DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91N–0487]

Medical Devices; Protective Restraints; Draft 510(k) Guidance Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document for the preparation of premarket notification (510(k)) submissions for protective restraints and wheelchair accessories intended for use as restraints. The draft guidance document is intended to assist manufacturers in complying with premarket notification requirements. Elsewhere in this issue of the Federal Register, FDA is publishing a final rule revoking exemptions for these devices from premarket notification and current good manufacturing practices regulations.

DATES: Written comments by June 3, 1996.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, or 1–800–638–2041. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the 510(k) guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: James E. Dillard, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

SUPPLEMENTARY INFORMATION: FDA is revising the classification regulations for protective restraints (21 CFR 880.6760) and wheelchair accessories intended for use as restraints (21 CFR 890.3910). In a final rule published elsewhere in this issue of the Federal Register, FDA is revoking the existing exemptions for these devices from premarket notification and current good manufacturing practices regulations. This action is being taken in response to a number of recent reports of deaths and serious injuries that may have been associated with improper supervision of restrained patients or improper application of protective restraints.

Manufacturers and initial distributors of protective restraints and wheelchair accessories intended for use as restraints will be required to submit premarket notification submissions by September 3, 1996. Therefore, FDA is announcing the availability of a draft guidance document for the preparation and submission of 510(k) submissions for these devices. This draft guidance will be used by FDA reviewers to assist in evaluating 510(k) submissions. Characteristics that manufacturers should address in their 510(k) submissions for restraints include the following: (1) Specific intended use of the device; (2) ease of release of the device in the event of emergencies; (3) tear strength of the materials; (4) potential for injury (e.g., whether there are abrasive materials, such as metal fasteners, that would come in contact with the patient's skin, and similar considerations); (5) ease of identification of size; (6) completeness, conspicuousness, and simplicity of directions and labeling; (7) care/cleaning instructions; (8) whether the material is biocompatible; (9) any safety testing data available for the device, including an analysis of bench simulation testing data; and for certain circumstances, (10) patient testing data. The draft guidance document contains more detailed information on restraint premarket submission requirements and should be useful to manufacturers during 510(k) preparation. The draft guidance document may be obtained from the Division of Small Manufacturers Assistance (address above). Manufacturers may contact the reviewing division to discuss the appropriate contents of their submissions on a case-by-case basis.

Guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or others; however, they do represent the agency's current thinking on the subjects of the guidance documents. Interested persons may, on or before June 3, 1996, submit to the Dockets Management Branch (address above) written comments on the 510(k) guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 15, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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