DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
SIlver Spring, MD 20993

SUPPLEMENTAL NDA APPROVAL

NDA 12-041/S-036
NDA 14-901/S-037

Apothecon Inc.
C/O Bristol Myers Squibb Co.
P.O. Box 4000
Princeton, NJ 08543-4000

Attention: David L. Silberstein
Associate Director, Regulatory Affairs

Dear Mr. Silberstein:

Please refer to your supplemental new drug applications dated February 5, 2008, received February 6, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kenalog-10 (triamcinolone acetonide) Injection (NDA 12-041) and Kenalog-40 (triamcinolone acetonide) Injection (NDA 14-901).

We acknowledge receipt of your submission dated October 6, 2008.

These "Changes Being Effected" supplemental new drug applications provide for the revisions to the **WARNINGS** section of the Package Insert.

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

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. 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 12-041/S-036"** and **"SPL for approved NDA 14-901/S-037**."

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Christopher Hilfiger, Regulatory Project Manager, at (301) 796-4131.

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-14901	SUPPL-37	APOTHECON INC DIV BRISTOL MYERS SQUIBB	KENALOG-40 (STERILE TRIAMCINOLONE ACETON
NDA-12041	SUPPL-36	APOTHECON INC DIV BRISTOL MYERS SQUIBB	KENALOG PARENTAL (TRIAMCINOLONE ACETONID

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
01/28/2010