

TruHearing

Bringing You the Sounds of Life

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December 16, 2003

Food and Drug Administration
Dockets Management Branch
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: FDA Dockets 2003P-0362; Comments in Support of Citizen Petition

Dear Sir or Madam:

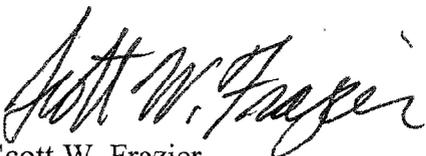
The following comments are submitted in support of the citizen petition submitted by Mead C. Killion, Ph.D., of Etymotic Research, Inc. (2003P-0362) ("Killion Petition").

The Killion Petition requests that the Commissioner of the FDA create a new over-the-counter hearing aid classification to allow OTC sale of hearing aids that meet FDA safety and efficacy requirements.

We support the Killion Petition for the following reasons:

1. There are now high quality hearing aids available for mild or moderate hearing loss that do not require professional fitting. We sell two of these products, and also sell traditional hearing aids.
2. There is little harm that can be done with an individual purchasing and using such a product without involvement from an audiologist or other medical personnel. Realistically, a the worst that could happen is that he could push ear wax deeper into his ear canal necessitating a visit to the family doctor for cerumen removal.
3. The hearing aids suitable for OTC distribution are a very good value to the consumer. The cost per year, per ear, is about \$250 vs at least \$500 per year, per ear, for a traditional hearing aid when cleaning, repair, etc. is included.

Yours truly,


Scott W. Frazier
President

2003P-0362

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