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Draft Guidance for Industry and Food and Drug Administration Staff; Hospital Bed System Dimensional Guidance to Reduce Entrapment; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Hospital Bed System Dimensional Guidance to Reduce Entrapment.'' This draft guidance provides recommendations intended to reduce life-threatening entrapments associated with hospital bed systems.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DATES: Submit written or electronic comments on this draft guidance by November 29, 2004.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Hospital Bed System Dimensional Guidance to Reduce Entrapment'' to the Division of Small Manufacturers, International, and Consumer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Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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This draft guidance identifies special issues associated with hospital bed systems and provides recommendations intended to reduce life-threatening entrapments associated with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