DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

0022 5 MAR 24 P1:54

February 25, 2005

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

Re: 2004P-0329

Dear Dr. Thomsen:

This is in response to the petition you filed with the Food and Drug Administration on July 12, 2004, requesting that the Commissioner of Food and Drugs hold public hearings to consider the appropriate regulatory status for Doppler hand-held fetal heart listening devices, also referred to as Doppler fetoscopes. Specifically, you request that hand-held fetoscopes producing a maximum Doppler ultrasound output less than or equal to 20mW/cm^2 be subject to labeling and design requirements that would permit over-the-counter (OTC) use of these devices.

As we explained in response to your previous petitions, 2002P-0338 and 2003P-0438, your request to permit OTC use of these devices raises significant considerations regarding the safety of exposing a developing fetus to Doppler ultrasound without the order or instructions of a physician. FDA has concluded that additional guidance from outside experts could help the agency better identify and evaluate the risks and benefits that may result from such exposures. CDRH, therefore, is planning to convene a public meeting to discuss these issues. When that meeting is arranged and scheduled, we will inform you and all other interested parties of the venue and the opportunity for public presentations. FDA expects to publish a notice announcing a meeting in the public register within the next several months.

If you have any questions about this response, please contact Ms. Domini Cassis at 301-827-2964.

Sincerely yours,

Linda S. Kahan

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

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