BD Infusion Therapy Systems, Inc
9450 S. State St.
Sandy, UT 84070
tel: 801.565.2300
fax: 801.565.2543
www.bd.com

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BD
Indispensable to human health

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

Re: Docket No. 75N-183H. Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Health Care Antiseptic Drug Products.

To Whom it May Concern:

The purpose of this communication is to comment on the reopened administrative record regarding the Tentative Final Monograph (TFM) for Over-the-Counter (OTC) Health-Care Antiseptic Drug Products, 59 Fed. Reg. 31401 (June 17, 1994). These comments provide supportive evidence for aligning testing guidelines in the TFM with currently-accepted testing protocols (*e.g.,* The American Society for Testing and Materials, *a.k.a.*ASTM).

The Tentative Final Monograph (TFM) currently contains specific recommendations on the dosage to use for testing surgical hand scrub drug products (§333.465.c.1). The recommendation is 5 mL, or one teaspoonful. Rather than specifying a dosage in the testing, we believe that manufacturers' use instructions should be followed for conducting this testing. This approach is already incorporated into the ASTM test methods (*e.g.*, Standard Test Method for Evaluation of a Pre-Operative Skin Preparation, E 1173).

As new technologies are being developed to provide more effective surgical scrub products, it is important that the FDA support outcome-based test procedures. One of the more recent developments in this field is the new alcohol-based products. These products vary in formulation, including recommended dosage, contact time, and method of use (*i.e.*, rinsed or rinseless). As such, they also have different Instructions For Use (IFU) as determined by the manufacturer to be effective for that product.

Becton Dickinson and Company currently markets two different alcohol-containing surgical scrub products. Copies of the labels, including the IFU, from each product are attached. Both are alcohol-based products used for surgical scrub procedures, but due to the differences in formulation, the IFU's are different. Nevertheless, test results (available on request) show that both products, when used according to recommendations, meet the criteria outlined by the TFM as a surgical scrub product.

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In summary, it is our recommendation that when referring to testing of a surgical scrub product, the Final Monograph defers to the manufacturers instructions for dosage and contact time, as supported by independent product testing. Testing should include outcome studies (*i.e.*, antimicrobial activity compared to baseline and cumulative persistence over five days) as is currently recommended in the TFM.

Sincerely,

Steven C. Felton, Ph.D., SM(ASCP)
Senior Scientist

Attachments: BD E-Z Care™ Rinseless, Brushless Antiseptic Label Copy

BD E-Z Care™ Brushless Antiseptic with Moisturizers Label Copy

cc: C. Ganley
D. Lumpkins