DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

MAY 26 1998

James L. Yeager, Ph.D.
Vice President
NexMed, Inc.
350 Corporate Boulevard
P.O. Box 10950
Robbinsville, N.J. 08691

RE:

Alprox-TD (alprostadil)
MACMIS ID #6651

Dear Dr. Yeager:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for Alprox-TD (alprostadil) that are in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. DDMAC specifically refers to the press release issued by NexMed Inc. (NexMed) on May 11, 1998, announcing the results of a clinical study for Alprox-TD. DDMAC finds the press release violative for the following reasons.

Pre-Approval Promotion

Section 21 C.F.R. 312.7, states, among other things, that an investigational new drug may not be promoted as being safe or effective for the uses under investigation. The press release in question is considered to be violative pre-approval promotion because it makes several claims regarding the safety and efficacy of the product. These claims include statements about the drug's specific use in the treatment of erectile dysfunction (ED) and other claims, such as:

- "We believe Alprox-TD is a safe, effective, patient friendly and appealing treatment for ED," said Joseph Mo, NexMed's chief executive officer.

- "From the results of our study, we conclude that 500 mg of a 0.4 percent alprostadil cream incorporating the NexACT (TM) enhancer applied to the glans, produced a similar hemodynamic effect...as that seen following intracavernosal injection of alprostadil and sexual stimulation."

- "...Alprox-TD, a topical formulation incorporating the NexACT (acute transdermal drug delivery technology: new, specially designed ingredients that promote the rapid penetration of the active ingredient though the skin and to the site of action...."
- "...NexACT enhancers result in the rapid delivery of alprostadil through the stratum corneum...as well as tissue below the skin."
- "The product [Alprox-TD] has a shelf life of two years when refrigerated or one month at room temperature."

NexMed should immediately cease its use of promotional materials that contain these or similar claims or representations. NexMed should respond in writing by June 8, 1998, including a list of all similarly violative material and a description of its method for discontinuing their use.

If NexMed 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 NexMed that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #6651 in addition to the IND number.

Sincerely,

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