DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 24 1997

TRANSMITTED VIA FACSIMILE

Sandra A. Wilson
Associate Manager, Labeling
Schwarz Pharma, Inc.
5600 W. County Line Road
P.O. Box 2038
Milwaukee, WI 53201

RE: NDA# 20-649
Edex (alprostadil for injection)
MACMIS ID # 5076

Dear Ms. Wilson:

Reference is made to Schwarz Pharma's December 11, 1996, FDA Form 2253 submission to the Division of Drug Marketing, Advertising and Communications (DDMAC), for Edex (alprostadil for injection). This submission consists of a promotional leaflet (SP2647). DDMAC has determined that this "coming soon" leaflet is in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations. Specifically, this advertisement promotes an unapproved new drug.

DDMAC refers Schwarz Pharma to the April 1994 guidance letter to Industry, which discussed pre-approval promotion. As you know, the regulations promulgated pursuant to the Act, 21 CFR 312.7, state, among other things, that an investigational new drug may not be promoted as being safe and effective for the uses under investigation. Therefore, DDMAC usually considers pre-approval promotion of drug products to be violative. However, DDMAC has traditionally recognized two methods in which sponsors may discuss products under FDA review, without making promotional claims of safety or efficacy that are prohibited by the Act.

The first method of permissible pre-approval promotion is "Institutional Promotion." Institutional advertisements state that a particular drug company is conducting research in a certain therapeutic area to develop new and important drugs. The advertisement may not suggest any particular drug by name (proprietary or established) or otherwise suggest that a particular drug will soon be approved for use in the therapeutic area under consideration.

The second method of permissible pre-approval promotion is "Coming soon promotion." Coming soon advertisements announce the name of a new product that will be available soon, but do not make written, verbal, or graphic representations or suggestions concerning the safety, efficacy, or intended use of the product.

The leaflet referenced above is violative in that it makes several graphic representations and suggestions about the intended use of the product.

The dissemination or publication of this, and all similarly violative materials, should be discontinued immediately upon receipt of this letter. Schwarz Pharma should respond to this letter in writing by February 4, 1997. Schwarz's response should include a list of all similarly violative materials and a description of its method for discontinuing their use.

If Schwarz has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Schwarz that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID # 5076 in addition to the NDA number.

Sincerely,

Mark W. Askine, R.Ph.
Regulatory Review officer
Division of Drug Marketing,
Advertising and Communications