DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 19 2003

Russel J. Thomsen, M.D.
11018 Peony Place NW
Silverdale, Washington 98383

Re: 02P-0338

Dear Dr. Thomsen:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition dated July 29, 2002. In your petition you request that the Commissioner of Food and Drugs grant over-the-counter (OTC) sales, distribution, and use status to ultrasound prenatal listening devices, otherwise called Doppler fetoscopes, having a maximum Doppler ultrasound output no greater than 20mW/cm^2. We apologize for the delay in responding to your petition. After carefully reviewing all relevant information, we have concluded that we must deny your petition for the reasons discussed below.

I. Preamendment Status

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. § 360c(f)), devices that were in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments (the amendments), are considered preamendment devices by the FDA. You maintain that the technology underlying hand-held, battery powered Doppler fetoscopes predates the amendments, that these devices were manufactured both in the United States and abroad, and widely sold and used in the United States without FDA regulation or control. As examples, you provided information regarding the "Pocket Sonicaid," Medsonics' "FP3A Ultrasound Stethoscope," and Oxford's "hand-held ultrasonic fetal heart detector."

While it is true that these devices were in commercial distribution before enactment of the amendments, there is no evidence to suggest these devices were available for OTC use. First, the material you provided referencing devices or technology by Sonicaid, Oxford Instruments, and Medsonics, Inc. are promotional materials, so the absence of a prescription statement in these advertisements does not mean that these products were sold over-the-counter. Further, these promotional materials discuss diagnostic applications clearly intended for a professional audience. Specifically, Sonicaid, advertising in Contemporary Ob/Gyn magazine, represents that its device can be used for "early diagnosis of multiple pregnancy," "location of placenta

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prior to amniocentesis," and "identification of umbilical cord flow." Similarly, Medsonics, Inc. states that its instrument is used for "the detection of fetal life," "confirms fetal life throughout pregnancy," and "augments the obstetrician's diagnostic skill." In fact, Oxford Instruments describes itself as a "patient monitoring company that serves health care professionals working in cardiology, neurophysiology and obstetrics."

II. Prescription vs. OTC Use

In both your petition and supplemental correspondence you state that FDA should grant OTC access to these devices because they have been used safely and effectively for years. You further assert that FDA's decision to classify hand-held Doppler fetoscope devices was made under invalid scientific and medical assumptions. Finally, you state that the Agency wrongly considered it dangerous for a woman to hear the sounds of her unborn baby. I will try to address each of your assertions and explain why FDA does not find them persuasive.

FDA regulations (21 C.F.R. § 801.109) state that a prescription device is one that is not safe except under the supervision of a practitioner licensed by law due to a potential for harmful effect or the collateral measures necessary to its use. Doppler fetoscopes have been used safely while being used under the supervision of health care professionals. OTC purchase and use of Doppler fetoscopes by a lay user raises new issues of safety and effectiveness.

These products introduce acoustic energy into the body. The potential for adverse effects from long-term exposure to the fetus in early pregnancy are unknown. For example, there are some studies that suggest exposure to diagnostic ultrasound during pregnancy can have an effect on human development. (Keiler et al., Early Human Development 50:233-245 (1998); Keiler et al., Epidemiology 12:618-623 (2001).) You may also be aware of ultrasound bone healing devices that operate at frequencies and output levels similar to those of ultrasound Doppler monitors. These devices have been shown to produce biological effects in humans when used for only 20 minutes daily. (Duarte, L.R., Arch. Orthop. and Trauma Surg., 101:153-159 (1983).) The agency has concluded that unsupervised exposure to ultrasound may pose a risk to the health of the mother or a developing fetus. This is particularly true when the exposure may be of uncontrolled duration, and may occur at any and all times, including early pregnancy. Moreover, since this device does not provide an image, the user will have no idea what parts of the fetus are being subjected to the possible risk associated with prolonged exposure.

FDA has seen no evidence that there are benefits that would outweigh these possible risks associated with OTC availability of fetal ultrasound devices. The materials you have provided do not establish that OTC purchase and use of these products would result in any medical benefit to the fetus or the mother. FDA cannot rely upon the

absence of specific adverse events as a basis to determine that repeated, prolonged, and unsupervised ultrasound is safe. In the absence of any valid scientific evidence to support a benefit to the fetus or the mother, it would be the burden of the manufacturer to establish that a hazard does not exist in order for the agency to conclude that the device can be safely marketed to lay users.

III. Privacy Issues.

FDA's responsibility under the Federal Food, Drug, and Cosmetic Act is to ensure that the public has access to safe and effective products. FDA's decision about the safety and effectiveness of medical products, including the review of Doppler fetoscopes, is not intended to impinge on the constitutional rights of consumers.

IV. Present Day OTC Use.

Your petition recognizes the OTC availability of other acoustic pre-natal listening devices, but you argue that these devices are unreliable and inferior. You suggest, alternatively, that hand-held Dopplers be made available OTC, but only those devices which have a maximum output no greater than 20mW/cm^2. At the same time, you contend that "there always has been totally unrestricted (by the FDA) use of [D]oppler fetoscopes in the home or outside the medical profession." Finally, you contend that these devices should be made available OTC so a woman can hear the sounds of her unborn baby.

Ultrasound Doppler fetal heart rate monitors, unlike passive pre-natal listening devices, introduce acoustic energy into the body. As discussed above, FDA disagrees with your assumption that the relatively low level of energy output is sufficient to qualify them for OTC availability without evidence that there is benefit to outweigh potential risks to mother and fetus.

FDA also disagrees with your statement that there is and always has been unrestricted use of these products outside a medical setting. They are available only by prescription because of the agency's determination that their safe use requires the supervision of a licensed practitioner. The agency's regulations require the manufacturer to place a prescription label on the devices (see 21 U.S.C. § 352(r).) Failure to do so may result in regulatory action under the Federal Food, Drug, and Cosmetic Act. A supplier who sells a Doppler fetoscope without proof of a prescription will be subject to the regulatory controls of the state in which the violation occurred because each state determines who is licensed to prescribe or use devices. In the event that the FDA would uncover such activity, we would refer the matter to the appropriate state authority for

follow-up. We appreciate and will evaluate your information about ongoing Internet promotion and sales of OTC fetal Doppler devices.

While I agree that women want to hear their unborn babies, I do not believe that consumers would purchase devices enabling them to achieve that purpose if the device might potentially cause harm to the fetus through uncontrolled and unlimited use. The agency believes that professional health care providers should determine when circumstances indicate hand-held acoustic ultrasound devices may contribute to helping mothers properly monitor the progress of their pregnancy or "save the life of their unborn babies." The prescription status of these products ensures that women will have professional guidance to use these devices, as appropriate, to contribute to the well-being of the mother and fetus.

V. Conclusion.

FDA has carefully considered the information provided in your petition. For the reasons discussed above, the agency has concluded that the interest of public health would not be served by making hand-held Doppler fetoscopes available over-the-counter. If you have any questions about this response, please contact Mr. Joseph M. Sheehan at 301-827-2974.

Sincerely,

Linda S. Kahan
Deputy Director
Center for Devices
and Radiological Health