DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-381/S-025

Kos Life Sciences, Inc.
Attention: Valerie Ahmuty
Director, Regulatory Affairs
220 North Commerce Parkway, Suite 300
Weston, FL 33326-3258

Dear Ms. Ahmuty:

Please refer to your supplemental new drug application dated October 7, 2005, received October 11, 2005, submitted pursuant to section 505(b)(2) 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 following changes to the package insert:

1. Modification of the DESCRIPTION section to clarify the use as an antihyperlipidemic agent at pharmacological doses.
2. Revision of the "Manufactured by" statement to "Manufactured for" Kos Pharmaceuticals.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the attached final printed labeling.

At the next printing, please revise the first sentence of the DESCRIPTION section to add an "s" to "contain".

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 Kati Johnson, Chief, Project Management Staff, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD
Acting Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure – Package Insert

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Eric Colman

4/11/2006 03:09:34 PM

Eric Colman for Mary Parks