

# **MICROBIOTEST, INC**

*The Microbiology and  
Virology Laboratory*

August 1, 2003

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Docket No. 75N-183H  
RIN 0910-AA01

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Health-Care Antiseptic Drug Products; Reopening of the Administrative Record.

To Whom It May Concern:

MICROBIOTEST, INC. submits the enclosed protocol entitled "Using The Fingerpads Of Adult Subjects To Investigate The Virucidal Activity Of Handwash And Handrub Agents" for consideration as a standard protocol to evaluate antiviral activity of hand scrubs, alcoholic hand rubs and other skin antiseptics.

Although human pathogenic viruses are not members of normal skin microflora, it is well known that human hands can act as vehicles for the transmission of enteric, respiratory, ocular and possibly genital viral infections. Unquestionably pediatric and geriatric wards are particularly prone to nosocomial infections from viruses. Therefore we request that this protocol be added to The Final Monograph when it is published.

**75N-183H**

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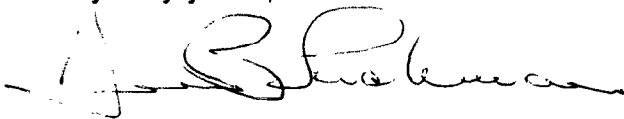
**SUP 10**



We believe it is appropriate for The Center for Drug Evaluation and Research to approve this protocol to evaluate antiviral effectiveness of skin antiseptics.

Khalid Ijaz, DVM, Ph.D. our virologist who will be the principal investigator on these studies and I will be available for any discussion or questions.

Very truly yours,

A handwritten signature in black ink, appearing to read "Donna B. Suchmann". The signature is written in a cursive style with a horizontal line underneath.

Donna B. Suchmann  
President

Cc: Ijaz, Bashir, Hollingsworth, MICROBIOTEST, INC.  
Sheldon, Lumpkins, CDER (electronically)