



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 19-683/S-027

Hospira, Inc.  
275 N. Field Drive  
Bldg. H2, Dept. 389  
Lake Forest, IL 60045-5046

Attention: Jeremy Rybicky  
Senior Specialist, Global Regulatory Affairs

Dear Mr. Rybicky:

Please refer to your supplemental new drug application dated July 5, 2005, received July 6, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aminosyn II (Amino Acid Injection).

This "Changes Being Effected in 30 days" supplemental new drug application provides for annual reportable changes. The changes listed in the DESCRIPTION section and PRECAUTIONS section, *Geriatric Use* subsection, were previously approved under Supplement S-019.

We have completed our review of this application and it is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert) submitted July 5, 2005.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-683/S-027.**" Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Pratibha Rana, Regulatory Project Manager, at (301) 827-7412.

Sincerely,

*{See appended electronic signature page}*

Bob A. Rappaport, MD  
Director  
Division of Anesthesia, Analgesia and  
Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Bob Rappaport  
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