DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-117/S-037

Kos Pharmaceuticals Inc.
2100 North Commerce Parkway
Weston, FL 33326-3256

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

Dear Dr. Medley:

Please refer to your supplemental new drug application dated October 14, 2005, 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 December 2, 14, and 23, 2005, and January 26, February 21, March 3, June 14, July 31, and August 7, and 22, 2006. Your submission of June 14, 2006, constituted a complete response to our February 15, 2006, action letter.

This supplemental new drug application provides for the replacement of the current [(b)(4)] with a suitable alternative and labeling revisions to the carton, container, and DESCRIPTION, CLINICAL TRIALS, ADVERSE REACTIONS, OVERDOSAGE, DOSAGE and ADMINISTRATION, and HOW SUPPLIED sections of the package insert.

We have 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 labeling (text for the package insert, immediate container and carton labels) submitted August 7, 2006.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* 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 18-117/S-037**." 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 20857

We have the following comments.

1. Submit the final specifications for canister extractables and drug product leachables when adequate data from commercial production becomes available.

2. The acceptance criteria should be supported by data. Your practice of adding 9 times of standard deviations to the mean is not the current pharmaceutical industry standard. In the future, two to three standard deviations may be added and/or subtracted from the mean, depending on the quantity and quality of data.

3. In setting expiry dating, the acceptance criteria line should be intersected by the upper or lower 90% confidence interval instead of the extrapolated data line.

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

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
9/5/2006 05:19:00 PM