DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-627/S-046

APP Pharmaceuticals
1501 East Woodfield Road
Suite 300 East
Schaumburg, IL 60173

Attention: Lisa L. McChesney-Harris, Ph.D.
Vice President, Regulatory Affairs

Dear Dr. McChesney-Harris:

Please refer to your supplemental new drug application dated April 13, 2007, received April 16, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Diprivan® 1% (propofol) Injectable Emulsion.

We acknowledge receipt of your submissions dated May 29, December 12 and 18, 2007, and February 28, 2008.

This supplemental new drug application provides for changes to the **CLINICAL PHARMACOLOGY, SUMMARY OF DOSAGE GUIDELINES,** and **HANDLING PROCEDURES** sections of the Package Insert, and carton and container labels.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels).

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling text for the package insert and patient package insert. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 19-627/S-046 " 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Allison Meyer, Regulatory Project Manager, at (301) 796-1258.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and
Rheumatology Drugs
Office of New Drugs II
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Bob Rappaport

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