DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

TRANSMITTED VIA FACSIMILE

APR - 1 1998

Carol D. Karp
Vice President, Regulatory Affairs
Vivus, Inc.
605 East Fairchild Drive
Mountain View, CA 94043

RE: NDA# 20-700
MUSE (alprostadil) urethral suppository
MACMIS ID #6492

Dear Ms. Karp:

Reference is made to Vivus, Inc.'s (Vivus) March 20, 1998, Form FDA 2253 submission of a direct-to-consumer (DTC) journal advertisement (870-002) for MUSE (alprostadil) urethral suppository to the Division of Drug Marketing, Advertising and Communications (DDMAC). Reference is also made to DDMAC's letters to Vivus dated February 19, 1998, and March 19, 1998, regarding DTC advertisements for MUSE.

DDMAC has reviewed the journal ad and finds that it is in violation of the Federal Food, Drug and Cosmetic Act and applicable regulations for the following reasons:

The journal ad is misleading because it fails to communicate an important material characteristic of the product. DDMAC considers the term "urethral suppository" to be an unfamiliar medical term that does not communicate this product characteristic to the average consumer. Specifically, as stated in our letters dated February 19, 1998, and March 19, 1998, the majority of men exposed to this advertisement will not understand that MUSE is a suppository designed to be inserted into the opening of a man's penis, given the current disclosure about the dosage form ("urethral suppository"). In addition, the ad is misleading because the subhead "For Many Men There May Be A Solution" lacks the prominence necessary to provide the context needed for the headline "IMPOTENCE IS OPTIONAL."

In order to address these objections, DDMAC recommends that Vivus take the following actions:

1. Immediately discontinue the use of these, and all other promotional materials for MUSE that contain the same or similar violations.

2. Provide to DDMAC, in writing, a letter stating Vivus' intent to comply with #1 above. Your response should be received by April 15, 1998.

3. Provide a list of all promotional materials that have been discontinued.

If Vivus 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 Vivus that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #6492 in addition to the NDA number.

Sincerely,

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