, Stephens Spine Center, Hamlin Board Room, 501 Jack Stephens Dr., Little Rock, AR 72205.

Contact Person: Leonard Schechtman, Executive Secretary, National Center for Toxicological Research, Food and Drug Administration, 5600 Fishers Lane, rm. 16–85, Rockville, MD 20857, 301–827–6696, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512559. Please call the Information Line for up-to-date information on this meeting.

Agenda: On August 29, 2006, the SAB will hear presentations from the NCTR Divisions that will update them on ongoing research activities. The SAB will be presented with a response to the evaluation of the Division of Neurotoxicology. The evaluation was the product of a site visit team that conducted an on-site review of the Division in January 2004. The response will address the issues raised and recommendations made by the site visit team. On August 30, 2006, the NCTR Director will provide a Center-wide update on scientific endeavors and will discuss the NCTR realignment and strategic focus.

Procedure: On August 29, 2006, from 8:30 a.m. to 4:30 p.m., and August 30, 2006, from 8 a.m. to 10:30 a.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 August 14, 2006. Oral presentations from the public will be scheduled on August 29, 2006, between approximately 12:30 p.m. to 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should likewise 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 August 14, 2006.

Closed Committee Deliberations: On August 29, 2006, from approximately 11 a.m. to 12:30 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)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

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 the office of the Executive Secretary at least 7 days in advance of the meeting.

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

Dated: August 2, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12863 Filed 8–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1992S–0251] (formerly 92S–0251)

Food and Drug Administration Electronic Submissions Gateway

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the FDA Electronic Submissions Gateway (ESG) for the receipt and processing of electronic submissions provided so that the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), and the Center for Devices and Radiological Health (CDRH) can receive regulatory submissions electronically. The FDA ESG enables applicants to send applications and other submissions for review using the Internet, provides a single point of entry for these submissions, and fulfills goals identified in the Prescription Drug User Fee Act (PDUFA III).

FOR FURTHER INFORMATION CONTACT: Michael B. Fauntleroy, CBER (HFM–25), Food and Drug Administration, 11400 Rockville Pike, RKWL rm. 4119, Rockville, MD 20857, 301–827–5132, e-mail: *michael.fauntleroy@fda.hhs.gov* or William H. Taylor, Office of the Commissioner (HFA–83), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–45, Rockville, MD 20857, 301–255–6734, e-mail: *william.taylor@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA receives a variety of electronic submissions under 21 CFR 11.2(b), including biological license applications (BLAs), new drug applications (NDAs), drug master files (DMFs), investigational new drug applications (INDs), and investigational device exemptions (IDEs), as well as their associated correspondence and other types of regulatory submissions. The FDA ESG supports the receipt and processing of electronic submissions through the use of a single point of entry.

The increasing number of electronic submissions highlights a critical need to automate and standardize the receipt of these submissions and their delivery to the appropriate centers. The FDA ESG automates the receipt, acknowledgment (to the applicant/sponsor), routing, and notification (to a receiving center) of electronic submissions via the Internet and meets the standards for the electronic exchange of information adopted by the American National Standards Institute (ANSI) and the National Institute of Standards and Technology (NIST).

The FDA ESG offers two secure communication options for applicants that have established gateway systems. One utilizes simple mail transfer protocol (SMTP) with secure multi-purpose internet mail extensions (S/MIME) to provide secure e-mail communication and the other supports faster information exchange and utilizes hypertext transfer protocol secure (HTTPS) to provide real-time Internet communication. The FDA ESG also offers a secure WebTrader submission option for applicants who do not have gateway systems. The WebTrader is a no-cost applet which can be downloaded from FDA and requires only a standard security certificate to provide the applicants with a secure Internet connection to FDA. The WebTrader addresses the need to expand participation in electronic submissions without costly expenditures for infrastructure upgrades and gateway systems.

Use of the FDA ESG is voluntary. Electronic format submissions may be made through the gateway or may continue to be made on physical media. Information on the FDA ESG is available on the following Web site: *http://www.fda.gov/esg/*. Except where FDA has promulgated regulations requiring submission in electronic format, applicants/sponsors may also continue to make regulatory submissions on paper.

If you wish to use the FDA ESG, you should send an e-mail to *esgprep@fda.gov* to begin the registration process. Include your name, phone number, and the name of the company you represent. Please state whether you are using the WebTrader, SMTP, or HTTPS for submissions.

Dated: July 31, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–12808 Filed 8–7–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0296]

International Conference on Harmonisation; Draft Guidance on Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria; Annex on Residue on Ignition/Sulphated Ash General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria; Annex 1: Residue on Ignition/Sulphated Ash General.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides the outcome of the ICH Q4B evaluation of the Residue on Ignition/Sulphated Ash General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The draft guidance conveys acceptance of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the acceptance. The draft guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing and different acceptance criteria in favor of a common testing strategy in each regulatory region. Elsewhere in this issue of the *Federal Register*, FDA is announcing the availability of a draft guidance entitled ''Q4B Regulatory Acceptance of Analytical Procedures and/or Acceptance Criteria.''

DATES: Submit written or electronic comments on the draft guidance by October 10, 2006.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the draft 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert H. King, Sr., Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10993 New Hampshire Ave., Bldg. 21, rm. 3542, Silver Spring, MD 20993–0002, 301–796–1242; or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–435–5681.

Regarding the ICH:Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane,Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION: