DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 009866/S-077 and S-079 **APPROVAL LETTER**

Pfizer Global Research & Development
235 East 42nd Street
New York, NY 10017

Attention: Tricia Douglas, MS, RAC
Regulatory Manager
Worldwide Regulatory Strategy

Dear Ms. Douglas:

Please refer to your supplemental new drug applications dated July 30, 2007, and July 11, 2008, received July 31, 2007, and July 11, 2008, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Solu-Cortef (hydrocortisone sodium succinate for injection, USP).

Reference is also made to the Agency's February 16, 2001, Approvable letter for multiple labeling supplements submitted between August 9, 1982, and December 8, 1995, a supplement request letter dated March 14, 2006, requesting revisions to the **WARNINGS, PRECAUTIONS,** and **DOSAGE AND ADMINISTRATION** sections of the Package Insert and Carton and Container labels, and an email correspondence dated April 29, 2008, requesting additional revision to the **WARNINGS** section of the Package Insert.

These supplemental new drug applications provide for revisions to the **WARNINGS, PRECAUTIONS,** and **DOSAGE AND ADMINISTRATION** sections of the Package Insert, and revised Carton and Container labels.

We have completed our review of these applications, and they are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text for the Package Insert.

CONTENT OF LABELING

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. 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 sNDA 009866/S-077 and sNDA 009866/S-079."

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your July 30, 2007, submission containing final printed carton and container labels.

LETTERS TO HEALTH CARE PROFESSIONALS

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ayanna Augustus, Regulatory Project Manager, at (301) 796-3980.

Sincerely,

{See appended electronic signature page}

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

Enclosure
Package Insert
Carton and Container Labels

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

/s/

BOB A RAPPAPORT
09/01/2009