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This draft guidance provides FDA’s recommendations to manufacturers of bone sonometers for identifying risks to health and mitigation measures that can be taken to offset those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. 360c(f)(1)), 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This draft guidance is being issued consistent with FDA’s good guidance practice regulation (21 CFR 10.115). The draft guidance, if finalized, would represent the agency’s current thinking on bone sonometers.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This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995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 The collections of information addressed in the draft guidance have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB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 The labeling provisions addressed in the draft guidance have been approved by OMB under the PRA under OMB control number 0910–0485 and expires June 30, 2008.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Interested persons may submit written or electronic comments on the draft guidance to the Division of Dockets Management (see ADDRESSES).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 The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.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


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.
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/ceder/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