



APPENDIX I

Total number of pages = 13

**IRB Approval Letter, Approved Consent Forms,
Subject Instructions and IRB Membership Directory**

INSTITUTIONAL REVIEW BOARD

OF

HILL TOP RESEARCH, INC.

Nancy J. Pelc, M.D., Chairman

PROJ. NO.	03-122085-106
PAGE NO.	I-1

July 14, 2003

E. Linn Jones, M.D., D.A.B.D.
Hill Top Research, Inc.
Main and Mill Streets
Miami, OH 45147

Ref: 03-122085-106
Title: EFFICACY EVALUATION OF HEALTH CARE PERSONNEL
HANDWASH PRODUCTS
Protocol Date: July 10, 2003
Sponsor: Bayer Chemicals Corporation

Dear Dr. Jones:

The Institutional Review Board of Hill Top Research, Inc. has reviewed and approved the above referenced study by the expedited review procedure. Documents included in this review were: protocol, consent forms (2), subject instructions and safety information. Approval of this study has been granted for one year from the date of this letter.

Please remember that the FDA requires you to receive approval from the IRB for any amendments or changes in the protocol or consent form and for any new advertisements. Serious and unexpected adverse experiences and unanticipated problems involving risk to subjects must be reported promptly to the IRB. If the study is expected to last beyond the one-year approval, you must request re-approval for continuation at least 30 days in advance of the expiration date.

The Institutional Review Board of Hill Top Research, Inc. is a duly constituted institutional review board under CFR, Title 21, Parts 50 and 56.

Sincerely,



7-14-03

Nancy J. Pelc, M.D.
Chairman

Date

NJP/sll

Institution: Hill Top Research, Inc.
Investigator: E. Linn Jones, M.D., D.A.B.D.
Study Title: "Efficacy Evaluation of Health Care Personnel Handwash Products"

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CONSENT FORM

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to measure the ability of three liquid soap products to reduce the number of bacteria on the hands after repetitive use. Approximately one hundred fifty (150) people between and including the ages of 18 – 65 will be screened as potential subjects in this study. Ninety (90) subjects are expected to complete the three-visit study.

TEST ARTICLES: Two experimental liquid soap products and one marketed antibacterial liquid soap product are being tested in this study. You will be assigned to one of the three liquid soap products. Two out of every three subjects will be assigned to one of the experimental liquid soap products.

STUDY PROCEDURES: Prior to enrollment in the test, you will be asked to complete this consent form and a brief medical history questionnaire. It is possible that you may not be able to participate based on your answers to these questions. If you qualify, you will have your blood drawn (approximately 1 teaspoon) to check your blood count. Your lab results will be reviewed prior to your return to the lab. If you do not qualify, you will be contacted.

You will also be given a kit containing non-antibacterial bar soap, shampoo, Ban® antiperspirant/deodorant, and rubber and poly gloves to be used at least one week prior to the start of the actual study. You will be given written instructions on how to use the kit.

After at least one week, you will be required to return to the lab. You will be asked to complete another brief medical history questionnaire. It is possible that you may not be able to participate based on your answers to these questions or the condition of the skin on your hands and wrists. You will wash your hands with a non-medicated soap. Then, your hands will be contaminated with a watery liquid containing bacteria (*Staphylococcus aureus* or *Serratia marcescens*). This liquid containing the bacteria will be spread over the surfaces of the hands, and the hands will be allowed to air dry. Following air drying, the hands will be sampled. Sampling is accomplished by having you place your hands into large plastic bags to which will be added a mild soap-like solution. A laboratory technician will massage each bagged hand for one minute. The hands will be removed from the bags and the solution from each bag will be tested to determine the number of test bacteria added to the hands. Following the baseline sampling, your hands will be washed with

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a non-medicated soap, rinsed with tap water and dried. You will then begin the treatment part of the study. Prior to each treatment, your hands will be contaminated with bacteria as described above. Your hands and wrists will then be treated (washed) with the test material, following specific instructions. Your hands will be contaminated and treated eleven (11) times. Your hands will be sampled (to determine the number of bacteria removed or killed by treatment) after the 1st and 11th washes. After the 1st sampling wash, the hands are rinsed with tap water and washed with a non-medicated soap and dried. Following the last sampling, your hands will be rinsed with water, washed with Hibiclens®, an antimicrobial soap, treated with alcohol, and possibly treated with Polysporin® prior to leaving the lab.

After completing the treatment visit and until your follow-up visit, you will need to check the skin on your hands each day for any pimples, bumps or rashes. Within four to eight days after you have completed treatment, you will be required to return to the lab for a follow-up visit. Your hands will be checked for infection by a Dermatologist trained in observing infection. If your hands develop irritation or a skin infection, you will be required to return to the laboratory for an extra visit to verify that the skin infection is cleared.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study.

RISKS: The risks associated with this test are primarily related to contamination with the test bacteria. There is the possibility of a getting a skin infection. Approximately 25% of study participants develop a skin infection. For most study participants, no treatment is required.

Though these bacterial strains are considered relatively harmless, testing has been conducted to find antibiotics that are effective in treating infections it may cause.

You may also develop a reaction on your hands and forearms from the test materials. A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, blistering. If you have extremely sensitive skin, your hands and forearms may develop minor irritation that should lessen after treatment is completed. Also, accidental eye contact may cause minor discomfort and the affected eye should be rinsed thoroughly with water. No risks to you as a study participant, other than those described above, are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

You may experience risks or side effects that are not known at this time. You will be informed in a timely manner if new information becomes available that may influence your willingness to continue in this study.

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BENEFITS: You will not benefit from the applications of test articles but the study results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study records. The records will be coded to protect your identity. In addition, the sponsoring company, the Institutional Review Board (IRB) and government regulatory agencies, including the U.S. Food and Drug Administration (FDA), may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Glenna, at 513-831-3114 ext. 2920 during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at 513-831-3354 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at 1-513-831-3114.

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VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to follow study instructions, your participation may be ended.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid \$95.00 for the completion of this study. You will be compensated according to the following schedule:

If you are eliminated prior to the blood draw	Visit 1	You will receive	\$10.00
If you complete	Visit 1	You will receive	\$25.00
If you do not qualify	Visit 2	you will receive	\$30.00
If you qualify but are eliminated as an extra subject	Visit 2	you will receive	\$35.00
If you complete	Visit 2	you will receive	\$60.00
If you complete	Visit 3	you will receive	\$95.00*

* If an extra visit is required, to insure that your hands are clear of irritation or skin infection, you will be paid an additional \$10.00. (You will not be permitted to enroll on another clinical study until your skin is clear)

Payments will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you. (Soap, shampoo, antiperspirant/deodorant and gloves)

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Institution: Hill Top Research, Inc.
Investigator: E. Linn Jones, M.D., D.A.B.D.
Study Title: "Efficacy Evaluation of Health Care Personnel Handwash Products"
Neutralizer Validation Study

HTR Study No. 03-122085-106

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CONSENT FORM-2

INTRODUCTION: You are being asked to take part in a research study. Before you give your consent to be a subject, it is important that you take enough time to read and understand what your participation would involve. In preparing this consent form, it has been necessary to use some technical language. Please ask questions if there is anything you do not understand.

You will be given a signed copy of this consent form and any other necessary written information prior to the start of the study.

PURPOSE: The purpose of this research study is to assure that the materials used in the main study, for growing and counting bacteria recovered from the hands of subjects, will allow the growth of the bacteria. Approximately twelve (12) people between and including the ages of 18 - 65 will be screened as potential subjects in this study. Nine (9) subjects are expected to complete the one visit study.

TEST ARTICLES: Two experimental liquid soap products and one marketed antibacterial liquid soap product are being tested in this study. You will be assigned to one of the three liquid soap products.

STUDY PROCEDURES: As a participant, your hands and wrists will be washed with a non-medicated soap prior to the first treatment with the test product and after the sampling following the first treatment with the test product. Then you will wash eleven times with the assigned test product following specific directions. One of your hands will be sampled after the first and eleventh wash. Sampling is accomplished by having you place your hand into large plastic bags to which will be added a mild soap-like solution. A laboratory technician will massage your bagged hand for one minute. Your hand will be removed from the bags and the solution from each bag will be taken to the laboratory. The solution collected after the 1st wash will be discarded. The solution collected after the 11th wash will be tested to determine if it can be neutralized to allow growth of bacteria, which the laboratory will add to it. Following the sampling, you will rinse your hands and forearms in tap water.

FEMALES OF CHILDBEARING POTENTIAL: You may not participate in this study if you are pregnant or nursing. As part of giving your consent you must agree to have a urine pregnancy test at the start of the study.

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RISKS: You may also develop a reaction on your hands and forearms from the test materials. A reaction could be redness, swelling, itching, cracking, peeling, or in rare cases, blistering. If you have extremely sensitive skin, your hands and forearms may develop minor irritation that should lessen after treatment is completed. Also, accidental eye contact may cause minor discomfort and the affected eye should be rinsed thoroughly with water. No risks to you as a study participant, other than those described above, are anticipated during the study. Reactions are usually due to irritation, although an allergic reaction might occur. If you become allergic, it is possible that future exposures to the same ingredient may cause a skin reaction. If this occurs, you will be provided with information to minimize the chance for future exposures.

BENEFITS: You will not benefit from the applications of test articles but the test results may allow a new or improved product to be marketed.

ALTERNATIVE PROCEDURES/TREATMENTS: Because you are not being treated for a medical condition, alternative treatments do not apply to this study.

CONFIDENTIALITY: Information concerning you that is obtained in connection with this study will be kept confidential by Hill Top Research, except that the sponsoring company whose product is being tested will receive a copy of the study data. The data will be coded to protect your identity. In addition, the sponsoring company, the Institutional Review Board (IRB) and government regulatory agencies, including the U.S. Food and Drug Administration (FDA), may inspect the records of the study. Information obtained in the study may be used for medical or scientific publication, but your identity will remain confidential.

MEDICAL TREATMENT: If in the course of this study you experience illness, discomfort or injury that appears to be a result of the study, Hill Top Research will provide you with medical care at no cost to you. Providing such medical care is not an admission of legal responsibility. If such illness, discomfort or injury does occur, ask any staff member to arrange a meeting for you with the appropriate personnel.

In certain cases of illness or injury resulting from this study, workers' compensation coverage may be available. In accordance with Ohio law, Hill Top Research has secured workers' compensation coverage for participants in its studies and tests, and has paid and will pay appropriate premiums into the State Insurance Fund on behalf of such participants.

WHO TO CONTACT: If you have any questions about this study or in case of an emergency, contact Glenna, at 513-831-3114 ext. 2920, during business hours (M-F, 8:00 A.M. - 5:00 P.M.) or Ann Brady, Study Manager, at 513-831-3354 after hours. In addition, if you have any questions as to your rights as a research subject, contact the Institutional Review Board of Hill Top Research, Nancy J. Pelc, M.D., Chairman, at 1- 513-831-3114.

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VOLUNTARY PARTICIPATION/WITHDRAWAL: Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are entitled.

If you agree to participate in this study, you are also agreeing to provide Hill Top Research with accurate information and to follow study instructions as given to you. If you fail to follow study instructions, your participation may be ended.

Your participation in the study may be discontinued at any time without your consent by the Investigator, the IRB, the FDA, or the sponsoring company.

COMPENSATION: You will be paid \$30.00 for the completion of this study.

Payment will be made at the end of the study.

There are no anticipated expenses to you for participating in this study. All test related materials will be provided at no cost to you.

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EXHIBIT B

**EVALUATION OF HEALTH CARE PERSONNEL HANDWASH
SUBJECT INSTRUCTIONS**

Today you will be given a kit of products (bar soap, shampoo, and deodorant/antiperspirant) to use exclusively during this study. Please set aside all products you normally use in these categories and use only the products in the kit. In addition, please refrain from using perfumes, deodorants or antiperspirants (other than the ones furnished), powders, talc, oils and anti-dandruff hair shampoos, and do not swim in a chemically treated pool or hot tub during the study.

Beginning today, no body lotions, medicated/antibacterial lotions, creams or ointments should be applied to any area of your skin. Also, do not take any antibiotics. These medications may affect the bacteria of the skin. If antibiotics are necessary due to illness, please report this to Hill Top Research at the phone number below.

Please use the rubber gloves provided with the product kit for dishwashing and all household chores involving dishwashing liquids, detergents, acid, alkalis, and solvents until the completion of the study.

SUBJECT SCHEDULE

TEST DAY

Time of Visit: _____

1. Plan to arrive at the laboratory about 10 minutes before your scheduled time. You are expected to be prompt.
2. Please wear clothing that will allow easy access to your hands.
3. You will be required to remove all jewelry, watches, and bracelets before washing.
4. You will undergo a supervised wash regimen at the laboratory.
5. Approximate time at the laboratory - hours.
6. Additional instructions will be provided for the Follow Up Visit.

FOLLOW UP VISIT

Time of Visit: _____

1. A Dermatologist will check your hands for infection
2. Approximate time at the lab - 1/2 hour.

If you have any questions regarding this study, please contact Glenna, Study Coordinator, at 513-831-3114 ext. 2920 between 8:00 a.m. - 5:00 p.m. or Ann Brady, Study Manager, after hours and on weekends at 513-831-3354.

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EXHIBIT D

SUBJECT'S INSTRUCTIONS FOLLOWING STUDY COMPLETION

You have just completed participation in a clinical study, "Efficacy Evaluation of Health Care Personnel Handwash Products". During this study, your hands were in contact with a liquid containing bacteria (*Serratia marcescens* or *Staphylococcus aureus*). Although we do not expect you to have any adverse experience as a result of participation in this study, there is a possibility that an infection may develop on your hands.

To determine whether you have developed an infection from the test bacteria, we would like you to examine your hands and wrists daily. If you notice the appearance of any pimples, blisters or raised bumps surrounded by redness and/or swelling, please contact Glenna, Study Coordinator at (513) 831-3114 ext. 2920 during normal business hours (8:00 am- 5 pm) or Ann Brady at (513) 831-3354 after hours.

You are required to return to the test site for a follow-up visit. Your follow-up is scheduled for:

Date

Time

Thank you for your cooperation.

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Nancy J. Pelc, M.D., Chairman

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5/02