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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled ''Class II Special Controls Guidance Document: Bone Sonometers.'' The draft guidance was developed to support the reclassification of bone sonometers from class III (premarket approval) into class II (special controls).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 This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on the draft guidance by May 16, 2006.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Bone Sonometers'' to the Division of Small Manufacturers, International, and Consumer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., 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Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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This draft guidance provides FDA's recommendations to manufacturers of bone sonometers for identifying risks to health and mitigation measures that can be taken to offset those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: January 17, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–2078 Filed 2–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0001] (formerly 03D–0001)

Guidance for Industry on Nonclinical Safety Evaluation of Pediatric Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Nonclinical Safety Evaluation of Pediatric Drug Products.'' This document provides guidance on the role and timing of animal studies in the nonclinical safety evaluation of therapeutics intended for the treatment of pediatric patients. The guidance discusses some conditions under which juvenile animals can be meaningful predictors of toxicity in pediatric patients and makes recommendations on nonclinical testing.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Karen L. Davis Bruno, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 3108, Silver Spring, MD 20993–0002, 301–796–2290.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Nonclinical Safety Evaluation of Pediatric Drug Products.'' Many therapeutics marketed in the United States and used in pediatric patients lack adequate information in the labeling for use in that population. Recent FDA regulations have focused attention on current practices for evaluating drug safety in this population. Traditionally, safety data from clinical studies in adults, supported by nonclinical studies in adult animals, have been used to support the use of a drug in pediatric patients. These studies may not always assess possible drug effects on developmental processes specific to pediatric age groups. Some effects may be very difficult to detect in clinical trials or during routine postmarketing surveillance.

In the **Federal Register** of February 3, 2003 (68 FR 5301), FDA announced the availability of a draft version of this guidance entitled ''Nonclinical Safety Evaluation of Pediatric Drug Products.'' Interested persons had the opportunity to submit comments. Based on the public comments received, changes to wording have been added for clarity and the guidance has been finalized. This document provides guidance on the role and timing of animal studies in the safety evaluation of therapeutics intended for the treatment of pediatric patients. It is intended to serve as a resource for general considerations in testing and provide specific recommendations based on available science and pragmatic considerations. The scope of this guidance is limited to safety effects that cannot be reasonably, ethically, and safely assessed in pediatric clinical trials.

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 nonclinical safety evaluation of pediatric drug products. 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 statutes and regulations.

II. 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 paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 8, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–2139 Filed 2–14–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Assessment of the Engagement of Historically Black Colleges and Universities in Campus and Community-based Activities To Eliminate Health Disparities (NEW)

The Health Resources and Services Administration (HRSA) plans to conduct a survey of 525 university administrators at Historically Black Colleges and Universities (HBCUs) to collect information not otherwise available about the extent to which HBCUs have engaged in health promoting activities on campus and in their surrounding communities that are designed to eliminate health disparities among African Americans. The results of this survey will be used by HRSA's Office of Minority Health and Health Disparities (OMHHD) to obtain information regarding the engagement of HBCUs in health disparities activities. The results of the survey will also permit OMHHD (1) to describe the origins, structure, content, and intensity of such activities, (2) to document the level of support for campus and community activities among administrative leaders at HBCUs, (3) to document the factors that facilitate or hinder the ability of HBCUs to engage in campus and community activities to eliminate health disparities, and (4) to determine whether there is a need among HBCUs for additional assistance that will allow them to expand their role and improve their effectiveness in addressing health disparities.

The survey process will include a web-based survey to be completed by targeted respondents. Follow-up