

The third wave will occur in fall 2007 and will involve follow-ups with children who at this time are starting their second year in Head Start. Data collection will follow the same procedures as in fall 2006.

The fourth wave will occur in spring 2008 and will involve follow-ups with children who at this time are either completing a second year in Head Start or completing kindergarten. For those children who are still attending Head Start, data collection will follow the same procedures as in spring 2007. For those children attending kindergarten, data collection will include assessments of children, an "update" survey of the information collected from the parent

interview, and ratings of the children's academic progress and school adjustment by kindergarten teachers.

The fifth wave of data collection will occur in spring 2009. Children who attended kindergarten the previous year will not be included in this wave. The procedures for this effort will be the same as for kindergartners in spring 2008.

This schedule of data collection is necessitated by the mandates of the Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103-62), which requires that the Head Start Bureau move expeditiously toward development and testing of Head Start Performance Measures and, by the 1994

reauthorization of Head Start (Head Start Act, as amended, May 18, 1994, Section 649(d)), which requires periodic assessments of Head Start's quality and effectiveness.

Respondents: Federal Government, Individuals or Households, and Not-for-Profit Institutions.

Annual Burden Estimates

Estimated Response Burden for Respondents to the Head Start Family and Child Experiences Survey (FACES 2006)—Fall 2006, Spring 2007, Fall 2007, Spring 2008, Spring 2009.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Year 1—Fall 2006:				
Head Start Parent Interview	3,464	1	1.00	3,464
Head Start Child Assessment	3,464	1	0.66	2,286
Teacher Child Rating	350	9.4	0.25	823
Program Director Interview	60	1	0.25	15
Center Director Interview	120	1	0.80	96
Education Coordinator Interview	120	1	0.75	90
Teacher Interview	350	1	1.00	350
Spring 2007:				
Head Start Parent Interview	2,789	1	0.75	2,092
Head Start Child Assessment	2,882	1	0.66	1,902
Teacher Child Rating	370	8.2	0.25	759
Head Start Teacher-new	70	1	1.00	70
Head Start Teacher-continuing	300	1	0.50	150
Year 2—Fall 2007:				
Head Start Parent Interview	1,333	1	0.40	533
Head Start Child Assessment	1,425	1	0.66	941
Teacher Child Rating	200	7.5	0.025	375
Spring 2008:				
Head Start Parent Interview	1,172	1	0.75	879
Head Start Child Assessment	1,282	1	0.66	846
Teacher Child Rating	200	6.7	0.25	335
Head Start Teacher Interview	200	1	200	200
Kindergarten Parent Interview	1,171	1	0.75	878
Kindergarten Child Assessment	1,102	1	0.75	827
Kindergarten Teacher Questionnaire and Child Rating	964	1	0.50	482
Year 3—Spring 2009:				
Kindergarten Parent Interview	1,172	1	0.75	879
Kindergarten Child Assessment	1,103	1	0.75	827
Kindergarten Teacher Questionnaire and Child Rating	965	1	0.50	483

Estimated Total Burden Hours:
20,582.

Estimated Total Annual Burden Hours (average of 3 years): 6,861.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF. E-mail address: Katherine_T.Astrich@omb.eop.gov.

Dated: March 6, 2006.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration.

ACTION: Notice.

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]

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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/ecommments>. 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