



NDA 21-097/S-007 and S-009

Inkine Pharmaceutical Company, Inc.
Attention: Martin Rose, M.D., J.D.
Executive Vice President, Research and Development
1787 Sentry Park West
Building 18, Suite 440
Blue Bell, PA 19422

Dear Dr. Rose:

Please refer to your supplemental new drug applications dated July 17, 2002 (S-007) and January 14, 2004 (S-009), received July 18, 2002 and January 15, 2004 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Visicol® Tablets.

We acknowledge receipt of your submissions dated December 15, 2003, February 17, 2004, and August 17, 2004 for supplement 007.

We acknowledge receipt of your submissions dated January 30, 2004, and August 17, 2004 for supplement 009.

Your submission of August 9, 2004 to supplements 007 and 009 constituted a complete response to our June 15, 2004 (S-007) and July 14, 2004 (S-009) action letters.

Supplemental new drug application 007 provides for: revisions to the Precautions Section of your package insert, regarding the risk of seizures and loss of consciousness.

Supplemental new drug application 009, "Changes Being Effected in 30 days", provides for the market of Visicol® Tablets in an (b) (4) bottle containing 100 tablets.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 9, 2004 to supplements 007 and 009.

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 Tanya Clayton, B.S., Regulatory Health Project Manager, at (301) 827-4005.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastrointestinal and Coagulation Drug
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

Kathy Robie-Suh
2/10/05 09:12:06 AM
signing for Dr. Joyce Korvick