DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 12-041/S-033

Apothecon Inc.
A Bristol-Meyer Squibb Company
P.O.Box 4500
Princeton, NJ 08543-4500

Attention: Elisabeth Sagan-Graves
Associate Director, Global Regulatory Sciences

Dear Ms. Sagan-Graves:

Please refer to your supplemental new drug application dated August 29, 1997, received September 5, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kenalog-10 (triamcinolone acetonide) Injection.

We acknowledge receipt of your submission dated October 5, 2006, which constituted a complete response to our May 17, 2001, action letter.

This supplemental new drug application provides for a revised **PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE, DOSAGE AND ADMINISTRATION,** and **HOW SUPPLIED** sections of the package insert.

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.

Please submit an electronic version of the FPL. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 12-041/S-033**." 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 Pratibha Rana, Regulatory Project Manager, at (301) 796-1277.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation 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/

Rigoberto Roca
11/20/2006 07:54:49 PM
for Bob Rappaport, M.D.