

Draft

March 8, 2006

Ms. Domini Cassis
Regulatory Counsel, CDRH
U.S. Food and Drug Administration
1350 Piccard Dr.
Rockville, MD 20850

Dear Ms. Cassis:

In holding this public workshop to discuss whether hand-held Doppler ultrasound prenatal listening devices should be made available for use over-the-counter (OTC), the FDA has asked for 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.

We would like to address some of the benefits to mothers when using hand-held Dopplers at home during pregnancy. I will discuss:

- Brief background of BabyBeat and the market of mothers using Dopplers at home.
- Results of a recent survey conducted by BabyBeat of mothers using Dopplers at home.
Attached are the survey questions. There is also the additional comments section that will be discussed.

If you need additional information please let me know.

Sincerely,

Stacie Hansen