DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 77-394

NOV 9 2005

Hospira, Inc.
Attention: Judith Zutkis, Associate Director
Dept. 0389, Bldg. H2-2
275 North Field Drive
Lake Forest, IL 60045-5046

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated November 19, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Sodium Bicarbonate Injection USP, 7.5% (0.9 mEq/mL) and 8.4% (1 mEq/mL) packaged in 50 mL single-dose ANSYR® II syringes.

Reference is also made to your amendments dated May 20, August 25, and October 12, 2005.

We note that the reference listed drug product (RLD) upon which you have based this application, Sodium Bicarbonate Injection packaged in Abboject® vials of Abbott Laboratories (Abbott), is no longer being marketed in the United States. Thus, the RLD currently appears in the Discontinued section of the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book". Reference is made to the Federal Register notice dated November 29, 2004 (Volume 69, Number 228) in which the agency announced its determination that Abbott's Sodium Bicarbonate Injection, 7.5% and 8.4% was not withdrawn from sale for reasons of safety or effectiveness. This determination allows the agency to approve ANDAs for the discontinued drug product.

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 Sodium Bicarbonate Injection USP, 7.5% and 8.4% to be bioequivalent and, therefore, therapeutically equivalent

to the listed drug (Sodium Bicarbonate Injection, 7.5% and 8.4%, respectively, of Abbott Laboratories).

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.

Postmarketing 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
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

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,

Robert L. Lesti/for

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