



FILE COPY

June 18, 1992

Charles J. Raubicheck
SKADDEN, ARPS, SLATE, MEAGHER & FLOM
Attorneys for N2 Products Corporation
919 Third Avenue
New York, New York 10022

Dear Mr. Raubicheck:

Your petition requesting the Food and Drug Administration to issue an order obligating manufacturers and distributors of all commercially sold root canal filling materials and sealers to fulfill the new drug approval or medical device premarket approval requirements of the Federal Food, Drug, and Cosmetic Act was received by this office on June 17, 1992. It was assigned docket number 92P-0262/CP 1 and it was filed on June 18, 1992. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Gaffe
Dockets Management Branch