DEPARTMENT OF HEALTH & HUMAN SERVICES

F01

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

JAN 28 1999

Joseph Hines
President
Zila, Inc.
5227 North 7th Street
Phoenix, Arizona 85014-2800

RE: NDA 20-765
ORATEST
MACMIS ID# 7535

Dear Mr. Hines:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of a press release issued on January 13, 1999, by Zila, Inc. (Zila), regarding Oratest that violates the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations.[1] DDMAC requests that the use of the above referenced material and those containing similar promotional claims cease immediately.

The January 13, 1999, press release is in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations because it promotes an unapproved drug product (Oratest) by making implied claims of safety and effectiveness that have not been demonstrated by substantial evidence. Some examples of pre-approval promotional claims include the following statements from the press release:

- "Oratest can increase the probability that high-risk patients will be identified earlier, targeted education and treatment initiated more effectively, and most importantly, the quality of lives and lives themselves saved."

- "If Oratest is approved, the benefit will hopefully be the reduction of devastating mortality and morbidity associated with this disease."

[1] See 21 CFR 312.7.

- "By promoting early detection, Oratest should help reduce the severe side effects of the treatment that accompanies later-stage detection. It will also reduce government expenditures for health care. Perhaps most importantly, widespread use of Oratest will raise public awareness of oral cancer, its causes and its effects. This will reduce incidence of the disease and improve treatment of those who contact it."

- "With Oratest and appropriate professional support and education, dentists will be more likely to perform thorough oral cancer exams on appropriate at-risk patients."

- When discussing the "major needs in terms of dealing with the impact of oral cancer" (i.e. a detection system that produces fast, accurate results), the press release states that the "Oratest system meets these needs."

The headline "FDA Advisory Panel Recommends Refinement of Data on Zila's Oratest Oral Cancer Detection System" is misleading because it does not accurately describe the findings of the FDA's Oncologic Drugs Advisory Committee. In fact, the committee recommended that Zila conduct a study with a different design to support approval.

Zila should immediately cease all activities that make the same or similar claims of safety or effectiveness for Oratest. Zila should submit a written response to DDMAC, on or before February 11, 1999, describing its intent and plans to comply with the above. In its letter to DDMAC, Zila should include a list of all promotional materials and activities that were discontinued, and the discontinuation date.

Zila should direct its response to the undersigned by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds Zila that only written communications are considered official. In all future correspondence regarding this matter, please refer to MACMIS#7535 and NDA 20-765.

Sincerely,

Michael A. Misocky, R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing, Advertising, and Communications.