29 July 2002

To:

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The Commissioner
Food and Drug Administration

Through:

Documents Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

CITIZEN PETITION

The undersigned submits this petition under relevant statutory sections of the Federal Food, Drug and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10) to request the Commissioner of Food and Drugs to revoke any regulation of prenatal listening devices commonly called "doppler fetoscopes".

A. Action requested

The Commissioner is asked to grant Over-the-Counter sales, distribution and use status to any and all brands of hand-held doppler fetoscopes which have a maximum doppler ultrasound output of no greater than 20mw/cm2. OTC labeling of these devices should be dictated by common sense and scientific knowledge.

B. Statement of Grounds

1. Hand held, battery powered doppler fetoscopes predate by a number of years the May 28, 1976 enactment of Medical Device Amendments by the Food and Drug Administration. Not only did the technology predate the Ammendments (making them "Pre-Amendment Devices), but they were manufactured both in the United States and imported for sale and use in the United States. Such Pre-Amendment devices include the English made Sonicaid and the American made Medsonics FP3A. Both of these devices were widely sold and used in the United States without FDA restriction, requirement of a Prescription or any other control.

2. The FDA classification of hand-held doppler fetoscopes as devices was made by default at the time of the May 28, 1976, Amendments under the general assumption that "Radiation emitting" devices were inherently needing of FDA regulation. This was not, of course, scientifically or medically valid at the time,

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nor have subsequent decades of use given any reason to validate that action (non-action).

3. There was a time (such as before 1970) when both medical professionals and the FDA considered it somehow possibly alarming or dangerous for a woman to hear the sounds of her unborn baby (even in a medical examining room). Hence, many of the early doppler fetoscopes had additional head-listen sets so only the doctor could hear the heartbeat. This logic was discarded by the medical profession by the early 1970's as pre-natal education, home delivery and educated patients became the norm.

4. The landmark ruling in 1973 of Rowe v Wade established that women have distinct rights to privacy related to their reproductive health. This, without doubt, gives women (and others they allow) the absolute right to listen to their unborn babies in the private surroundings of their own choosing. Regulatory opinion by the FDA to the quantrary without evidence of harm to mother or unborn is clearly unconstitutional.

5. The FDA has allowed without restriction the sale of hundreds of thousands of acoustic pre-natal listening devices under such names as BeBe Sounds or the Fischer-Price Pre-Natal to Nursery Monitor for home use. These are unreliable and inferior as listening devices. They are all imported, usually from China, and face no import or distribution FDA regulation.

6. Finally, the reality is that there always has been totally unrestricted (by the FDA) use of doppler fetoscopes in the home or outside the medical profession. The illusion that there has been FDA regulation has only served to keep the pricing of the devices at the hugely inflated "medical device" rate. These devices (under such OTC names as BabyBeat or Stork Radio) are identical to those sold to medical professionals. Not only are they sold through magazine ads, but widely through Internet sites and through auctions such as Ebay.com. Thousands of these devices are openly sold, without any evidence being developed through FDA postmarketing reporting of any danger or misuse. To the contrary, there are at least anecdotal reports of life-saving interventions being instituted because of the home use of doppler fetoscopes.

With over three decades of experience in the care of pregnant women, I know of know reason to restrict, through FDA regulations, their right to hear their unborn babies' hearts. I also know the regulatory and scientific history of this subject back to the early 1970's. From it I also conclude that the Commissioner should grant OTC status to hand held doppler fetoscopes. I also know the history of the Device Amendments enacted in 1976, and know that their intent was not to limit the privacy or health care decisions of women.

C. Environmental impact

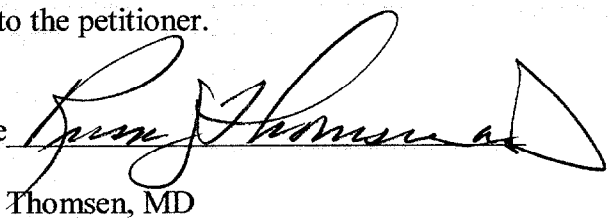
There are no issues about the OTC sales of doppler fetoscopes which would impact the environment.

D. Economic Impact

The economic impact would be a decrease in the retail sales price of hand held doppler fetoscopes so that all women, regardless of social-economic status, could listen to their unborn babies in the private surroundings of their choosing. Furthermore, this would, potentially put in their hands an item which might save the life of their unborn babies.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data, and information, known to the petitioner which are unfavorable to the petitioner.

Signature 

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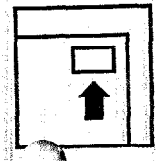
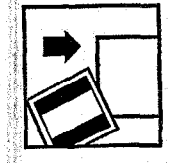
HOW TO USE:

1. COMPLETE ADDRESS LABEL AREA
Type or print required return address and addressee information in customer block (white area) or on label (If provided).



2. PAYMENT METHOD
Affix postage or meter strip to area indicated in upper right hand corner.



3. ATTACH LABEL (If provided)
Remove label backing and adhere over customer address block area (white area).

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