



NDA 16-741/S-035

B. Braun Medical Inc.
2525 McGraw Avenue
Irvine, CA 92614-5895

Attentions: Jeanne Lanahan
 Manager, Regulatory Affairs

Dear Ms. Lanahan:

Please refer to your supplemental new drug application dated November 14, 2002, received November 15, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 3.3% Sorbitol Irrigation USP in Plastic Containers.

This supplemental new drug application provides for revision to the TITLE, DESCRIPTION, CLINICAL PHARMACOLOGY, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE, DOSAGE AND ADMINISTRATION and HOW SUPPLIED sections of the package insert.

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 draft labeling (submitted November 14, 2002).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 16-741/S-035." 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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, call Kimberly Compton, Regulatory Project Manager, at (301) 827-7432

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Acting Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

Bob Rappaport
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