The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Pediatric Advisory Committee. This meeting was announced in the **Federal Register** of February 1, 2006 (71 FR 5343). The amendment is being made to reflect a change in the *Date and Time* and *Agenda* portions of the document. The starting time of the meeting has been moved to 7:30 a.m. and the committee will now also hear and discuss information on cardiovascular adverse events possibly related to ADHD medications. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Jan N. Johannessen, Office of Science and Health Coordination (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 14C–06), Rockville, MD 20857, 301–827–6687, e-mail: *Jan.Johannessen@fda.hhs.gov*, or the FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 1, 2006, FDA announced that a meeting of the Pediatric Advisory Committee would be held on March 22, 2006, from 8 a.m. to 6 p.m., and that the committee would receive an update on efforts to better understand cardiovascular adverse events possibly related to ADHD medications. On page 5343, in the first column, the *Date and Time* portion of the document is amended to read as follows:

Date and Time: The meeting will be held on March 22, 2006, from 7:30 a.m. to 6 p.m.

On page 5343, in the second column, the *Agenda* portion of the document is amended to read as follows:

Agenda: The Pediatric Advisory Committee will hear and discuss a report by the agency, as mandated in Section 17 of the Best Pharmaceuticals for Children Act (BPCA), on adverse event reports possibly related to clofarabine (CLOLAR), irbesartan (AVAPRO), sibutramine (MERIDIA), and the mixed salts amphetamine product (ADDERALL). In continuation of a prior committee discussion of adverse events for the class of methylphenidate products used to treat attention deficit hyperactivity disorder (ADHD), the committee will hear and discuss neuropsychiatric adverse events possibly related to other approved ADHD medications. The presentations will focus on neuropsychiatric adverse event reports and clinical trial data from approved ADHD medications. The committee will also hear and discuss information on cardiovascular adverse events possibly related to ADHD medications.

The background material will become available no later than the day before the meeting and will be posted under the Pediatric Advisory Committee Docket site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2006 and scroll down to Pediatric Advisory Committee meetings.)

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: March 3, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–3435 Filed 3–9–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0343]

Guidance for Industry and Food and Drug Administration; Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment.'' This guidance provides recommendations intended to reduce life-threatening entrapments associated with hospital bed systems. It characterizes the body parts at risk for entrapment, identifies the locations of hospital bed openings that are potential entrapment areas, recommends dimensional criteria for bed systems, provides information about legacy beds including information to include when reporting entrapment adverse events, and provides the Hospital Bed Safety Workgroup (HBSW) test methods for assessing gaps.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jay A. Rachlin, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3173.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance identifies special issues associated with hospital bed systems and provides recommendations intended to reduce life-threatening entrapments associated with these devices. Manufacturers may use this guidance to assess current hospital bed systems and to assist in the design of new beds. This guidance may be used as part of a bed safety program to help identify entrapment risks that may exist with current hospital bed systems.

Previously, FDA announced the availability of a draft guidance document entitled ''Hospital Bed System Dimensional Guidance to Reduce Entrapment'' in the **Federal Register** of August 30, 2004 (69 FR 52907). FDA invited interested persons to comment on the guidance document by November 29, 2004. FDA received over 110 comments. FDA changed the draft guidance based on the comments received. The changes include the following: (1) Addition of the HBSW test methods for assessing gaps and (2) addition of the use of a test tool for assessing the potential for head and neck entrapment.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on appropriate dimensional limits for, and assessment of, gaps in hospital bed systems to prevent entrapment. 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 requirements of the applicable statute and regulations.

III. Electronic Access

To receive the ''Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment,'' you may either send a fax request to 301–443–8818 to receive a hard copy of the document, or send an e-mail request to *GWA@CDRH.FDA.GOV* to receive a hard copy or an electronic copy. Please use the document number (1537) to identify the guidance you are requesting.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 2, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–3369 Filed 3–9–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0088]

Draft Guidance for Industry on Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines,'' dated March 2006. The draft document is intended to provide to sponsors of pandemic influenza vaccines guidance on clinical development approaches to facilitate and expedite the licensure of influenza vaccines for the prevention of disease caused by pandemic influenza viruses. The draft guidance provides recommendations for clinical data to support biologics license application (BLA) license approval either as a supplement or as a new BLA using the accelerated approval pathway.

DATES: Submit written or electronic comments on the draft guidance by June 8, 2006 to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 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 draft guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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*.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, 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 draft document entitled ''Guidance for Industry: Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines,'' dated March 2006. The draft guidance is intended to provide to sponsors of pandemic influenza vaccines guidance on clinical development approaches to facilitate and expedite the licensure of influenza vaccines for the prevention of disease caused by pandemic influenza viruses. The approaches apply to ''split virus'' and whole virus inactivated pandemic vaccines propagated in embryonated chicken eggs, and are also applicable to cell-culture derived, recombinant hemagglutinin-based protein, and adjuvanted pandemic influenza vaccines. The draft guidance provides recommendations for clinical data to support BLA approval either as a supplement or as a new BLA using the accelerated approval. The draft guidance also addresses live attenuated influenza vaccines, but does not address influenza vaccines that do not contain a hemagglutinin component. The draft guidance does not address the nonclinical development of investigational vaccines, or the chemistry, manufacturing, control, or inspection of the manufacturing facility needed for licensure.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 draft 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 in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Comments

The draft guidance is being distributed for comment purposes only