DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 20-381/S-020

Kos Pharmaceuticals, Inc.
Attention: Kimberly Davis
Senior Manager, Regulatory Affairs
2200 N. Commerce Parkway, Suite 300
Weston, FL 33326-3258

Dear Ms. Davis:

Please refer to your supplemental new drug application dated February 15, 2005, received February 16, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Niaspan (niacin extended-release) Tablets, 500 mg, 750 mg, and 1000 mg.

This "Changes Being Effected" supplemental new drug application provides for:

- The addition of a "Geriatric Use" subsection to the PRECAUTIONS section.
- Revision of the ADVERSE REACTIONS section to include safety information for post-marketing experience reports.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 15, 2005.

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, HFD-410
FDA
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 Valerie Jimenez, Regulatory Project Manager, at (301) 827-9090.

Sincerely,

{See appended electronic signature page}

David Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products, HFD-510
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/

Mary Parks
6/8/05 01:12:25 PM
for Dr. Orloff