guidance is intended to assist sponsors in the preparation of the clinical/biostatistical and human pharmacokinetic sections of a BLA. This guidance does not address additional sections of a BLA, such as chemistry, manufacturing, and controls and pre-clinical toxicology, for an IGIV product for this indication.

In the **Federal Register** of December 1, 2005 (70 FR 72124), FDA announced the availability of the draft guidance of the same title dated November 2005. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes: Recommendations for compliance with the Pediatric Research Equity Act of 2007, refinements to the criteria for diagnosing serious infections, refinements to the recommended safety analyses of adverse experiences temporally related to infusions, and additional guidance on the methodology of pharmacokinetic studies. The guidance announced in this notice finalizes the draft guidance dated November 2005.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information regarding BLAs (21 CFR part 601) have been approved under OMB control number 0910–0338.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. 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. A copy of the 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: July 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–16395 Filed 7–16–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2003–D–0434] (formerly Docket No. 2003D–0420)

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Bone Sonometers.'' The guidance document describes a means by which bone sonometers may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying these devices from class III (premarket approval) into class II (special controls).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry and FDA Staff; 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 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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.regulations.gov*. 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, 240–276–3666.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 15, 2006 (71 FR 7894), FDA's Center for Devices and Radiological Health (CDRH) published a proposed rule to reclassify bone sonometers from class III (premarket approval) into class II (special controls) after reviewing current technological and scientific developments. Specifically, CDRH reviewed recent studies addressing performance characteristics of bone sonometers manufactured by different companies and determined that, when combined with mitigation measures to offset the risks of use associated with these devices, special controls would be adequate to assure the safety and effectiveness of bone sonometers. To support the reclassification, CDRH issued a draft class II special controls guidance document entitled ''Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Bone Sonometers'' (71 FR 7976). Interested persons were invited to comment on the proposed rule and guidance by May 16, 2006, and the agency received three comments. The comments FDA received were supportive of the proposed reclassification, but made specific suggestions on the guidance's content. The agency considered the suggestions and made appropriate revisions. FDA is now identifying the guidance document entitled ''Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Bone Sonometers'' as the guidance document that will

serve as the special control for these devices.

The guidance document provides a means by which bone sonometers may comply with the requirement of special controls for class II devices. Following the effective date of the final reclassification rule, any firm submitting a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for bone sonometers will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendation of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

II. Significance of the Guidance

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 bone sonometers. 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

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Bone Sonometers,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (1547) to identify the guidance you are requesting.

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 at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the information collections in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the information collections in 21 CFR parts 1002, 1003, and 1004 have been approved under OMB control number 0910–0025.

V. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: July 2, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–16094 Filed 7–16–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1995–N–0054] (formerly Docket No. 1995N–0304)

Small Entity Compliance Guide: Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing theavailability of a small entity compliance guide (SECG) for a final rule published in the **Federal Register** of February 11, 2004 (69 FR 6788), entitled ''Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk.'' This SECG is intended to set forth in plain language the requirements of the regulation and to help small businesses understand the regulation.

DATES: Submit written or electronic comments on the SECG at any time.

ADDRESSES: Submit written comments on the SECG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the SECG to *http://www.regulations.gov*. Submit written requests for single copies of the SECG to the Division of Dietary Supplement Programs, Office of Nutrition, Labeling, and Dietary Supplements (HFS–810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or fax your request to 301–436–2639. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the SECG.

FOR FURTHER INFORMATION CONTACT: Robert J. Moore, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2375.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 11, 2004, FDA issued a final rule declaring dietary supplements containing ephedrine alkaloids adulterated under the Federal Food,