Inspections and reinspections involve the same procedure, require the same amount of time, and are therefore charged at the same rate.

[FR Doc. 04–19703 Filed 8–27–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0343]

Draft Guidance for Industry and Food and Drug Administration Staff; Hospital Bed System Dimensional Guidance to Reduce Entrapment; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Hospital Bed System Dimensional Guidance to Reduce Entrapment.'' This draft guidance provides recommendations intended to reduce life-threatening entrapments associated with hospital bed systems.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, and recommends dimensional criteria for bed systems.

DATES: Submit written or electronic comments on this draft guidance by November 29, 2004.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Hospital Bed System Dimensional Guidance to Reduce Entrapment'' to the Division of Small Manufacturers, International, and Consumer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Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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*. 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This draft guidance identifies special issues associated with hospital bed systems and provides recommendations intended to reduce life-threatening entrapments associated with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.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on appropriate dimensional limits for 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 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 draft 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 copy. Received 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: August 11, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–19656 Filed 8–27–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Bureau of Citizenship and Immigration Services

Agency Information Collection Activities: Revision of Existing Collection; Comment Request

ACTION: Request OMB Emergency Approval: Immigrant Petition for Alien Workers, 1615–0015.

The Department of Homeland Security (DHS) and the Bureau of Citizenship and Immigration Services (CIS) has submitted an emergency information collection request (ICR) utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with section 1320.13(a)(1)(ii) and (a)(2)(iii) of the Paperwork Reduction Act of 1995. The DHS has determined that it cannot reasonably comply with the normal clearance procedures under this part because normal clearance procedures are reasonably likely to prevent or disrupt the collection of information. Therefore, immediate OMB approval has been requested. If granted, the emergency approval is only valid for 180 days. ALL comments and/or questions pertaining to this pending request for emergency approval MUST be directed to OMB, Office of Information and Regulatory Affairs, Attention: Desk Officer, Department of

Homeland Security, 725—17th Street, NW., Suite 10235, Washington, DC 20503; (202) 395–5806.

During the first 60 days of this same period, a regular review of this information collection is also being undertaken. During the regular review period, the DHS requests written comments and suggestions from the public and affected agencies concerning this the information collection. Comments are encouraged and will be accepted until [Insert the date of the 60th day from the date that this notice is published in the **Federal Register**]. During 60-day regular review, ALL comments and suggestions, or questions regarding additional information, to include obtaining a copy of the information collection instrument with instructions, should be directed to Mr. Richard A. Sloan, (202) 616–7600. Director, Regulations and Forms Services Division, Department of Homeland Security, Room 4034, 425 I Street, NW., Washington, DC 20536. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points.

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarify of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Revision of currently approved collection.

(2) *Title of the Form/Collection:* Immigrant Petition for Alien Workers.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–140, Bureau of Citizenship and Immigration Services (CIS).

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This form is used to classify a person under section 203(b)(1), 203(b)(2), or 203(b)(3) of the Immigration and Nationality Act. The data collected on this form will be used by the CIS to determine eligibility for the requested immigration benefit.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 96,000 responses at 60 minutes (1 hour) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 96,000 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan (202) 616–7600, Director, Regulations and Forms Services Division, Bureau of Citizenship and Immigration Services, Department of Homeland Security, Room 4304, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

Dated: August 24, 2004.

Richard A. Sloan,

Department Clearance Officer, Department of Homeland Security Bureau of Citizenship and Immigration Services.

[FR Doc. 04–19750 Filed 8–27–04; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF HOMELAND SECURITY

Bureau of Citizenship and Immigration Services

Agency Information Collection Activities: Extension of Existing Collection; Comment Request

ACTION: Request OMB Emergency Approval: Checklist for On-Site Review of Schools; OMB–35, 1615–0006.

The Department of Homeland Security (DHS) and the Bureau of Citizenship and Immigration Services (CIS) has submitted an emergency information collection request (ICR) utilizing emergency review procedures, to the Office of Management and Budget (OMB) for review and clearance in accordance with section 1320.13(a)(1)(ii) and (a)(2)(iii) of the Paperwork Reduction Act of 1995. The DHS has determined that it cannot reasonably comply with the normal clearance procedures under this part because normal clearance procedures are reasonably likely to prevent or disrupt the collection of information. Therefore, immediate OMB approval has been requested. If granted, the emergency approval is only valid for 180 days. ALL comments and/or questions pertaining to this pending request for emergency approval MUST be directed to OMB, Office of Information and Regulatory Affairs, Attention: Desk Officer, Department of Homeland Security, 725—17th Street, NW., Suite 10235, Washington, DC 20503; 202–395–5806.

During the first 60 days of this same period, a regular review of this information collection is also being undertaken. During the regular review period, the DHS requests written comments and suggestions from the public and affected agencies concerning this information collection. Comments are encouraged and will be accepted until October 29, 2004. During the 60-day regular review, ALL comments and suggestions, or questions regarding additional information, to include obtaining a copy of the information collection instrument with instructions, should be directed to Mr. Richard A. Sloan, 202–616–7600, Director, Regulations and Forms Services Division, Department of Homeland Security, Room 4034, 425 I Street, NW., Washington, DC 20536. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection: