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RESEARCH**

*APPLICATION NUMBER:*

**50-779**

**STATISTICAL REVIEW(S)**

New Drug Application, NDA 50-779  
Cefazolin for Injection USP and  
Dextrose Injection USP  
in the DUPLEX™ Container  
B. Braun Medical Inc.

#### 10. Statistical Section

There are no descriptions of statistical evaluations included in this application. These descriptions are not required since no clinical studies were performed by B. Braun Medical Inc. to support this application. B. Braun Medical Inc. has relied on the clinical studies performed on the reference listed drug, SmithKline Beecham's ANCEF® brand of sterile cefazolin sodium and cefazolin sodium injection (NDA 50-461).