DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 13 1999

TRANSMITTED VIA FACSIMILE

Louise C. Johnson
Associate Director, Regulatory Affairs
Athena Neurosciences
800 Gateway Boulevard
South San Francisco, CA 94080

RE: NDA #19-385
Permax (pergolide mesylate) Tablets
MACMIS #5943

Dear Ms. Johnson:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of a journal advertisement for Permax (pergolide mesylate) Tablets that is false, misleading, and in violation of the Federal Food, Drug, and Cosmetic Act. This advertisement appeared in the September 1997 issue of *Neurology Reviews* and the September 1997 issue of *Movement Disorders.*

Specifically, DDMAC objects to the following:

1. The journal advertisement is false and misleading because it fails to mention that Permax is indicated as adjunctive therapy in the treatment of Parkinson's disease and, instead, claims that Permax is useful for all stages of Parkinson's disease. The approved product labeling (PI) states that Permax is indicated as adjunctive treatment to levodopa/carbidopa in the management of Parkinson's disease. Further, there are currently marketed products indicated for all stages of Parkinson's disease, including patients that are not yet on levodopa therapy.

2. DDMAC has no record of receiving this advertisement on FDA Form 2253, thus the journal advertisement is in violation of 21 CFR §314.81 that states that promotional materials must be submitted to the FDA for review at the time of dissemination.

To address these objections, DDMAC recommends that Athena immediately discontinue the use of these materials and all other promotional materials for Permax that contain the same or similar presentations. Please respond to this letter, in writing, by January 23, 1998. This response should include a list of all violative promotional materials, including all journals in which this advertisement was featured, and Athena's methods for discontinuing their use.

If Athena 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.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5943 in addition to the NDA number.

Sincerely,

Lisa L. Stockbridge, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications