DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC - 2 1998

TRANSMITTED VIA FACSIMILE

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

RE: NDA# 20-397
Zanaflex (tizanidine HCl) Tablets
MACMIS ID # 7068

Dear Ms. Johnson:

Reference is made to the Division of Drug Marketing, Advertising and Communications' (DDMAC) September 23, 1998, letter requesting details regarding a group of luncheon and dinner discussions on the management of pediatric spasticity that were held at the American Academy of Cerebral Palsy and Developmental Medicine September 1998 Meeting. The discussions were sponsored by Athena Neurosciences (Athena) and featured Dr. Terence Edgar presenting case studies of his experience with Zanaflex (tizanidine HCl) and other agents in the pediatric population. We also refer to Athena's response dated October 7, 1998.

Zanaflex is not indicated for the treatment of spasticity in the pediatric population. Moreover, the Precautions section of the approved product labeling (PI) for Zanaflex states that there are no adequate and well-controlled studies to document the safety and efficacy of tizanidine in children.

In its response, Athena describes that the purpose of the program was to generate discussion and elicit feedback from leading physicians regarding the current treatment of spasticity in children, and that Athena had invited physicians in order to "facilitate the planning process for considering whether to seek regulatory approval for Zanaflex in children with spasticity." However, upon examination of the materials and Athena's response, DDMAC found that the Athena-sponsored programs did not fill this need. Instead of attempting to answer the question of whether Athena should seek approval for Zanaflex in the pediatric population, Dr. Edgar provided the "answer" and described how to use Zanaflex in children. Thus, the programs were promotional in nature. These programs promoted the unapproved use of Zanaflex in children. Accordingly, the programs are in violation of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

To address these objections, DDMAC recommends that Athena do the following:

1. Immediately refrain from promotional activities of this nature and discontinue slides and any other materials that discuss the use of Zanaflex in children.

2. Respond to this letter, in writing, by December 16, 1998. This response should include Athena's intent to comply with the above, a list of all violative promotional practices or materials that include the same or similar deficiencies, 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 #7068 in addition to the NDA number.

Sincerely,

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