

17-607, -> 5-122, 123

124

ANDAs: See Attached List

vol 19.1

Hospira, Inc.
Attention: Cheryl Mahon
275 North Field Dr.
Lake Forest, IL 60045

APR 10 2006

Dear Madam:

This is in reference to your supplemental new drug applications dated April 29, 2005 submitted under 505(j) of the Federal Food, Drug and Cosmetic Act, regarding your abbreviated new drug applications for the drug products noted on the attached list.

Reference is also made to your amendments dated June 1, 2005 and February 23, 2006.

The supplemental applications, submitted as "Prior Approval Supplements" provide for a modified flexible container, referred to as FC97; [REDACTED] (b)(4); and Labeling revisions to reflect the new packaging.

We have completed our review of these supplemental new drug applications, and they are approved effective on the date of this letter.

We remind you that you must comply with the requirements for approved abbreviated new drug applications described in 21 CFR 314.80-81.

The materials submitted are being retained in our files.

Sincerely yours,

[Signature] 4/7/06

Vilayat A. Sayeed, Ph.D.
Director
Division of Chemistry III
Office of Generic Drugs
Center for Drug Evaluation and Research

Attachment – List of applications

ANDA

Drug Product

16-366/S-166, S-167, S-168

0.9% Sodium Chloride Injection, USP,
500 mL and 1000 mL

17-607/S-122, S-123, S-124

5% Dextrose and 0.45% Sodium Chloride Injection, USP,
500 mL and 1000 mL

17-641/S-129, S-130, S-131

Lactated Ringer's Injection, USP,
500 mL and 1000 mL

cc: ANDA 16-366/ S-168
17-607/S-124
17-641/S-129

Division File
DUP File
Field Copy

Endorsements:

HFD-630/A. Srinivasan, Ph.D./ Chemistry Reviewer/9-19-05/ *ALS 4/6/06*

HFD-630/S. Liu, Ph.D./Team Leader/9-19-05/ *S.H. Liu 4/6/06*

HFD-617/L. Kwok/ Project Manager/S.Park for 4-04-06/ *SPM 4/6/06*

F/T by: sp/4-04-06

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TYPE OF LETTER: Global Supplements Approval