DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

DEC 27 2000

Mr. Charles Davis
Senior Director, Regulatory Affairs
Maxim Pharmaceuticals, Inc.
8899 University Center Lane, Suite 400
San Diego, CA 92122

RE: NDA:[ ]
Drug: histamine dihydrochloride injection
MACMIS ID # 9584

Dear Mr. Davis:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified certain promotional activities by Maxim Pharmaceuticals (Maxim) that are in violation of the Federal Food, Drug, and Cosmetic Act and its regulations. Specifically, DDMAC observed Maxim promoting the drug histamine dihydrochloride, an investigational drug, at the 35th American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting held in Las Vegas. Current regulations do not permit a sponsor, investigator, or any person acting on their behalf to represent–in a promotional context–that an investigational drug is safe or effective for the purpose under investigation.

On December 4, 2000, DDMAC observed one of your representatives at your exhibit booth explaining to visitors that histamine dihydrochloride

- "improved patient's quality of life"
- "more than doubled survival from four to eight months"
- "had transient adverse effects"

Maxim and its representatives should immediately cease making claims that promote histamine dihydrochloride as safe or effective prior to approval and should cease the distribution or use of any promotional materials for histamine dihydrochloride that contain the same or similar violative statements. Maxim should submit a written response, describing its method of discontinuing such oral or written statements, to DDMAC on or before January 10, 2001. This response should also include a list of similarly violative promotional materials that were discontinued.

Maxim should direct its response to me by facsimile at (301) 594-6771 or by written communication at the Division of Drug Marketing, Advertising and Communications, HFD-42, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. In all future correspondence regarding this matter, please refer to MACMIS ID # 9584 in addition to the NDA number. DDMAC reminds Maxim that only written communications are considered official.

Sincerely,

/S/

Joseph A. Grillo, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing, Advertising and Communications