DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-097/S-005

InKine Pharmaceutical Company, Inc.
Attention: Martin Rose, M.D., J.D.
1787 Sentry Parkway West
Building 18, Suite 440
Blue Bell, 19422

Dear Dr. Rose:

Please refer to your supplemental new drug application dated December 21, 2001, received December 21, 2001, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Visicol™ (sodium phosphate monobasic monohydrate, USP and sodium phosphate dibasic anhydrous, USP) Tablets.

Your December 21, 2001 submission requested an expedited review of this supplement. As was communicated to you by phone on January 2, 2001, by Ms. Kacuba of this Division, this request for expedited review was granted.

We acknowledge receipt of your submissions dated January 24, February 26, March 8, and March 11, 2002.

This supplemental new drug application provides for a change in the composition of the formulation for Visicol Tablets by reducing the percentage of microcrystalline (MCC) in the tablet from 23% by weight to 13% by weight.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter. The following agreed upon labeling revisions are terms of approval.

1. Revise the phrase "NEW FORMULATION" to use upper and lower case letters as follows: "New Formulation".
2. Delete the lines above and below the phrase.
3. This statement "New Formulation", can only be used for a period of time not to exceed 6 months.
4. Revise the established name to be at least half the size of the tradename per 21 CFR 201.10 (g)(2).

The final printed labeling (FPL) must be identical to the submitted draft labeling (immediate container and carton labels submitted February 26, 2002).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for

industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. 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 21097/S-005." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Gastrointestinal and Coagulation Drug Products and two copies of both the promotional materials and the package insert directly to:

We remind you of the agreements made in your March 8 and March 11, 2002 submissions regarding the bottle label revisions. These are terms of approval.

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 Alice Kacuba, R.N., MSN, RAC, Regulatory Health Project Manager, at (301) 827-1602.

Sincerely,

{See appended electronic signature page}

Liang Zhou, Ph.D.
Chemistry Team Leader for the
Division of Gastrointestinal and Coagulation Drug Products, (HFD-180)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Liang Zhou

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