NDA 20-221/S-012 JUN 24, 1999

US Bioscience
One Tower Bridge
100 Front Street
West Conshohocken, PA 19428

Attention: Eve Damiano
Director, Regulatory Affairs

Dear Ms. Damiano:

Please refer to your supplemental new drug application dated December 23, 1998, received December 24, 1998, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Ethyol for Injection.

We acknowledge receipt of your submissions dated as follows:

27 January 99	22 March 99
28 January 99	28 April 99
10 February 99	01 June 99
23 February 99	

This supplemental new drug application provides for the use of Ethyol to reduce the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer, where the radiation port includes a substantial portion of the parotid glands (see Clinical Studies).

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-221/S-012." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to

use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Maureen Pelosi, Project Manager, at (301) 594-5778.

Sincerely,

Robert L. Justice, M.D.
Acting Director
Division of OncologyDrug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research