DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-381/S-013

Kos Pharmaceuticals, Inc.
Attention: David H. Warnock, Ph.D.
Director, Regulatory Affairs
14875 N.W. 77th Avenue
Miami Lakes, Florida 33014

Dear Dr. Warnock:

Please refer to your supplemental new drug application dated March 29, 2002, received April 1, 2002, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Niaspan (niacin extended-release) Tablets, 500 mg, 750 mg, 1000 mg.

We acknowledge receipt of your submissions dated November 27, and December 4, 2002, and January 7, 2003.

Your submission of December 4, 2002, constituted a complete response to our November 20, 2002, action letter.

This supplemental new drug application provides for the use of Niaspan (niacin extended-release) Tablets in combination with lovastatin as an adjunct to exercise and diet for the treatment of adult patients with dyslipidemia.

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 draft labeling (package insert submitted December 4, 2002). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the FPL electronically according to the guidance for industry titled *"Providing Regulatory Submissions in Electronic Format – NDAs"*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-381/S-013." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 William C. Koch, R.Ph., Regulatory Project Manager, at (301) 827-6412.

Sincerely,

{See appended electronic signature page}

David G. 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/

David Orloff

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