



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 21 1993

Charles J. Raubicheck
Piper & Marbury
31 West 52nd Street
New York City, NY 10019-6118

Re: Docket No. 92P-0262/CP1

Dear Mr. Raubicheck:

Pursuant to 21 CFR 10.30(e)(2), this letter informs you that the agency is still considering the issues raised in your citizen petition requesting the Commissioner to issue an order requiring that manufacturers and distributors of root canal filling materials and sealers fulfill new drug approval or medical device premarket approval requirements of the Federal Food, Drug, and Cosmetic Act. FDA is still evaluating the requests made in your petition, and we will respond to your petition once this process is completed.

Sincerely yours,

Carl C. Peck, M.D.
Director
Center for Drug Evaluation and Research

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CASES MANAGEMENT BRANCH

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