

February 4, 2003

Ms. Tia Frazier
Division of Over-The-Counter Drug Products
Food and Drug Administration
5600 Fishers Lane
Rockville. Maryland 20857

Dear Ms. Frazier,

At the request of Mr. Kip Rabin, ILTC, I am responding to your request for additional information regarding testing performed for ILTC by BioScience Laboratories, Inc. (BSLI) (Fax dated January 30, 2003).

Regarding testing performed for International Laboratory Technology Corporation:

- 1. Study #990829 was the only pivotal Healthcarc Personnel Antiseptic Handwash study performed by BSLI for International Laboratory Technology Corporation.
- 2. Of the total of eight (8) data sets sent, Study #990829 is the only one that should be used in the Efficacy Evaluation of the Citizens' Petition for the Healthcare Personnel Antiseptic Handwash.

If I can be of further assistance, please do not hesitate to contact me.

Michael Douglas

Director of Sales & Marketing BioScience Laboratories, Inc.

P.O. Box 190

Bozeman, Montana 59771

MD/eb

Cc:

Kip Rabin

International Laboratory Technology Corporation

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH

DATE:	
FROM:	Director Division of OTC Drug Products, HFD-560
SUBJECT:	Material for Docket No. 75N 183H
TO:	Dockets Management Branch, HFA-305
	The attached material should be placed on public display under the above referenced Docket No.
	This material should be cross-referenced to Comment No.
	Carles Handy
	reference CP3 Charles J. Ganley, M.D.

Attachment