DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-685/S-069 **SUPPLEMENT APPROVAL**

Merck & Co., Inc.
Attention: Karen L. Henry
Associate Manager, Worldwide Regulatory Affairs
P.O. Box 1000, UG 2C-50
North Wales, PA 19454-1099

Dear Ms. Henry:

Please refer to your supplemental new drug application dated and received June 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for CRIXIVAN® (Indinavir Sulfate) capsules.

We also acknowledge receipt of your submission dated August 17, 2009.

This "Prior Approval" supplemental new drug application proposes removing information related to the CRIXIVAN® 333 mg capsules from the Description, Drug Interactions – Table 9, Dosage and Administration, and How Supplied sections of the package insert because this formulation is no longer marketed or available in the United States.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING
As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155657.htm that is identical to the enclosed labeling (text for the package insert, text for the patient package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 20-659/S-069.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Robert G. Kosko, Jr., Pharm.D., M.P.H., Regulatory Project Manager, at (301) 796-3979.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosures
Package Insert and Patient Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20685	SUPPL-69	MERCK RESEARCH LABORATORIES DIV MERCK CO INC	CRIXIVAN

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

/s/

KENDALL A MARCUS
10/15/2009