DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-381/S-023

Kos Life Sciences, Inc.
Attention: Valerie Ahmuty
Director, Regulatory Affairs
2200 North Commerce Parkway, Suite 300
Weston, FL 33326

Dear Ms. Ahmuty:

Please refer to your supplemental new drug application dated May 2, 2005, received May 5, 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.

We acknowledge receipt of your submission dated May 31, 2005.

This supplemental new drug application provides for a reformulated 1000 mg tablet that is bioequivalent to two Niaspan 500 mg tablets.

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 enclosed labeling (text for the package insert).

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 20-381/S-023**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Address all regulatory submissions (US Postal Service, overnight carrier, or courier service) as follows:

Food and Drug Administration, CDER
ATTN: Division of Metabolism and Endocrinology Products (DMEP)
Central Document Room (CDR)
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you have any questions, call Kati Johnson, Chief, Project Management Staff, at (301) 827-6380.

Sincerely,

{See appended electronic signature page}

David G. Orloff, MD
Director
Division of Metabolism & 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/

Mary Parks
9/9/2005 03:25:51 PM
for Dr. Orloff