



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 2 2001

Food and Drug Administration
Rockville MD 20857

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• Eric M. Mittleberg, Ph.D.
Vice President
Scientific Affairs
Zenith Goldline Pharmaceuticals, Inc.
140 Legrand Avenue
Northvale, NJ 07647

Re: Docket No. 00P-1445/CP1 & PSA1

Dear Dr. Mittleberg:

Pursuant to 21 CFR 10.30 (e)(2), this letter informs you that we are still considering your citizen petition request to issue a statement clarifying that all abbreviated new drug applications containing paragraph IV certifications delivered to FDA's Office of Generic Drugs on the same business day are submitted at the same time for 180-day exclusivity purposes.

We expect to conclude our evaluation shortly and will respond to your petition once that process is completed.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

cc: Thomas Scarlett
Hyman, Phelps & McNamara, P.C.

00P-1445

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