NDA 21-097

InKine Pharmaceutical Company, Inc.
Attention: Martin Rose, M.D., J.D.
Sentry Park East
1720 Walton Road
Blue Bell, PA 19422

Dear Dr. Rose:

Please refer to your new drug application (NDA) dated November 22, 1999, received November 23, 1999, 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.

We acknowledge receipt of your submissions dated December 28, 1999, January 6, January 19, February 10, February 25, March 2, March 14, March 22, March 29, March 31, April 6, May 9, May 12, June 1, June 6, June 14, June 22, June 28, July 3, July 12, July 25, July 26, July 27, August 7, August 22, August 31, September 5, September 6, September 12, September 14, September 18, and September 20, 2000.

This new drug application provides for the use of Visicol™ Tablets for cleansing of the bowel as a preparation for colonoscopy, in adults 18 years of age and older.

We have completed the review of this 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 enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed agreed upon labeling (text for the package insert submitted September 20, 2000 and immediate container label submitted September 21, 2000). 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 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. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 21-097." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitment specified in your submission dated August 31, 2000. This commitment, along with completion dates agreed upon, is listed below:

> Collection and submission to the Agency, within three months of approval, of additional dissolution data using lower rotational speeds of 50 rpm and 75 rpm (at sampling times of 15, 30, 45, 60, 75, and 90 minutes) to assess the appropriateness of the original method and specification.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.81(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Sufficient stability data has been provided to approve the drug product with an expiration dating period of 12 months.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

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:

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

Please submit one market package of the drug product when it is available.

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., M.S.N., CCRN, Regulatory Health Project Manager, at (301) 827-7450.

Sincerely,

Florence Houn, M.D., M.P.H., F.A.C.P.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure