DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 74-848

APR 19 2005

Bedford Laboratories
A Division of Ben Venue Laboratories, Inc.
Attention: Molly Rapp
300 Northfield Road
Bedford, OH 44146

Dear Madam:

This is in reference to your abbreviated new drug application dated February 2, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Propofol Injectable Emulsion, 10 mg/mL in 20 mL, 50 mL and 100 mL vials.

Reference is also made to your amendments dated July 17, 2000; February 28, June 3 and July 28, 2003; March 28, April 8, and April 13, 2005.

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 labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Propofol Injectable Emulsion, 10 mg/mL in 20 mL, 50 mL and 100 mL vials to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Diprivan® Injection, 10 mg/mL.

The listed drug product (RLD) referenced in your application, Diprivan® Injection, 10 mg/mL of AstraZeneca is subject to a period of patent protection. The following patent(s) and expiration dates are currently listed in the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book":

U.S. Patent Number		Expiration Date
5,714,520	(the '520 patent)	March 22, 2015
5,714,520*PED	(the '520*PED patent)	September 22, 2015
5,731,355	(the '355 patent)	March 22, 2015
5,731,355*PED	(the '355*PED patent)	September 22, 2015
5,731,356	(the '356 patent)	March 22, 2015
5,731,356*PED	(the '356*PED patent)	September 22, 2015
5,908,869	(the '869 patent)	March 22, 2015

5,908,869*PED (the '869*PED patent) September 22, 2015
Your application contains a patent certification to the '520, '355,'356 and '869 patents under Section 505(j)(2)(A)(vii)(IV) of the Act. This certification states that the '520,'355,'356 and '869 patents are invalid and will not be infringed by your manufacture, use, or sale of Propofol Injectable Emulsion, 10 mg/mL in 20 mL, 50 mL and 100 mL vials. Section 505(j)(5)(B)(iii) of the act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Bedford Laboratories for infringement of the '520, '355,'356 and '869 patents which was the subject of the paragraph IV certification. This action must be brought against Bedford Laboratories prior to the expiration of forty-five days from the date the notice you provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). You have notified the Agency that Bedford Laboratories complied with the requirements of Section 505(j)(2)(B) of the Act, and that no action for infringement of the'520,'355,'356 and '869 patents was brought against Bedford Laboratories within the statutory forty-five day period.

Under Section 506A 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.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of

Drug Marketing, Advertising, and Communications (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

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