

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. 2003D-0420]

Draft Guidance for Industry and Food and Drug Administration Staff; Medical Devices: Radiology Devices; Class II Special Controls Guidance Document: Bone Sonometers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled "Class II Special Controls Guidance Document: Bone Sonometers." The draft guidance was developed to support the reclassification of bone sonometers from class III (premarket approval) into class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify these devices accordingly. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Class II Special Controls Guidance Document: Bone Sonometers" to the Division of Small Manufacturers, International, and Consumer Assistance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.,

DDM
Display Date 2-14-06
Publication Date 2-15-06
Contact A. Corbin

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Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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: Robert A. Phillips, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1212, ext. 130.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance provides FDA's recommendations to manufacturers of bone sonometers for identifying risks to health and mitigation measures that can be taken to offset those risks. Bone sonometers are devices that transmit ultrasound energy into the human body to measure acoustic properties of bone that indicate overall bone health and fracture risk. These devices were classified into class III by statute (section 513(f)(1) of the Federal Food, Drug, and Cosmetic (the act) (21 U.S.C. 360e(f)(i))), however, FDA believes that sufficient information exists to establish special controls that, when followed and combined with the general controls of the act, would provide reasonable assurance of the safety and effectiveness of these devices.

II. Significance of the Guidance

This draft guidance is being issued consistent with FDA's good guidance practice regulation (21 CFR 10.115). The draft guidance, if finalized, would represent the agency's current thinking on bone sonometers. It would not create or confer any rights for or on any person and would 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. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the draft guidance have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120), which expires May 31, 2007. The labeling provisions addressed in the draft guidance have been approved by OMB under the PRA under OMB control number 0910–0485 and expires June 30, 2008.

IV. Comments

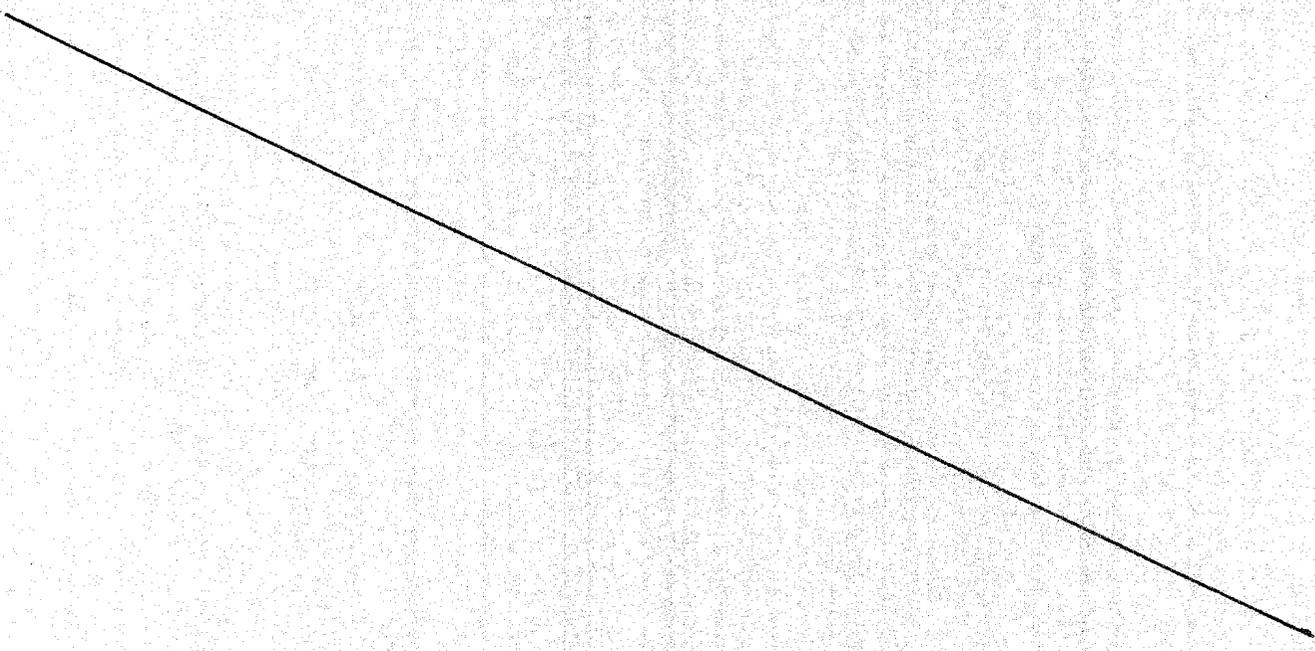
Interested persons may submit written or electronic comments on the draft guidance to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that an individual may submit one paper copy. Identify comments with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

The Center for Devices and Radiological Health (CDRH) Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

To receive a copy of "Class II Special Controls Guidance Document: Bone Sonometers," by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1547) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains a site 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.

Dated: 1/17/06
January 17, 2006.

Linda S. Kahan

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