DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

JUL 2 1999

TRANSMITTED VIA FACSIMILE

Ellen R. Westrick
Senior Director, Office of Medical/Legal
Merck & Co., Inc.
P.O. Box 4, WP37B-116
West Point, Pennsylvania 19486

RE: NDA 20-685
Crixivan (indinavir sulfate tablets)
MACMIS #7916

Dear Ms. Westrick:

This letter concerns Merck & Co., Inc.'s promotional materials for Crixivan. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these promotional materials as part of its routine monitoring and surveillance program. From its review, DDMAC has concluded that Merck has distributed materials that are false and/or misleading, in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations.

Reference is made to an advertisement in the May 1999 issue of POZ magazine for Crixivan by Merck & Co., Inc. Merck claims that Crixivan, among other protease inhibitors, is the number one choice of doctors based on IMS America data from 3/96-7/98. This claim is false and misleading for three reasons: (1) retail prescription data does not support the claim that Crixivan is the number one choice of doctors (other factors may influence a physician's decision to prescribe, e.g., treatment benefit plans), (2) IMS data for 3/96 does not support the claim that Crixivan is the number one prescribed protease inhibitor, and (3) according to the more recent IMS data from 10/98-5/99, Crixivan is the number two prescribed protease inhibitor. While Crixivan may have been number one from 4/96-7/98, it is false and misleading to imply that Crixivan is still number one by presenting outdated information or information that is unsubstantiated.

Merck should immediately cease publication or dissemination of promotional materials or activities that contain these or similar claims. Merck should respond in writing no later than July 19, 1999, describing its plan to comply. Merck should also include a list of materials being discontinued, as well as the date of discontinuation.

Your response should be directed to Ele Ibarra-Pratt by fax at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Merck that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID # 7916 in addition to the NDA number.

Sincerely,

Ele Ibarra-Pratt, R.N., M.P.H.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications