DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Office of Orphan Products Development *(HF-35)*
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

FEB 2 4 '97

February 18, 1997

The Ear Foundation
2420 Castillo Street, Suite 100
Santa Barbara, CA 93105

Attention: Joseph DiBartolomeo, M.D.

Dear Dr. DiBartolomeo:

Reference is made to your orphan drug application of April 23, 1996 submitted pursuant to section 526 of the Federal Food, Drug, and Cosmetic Act for the designation of Patul-End as an orphan drug (application #96-988). We also refer to your amendments dated October 30, 1996 and January 21, 1997.

We have completed the review of this application, as amended, and have determined that Patul-End qualifies for orphan designation for the treatment of severe patulous eustachian tube. Please note that it is Patul-End and not its formulation that has received orphan designation.

Prior to marketing approval, sponsors of designated orphan products are requested to submit written notification to this Office of their intention to exercise orphan drug exclusivity if they are the first sponsor to obtain such approval for the drug. This notification will assist FDA in assuring that approval for the marketing of the same drug is not granted to another firm for the statutory period of exclusivity.

Also please be advised that if Patul-End were approved for an indication broader than the orphan designation, your product might not be entitled to exclusive marketing rights pursuant to Section 527 of the FFDCA. Therefore, prior to final marketing approval, sponsors of designated orphan products are requested to compare the designated orphan indication with the proposed marketing indication and to submit additional data to amend their orphan designation prior to marketing approval if warranted.

Finally, please notify this Office within 30 days of submission of a marketing application for the use of Patul-End as designated. Also an annual progress report must be submitted within 14 months after the designation date and annually thereafter until a marketing application is approved [21 CFR 316.30]. If you need further assistance in the development of your product for marketing, please feel free to contact Dr. Donald R. Haggerty at (301) 827-0986.