

ANDA 73-416

March 14, 2000

Becton Dickinson Surgical System
Attention: George Nolan
9450 South State Street
Sandy, Utah 84070-3224

Dear Sir:

This is in reference to your abbreviated new drug application dated August 28, 1989, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for E-Z Scrub⁷ 106 (Chlorhexidine Gluconate Topical Scrub, 4%, packaged with a brush/sponge applicator).

Reference is also made to your amendments dated May 19, 1992; April 13, 1993; August 28, 1995; and January 13, February 22, and March 8, 2000.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted Over-The-Counter (OTC) labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your E-Z Scrub⁷ 106 to be bioequivalent to the listed drug (Hibiclens⁷ Topical Scrub, 4%, of Zeneca Pharmaceuticals).

Under Section 506(A) of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research