DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-117/S-030

Kos Life Sciences, Inc.
2100 N. Commerce Parkway
Weston, Florida 33326-3234

Attention: James H. Medley, Ph.D.
Director, Regulatory Affairs

Dear Dr. Medley:

Please refer to your supplemental new drug application dated January 6, 1999, received January 7, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Azmacort (triamcinolone acetonide) Inhalation Aerosol.

We acknowledge receipt of your submissions dated April 14, 2000, and February 2, 2007.

Your submission of February 2, 2007, constituted a complete response to our action letter.

This supplemental new drug application provides for revisions to the PRECAUTIONS, and ADVERSE REACTIONS sections of the package insert to include information on the growth suppressive effects of inhaled corticosteroids, as requested in our letter November 6, 1999.

We completed our review of this application, as amended. This application 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 submitted labeling, copy enclosed (package insert and patient instruction's for use submitted February 2, 2007).

Please submit an electronic version or 20 paper copies of the FPL as soon as it is available (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 18-117/S-030**." 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 Colette Jackson, Regulatory Project Manager, at (301) 796-1230.

Sincerely,

{See appended electronic signature page}
Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy 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/

Badrul Chowdhury

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