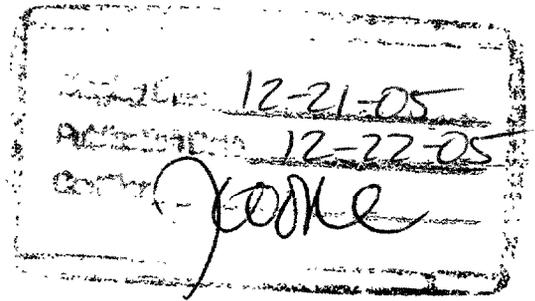


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004P-0329]

dmb



Hand-Held, Doppler Ultrasound Prenatal Listening Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop to discuss scientific information bearing on whether hand-held Doppler ultrasound prenatal listening devices should be made available for use over-the-counter (OTC). This 1-day workshop is intended to provide members of the academic, scientific, and clinical communities; industry; consumer, and patient advocacy groups; and others with a forum for presenting their perspectives about available scientific literature and clinical studies relating to hand-held Doppler ultrasound prenatal listening devices. Written comments submitted to the docket before the workshop and information gathered at the workshop will be used by FDA to further identify and evaluate the risks and benefits associated with possible OTC availability of hand-held prenatal Doppler ultrasound listening devices.

Date and Time: The public workshop will be held on Wednesday, March 29, 2006, from 9 a.m. to 3:30 p.m. The deadline for registration is Friday, March 10, 2006. Requests to make presentations at the public workshop and written or electronic comments will be accepted until Friday, March 10, 2006.

Addresses: The public workshop will be held at the Hilton Washington DC North, 620 Perry Pkwy., Gaithersburg, MD, 20877. Additional information

about and directions to the facility are available on the Internet at <http://www.hilton.com/en/hi/hotels/index.jhtml?ctyhocn=GAIGHHF>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) Submit written comments 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>.

Contact: Domini Cassis, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, e-mail: domini.cassis@fda.hhs.gov, 240-276-2342.

Agenda: At the workshop, FDA will hear presentations and oral comments from interested members of the public regarding Doppler ultrasound technology as used in hand-held prenatal listening devices. FDA anticipates that presenters may include representatives from the academic, scientific, and clinical communities; device, drug, and biological product manufacturers; consumer and patient advocacy groups; and others.

Registration and Requests for Presentations: There is no fee to attend this public workshop; however, registration is required. The deadline for registration is Friday, March 10, 2006. Early registration is recommended, as seats are limited. Space will be filled in order of receipt of registration. There will be no on-site registration. Please submit registration information (including name, title, firm name, address, e-mail address, telephone number, and fax number) by March 10, 2006 (see *Contact*). Interested persons who are unable to attend the workshop are encouraged to submit written comments (see *Request for Comments*).

Those who wish to make presentations during the public workshop should submit written notification including the following: (1) The specific issue(s) you intend to address; (2) the names and addresses of all individuals that will participate in your presentation; (3) the approximate amount of time your presentation will require; and (4) two copies of all presentation materials to Domini Cassis by March 10, 2006. Presentations will be limited to the topics outlined in the **SUPPLEMENTARY INFORMATION** section of this document and, depending on the number of speakers, FDA may limit the time allotted for each presentation. If you need special accommodations due to a disability, please contact Anne Marie Williams at 301-594-1283 at least 7 days in advance of the workshop.

Request for Comments: Interested persons may submit to the Division of Dockets Management (see *Addresses*) written or electronic comments regarding this document. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Transcripts: Following the workshop, transcripts will be available for review at the Division of Dockets Management (see *Addresses*).

SUPPLEMENTARY INFORMATION:

I. Background

Since July 2002, FDA has received three citizen petitions requesting that it grant OTC status to hand-held prenatal listening devices that produce no more than 20 mW/cm² of Doppler ultrasound intensity (FDA Docket Nos. 2002P-0338, 2003P-0438, and 2004P-0329.) Currently, these products are

class II devices that are legally available only by prescription. FDA denied petitions 2002P-0338 and 2003P-0438, citing its concern over the safety of exposing a developing fetus to Doppler ultrasound without the order or instruction of a physician, and referencing the following studies:

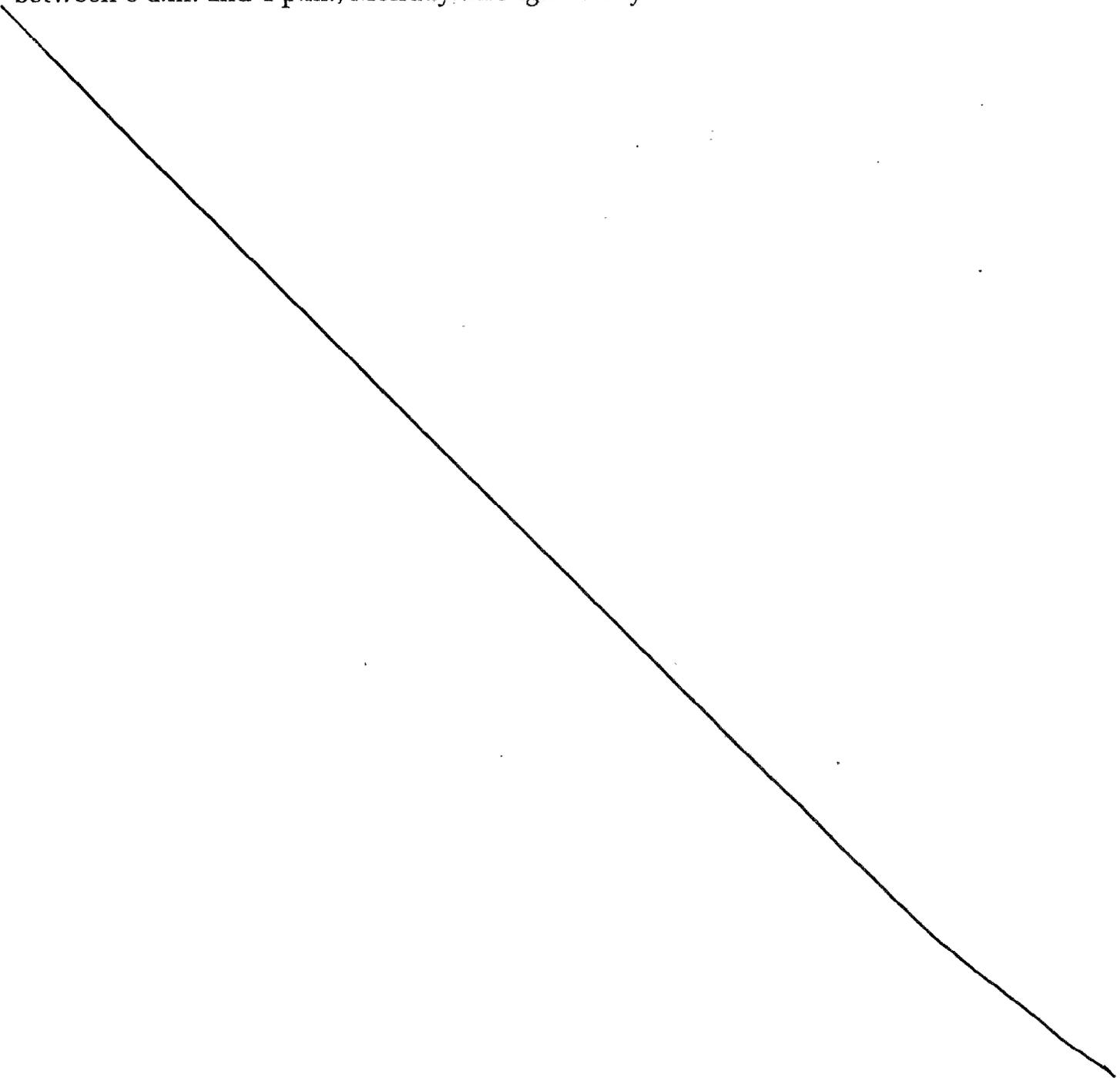
1. "Sinistrality—A Side-Effect of Prenatal Sonography: A Comparative Study of Young Men." Keiler, H., et al.; *Epidemiology*; 12:618–623 (2001).
2. "Acceleration of Fresh Fracture Repair Using the Sonic Accelerated Fracture Healing System (SAFHS): A Review." Warden, S.J., et al.; *Calcified Tissue International*; 66:157–163 (2000).
3. "Acceleration of Tibial Fracture-Healing by Non-Invasive, Low Intensity Pulsed Ultrasound." Heckman, J., et al.; *Journal of Bone and Joint Surgery*; 76A:26–34 (1994).
4. "Accelerated Healing of Distal Radial Fractures With the Use of Specific, Low-Intensity Ultrasound. A Multicenter, Prospective, Randomized, Double-Blind, Placebo-Controlled Study." Kristiansen, T., et al.; *Journal of Bone and Joint Surgery*, 79A:961–973 (1997).
5. "Routine Ultrasound Screening in Pregnancy and the Children's Subsequent Handedness." Kieler, H., et al.; *Early Human Development*; 50:233–245 (1998).

FDA reiterated its concerns in response to the most recent petition, 2004P-0329, but agreed to hold a public workshop in which relevant issues surrounding the proposal for OTC sales, distribution, and unsupervised use of these devices could be discussed. This public workshop is not intended to address legal or regulatory issues. Rather, FDA intends to collect information from outside experts and stakeholders that could help the agency better identify and evaluate the risks and benefits of uncontrolled exposure to

Doppler ultrasound energy introduced through hand-held prenatal listening devices.

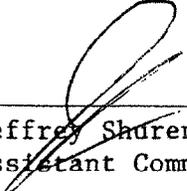
II. References

The above references have been placed on display in the Division of Dockets Management (see *Addresses*) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.



Dated: 12/16/05
December 16, 2005.

ch0562



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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