

23 August 2002

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Attention: Jennie Butler  
5630 Fishers Lane  
HFA-305, Room 1061  
Rockville, Maryland 20852

**Re: Docket Number 75N-183H/CP 3 – Supplemental Petition Supporting April 6, 2000 Citizen Petition to Request FDA Find Benzalkonium Chloride (0.11%-0.13%) is Generally Recognized as Safe and Effective as Defined by the Tentative Final Monograph for Health-Care Antiseptic Drug Products**

Dear Ms. Butler:

On April 6, 2000 the undersigned Company submitted a petition requesting that FDA find benzalkonium chloride (0.11%-0.13%) is generally recognized as safe and effective under the Tentative Final Monograph for health-care antiseptic drug products. In this supplemental petition, International Laboratory Technology Corporation (ILTC) is submitting additional testing data from BioScience Laboratories, Inc. as requested by Tia Frazier and Debbie Lumpkins. I do not think they were able to put it in the specific form requested (FAS), but BioScience felt this should provide you with the information necessary to complete your review.

Based on the data from ILTC's testing and other available data, FDA should find that benzalkonium chloride is generally recognized as safe and effective for use as the active ingredient in an OTC antimicrobial hand wash. If the Agency would like to discuss the data submitted, please feel free to contact us.

Respectfully submitted,



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**QALTC**

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