



2550 M Street NW
Washington, DC 20037 1350
202-457-6000

Facsimile 202-457-6315
www.pattonboggs.com

October 21, 2002

Daniel A. Kracov
(202) 457-5623
dkracov@pattonboggs.com

VIA COURIER

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Resources
5630 Fishers Lane
Room 1061
Rockville, MD 20857

**Re: Docket No. 75N-183H; Topical Antimicrobial Drug Products for OTC Use;
Tentative Final Monograph for First Aid Antiseptic Drug Products**

Dear Sir/Madam:

On behalf of our client, Lonza Inc., we are submitting the following additional information to support our previously filed Citizen Petition requesting that the Food and Drug Administration ("FDA") re-open the administrative record to allow for the evaluation of data supporting the Category I safety and efficacy classification of benzethonium chloride ("BZC") in the topical antimicrobial drug products for over-the-counter ("OTC") use monograph for health-care antiseptic drug products. The enclosed information includes:

- (1) November 30, 2000, Final Report, "Determination of the Antimicrobial Efficacy of One Test Product and one Reference Product Using Health Care Personnel Handwash Procedure." The data demonstrated that both the test (an antimicrobial handwash with 0.2% benzethonium chloride) and reference products showed significant log₁₀ reductions in bacterial populations from baseline populations;
- (2) November 30, 2000, Final Report, "Evaluation of One Test Product for Its Antimicrobial Properties When Challenged from Various Microorganism Strains Using an In-Vitro Time-Kill Method." This study used an In-Vitro Time-Kill method to evaluate the antimicrobial properties of the test product when challenged with fifty different microorganism strains – twenty-five

75N-183H

SUP7

Dockets Management Branch

October 21, 2002

Page 2

ATCC strains and twenty-five Clinical Isolates of those same species and fifteen second and thirty second exposure times; and

- (3) November 30, 2000, Final Report, "Determination of the Minimum Inhibitory Concentration (MIC) of One Product When Challenged with Various Microorganism Strains Using the Macrodiultion Broth Method." This study evaluated the MIC of one test product when challenged with fifty different microorganism strains.

These data should further support the safety and efficacy of BZC and permit FDA to make a final determination to include BZC as a permissible ingredient in any final health-care antiseptic monograph. Thank you for your consideration of this information.

Sincerely,



Daniel A. Kracov
Counsel to Lonza Inc.

Enclosures



1113 02 OCT 24 16:40

2550 M Street, NW
Washington, DC 20037 1350
202-457-6000

Facsimile: 202-457-6315
www.pattonboggs.com

October 23, 2002

Daniel A. Kracov
(202) 457-5623
dkracov@pattonboggs.com

VIA FACSIMILE

Ms. Helen Harris
Dockets Management Branch
Food and Drug Administration
Department of Health and Human Resources
5630 Fishers Lane
Room 1061
Rockville, MD 20857

**Re: Docket No. 75N-183H; Topical Antimicrobial Drug Products for OTC Use;
Tentative Final Monograph for First Aid Antiseptic Drug Products**

Dear Ms. Harris:

On behalf of our client, Lonza Inc., on October 21, 2002, we submitted the following information:

- (1) November 30, 2000, Final Report, "Determination of the Antimicrobial Efficacy of One Test Product and one Reference Product Using Health Care Personnel Handwash Procedure)."
- (2) November 30, 2000, Final Report, "Evaluation of One Test Product for Its Antimicrobial Properties When Challenged from Various Microorganism Strains Using an In-Vitro Time-Kill Method;" and
- (3) November 30, 2000, Final Report, "Determination of the Minimum Inhibitory Concentration (MIC) of One Product When Challenged with Various Microorganism Strains Using the Macrodilution Broth Method."

These materials were inadvertently marked as "confidential." The information is not confidential and was provided to us by Lonza Inc. to be submitted to FDA. Please contact me at (202) 457-5623 if you have any additional questions about this information.



Ms. Helen Harris
October 23, 2002
Page 2

2550 M Street, NW
Washington, DC 20037-1350
202-457-6000

Facsimile 202-457-6115
www.pattonboggs.com

Thank you for your time and attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Kracov', written over a horizontal line.

Daniel A. Kracov
Counsel to Lonza Inc.

Submission of Lonza, Inc

Re Docket No 75N 183H, Topical
Products for OTC Use; Tentative P
for First Aid Antiseptic Drug Produc

October 21, 2002

Volume 1



BIO SCIENCE
LABORATORIES • INC

November 30, 2000

FINAL REPORT #000918

**DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF
ONE TEST PRODUCT AND ONE REFERENCE PRODUCT USING
THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

Prepared for:

FIRST SCIENTIFIC (SPONSOR)
1877 West 2800 South, Suite 200
Ogden, Utah 84401

Prepared by:

BIO SCIENCE LABORATORIES, INC. (COMPANY)
300 North Willson Avenue
Bozeman, Montana 59715
(406) 587-5735

Copy # _____



Ms. Helen Harris
October 23, 2002
Page 2

2550 M Street, NW
Washington, DC 20037-1750
202-457-6000

Facsimile 202-457-6115
www.pattonboggs.com

Thank you for your time and attention to this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Kracov", written over a horizontal line.

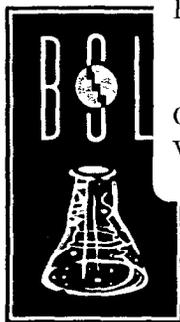
Daniel A. Kracov
Counsel to Lonza Inc.

Submission of Lonza, Inc.

Re: Docket No. 75N-183H; Topical Antimicrobial Drug
Products for OTC Use; Tentative Final Monograph
for First Aid Antiseptic Drug Products

October 21, 2002

Volume 1



BIO SCIENCE
LABORATORIES • INC

November 30, 2000

FINAL REPORT #000918

**DETERMINATION OF THE ANTIMICROBIAL EFFICACY OF
ONE TEST PRODUCT AND ONE REFERENCE PRODUCT USING
THE HEALTH CARE PERSONNEL HANDWASH PROCEDURE**

Prepared for:

FIRST SCIENTIFIC (SPONSOR)
1877 West 2800 South, Suite 200
Ogden, Utah 84401

Prepared by:

BIO SCIENCE LABORATORIES, INC. (COMPANY)
300 North Willson Avenue
Bozeman, Montana 59715
(406) 587-5735

Copy # _____