DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 25 1997

TRANSMITTED VIA FACSIMILE

David E. Riggs
Senior Vice President
Unimed Pharmaceuticals, Inc.
2150 East Lake Cook Road
Buffalo Grove, IL 60089-1862

RE:
Androgel (testosterone gel)
MACMIS ID #5339

Dear Mr. Riggs:

As part of its routine monitoring and surveillance activities, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of a news release dated March 31, 1997, disseminated by Unimed Pharmaceuticals, Inc. (Unimed) for Androgel (testosterone gel). This news release is in violation of the Federal Food, Drug and Cosmetic Act (the Act) and the applicable regulations. DDMAC finds the press release, which is considered labeling for Androgel, violative for the following reasons.

Pre-Approval Promotion

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.

The news release in question is considered pre-approval promotion and is violative because it makes several promotional claims about the product, including its specific use in testosterone deficiency in men. Further, it lists several other "potential uses" such as the treatment of geriatric hypogonadism in elderly men and the treatment for postmenopausal women. In addition, the press release contains several unsubstantiated superiority claims about Androgel, such as:

- "Unimed anticipates that its topical gel formulation will avoid many of the troublesome effects associated with currently marketed injectable and transdermal testosterone preparations and thus improve compliance."

- "Unimed believes that Androgel may represent a substantial advance over existing delivery methods for testosterone..."

In addition, the press release fails to contain the approved product labeling for Maxaquin.

The dissemination or publication of this news release, and all similarly violative materials, should be discontinued immediately upon receipt of this letter. Unimed should respond to this letter in writing by May 6, 1997. Unimed's response should include a list of all similarly violative materials and a description of the method for discontinuing their use.

If Unimed 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 Unimed that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5339 in addition to the NDA number.

Sincerely,

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