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June 3, 1998

BY FAX AND FIRST CLASS MAIL

Jane A. Axelrad
Associate Director for Policy (HFD-5)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Docket No. 92P-0262/CP1;
N2 Products Corporation

Dear Ms. Axelrad:

I have received your letter dated May 4, 1998 regarding the above-referenced Citizen Petition, which I filed nearly six years ago on behalf of N2 Products Corporation. (Since the Petition was filed, I have joined the firm of Sidley & Austin, as indicated in the above letterhead).

The Petitioner respectfully disagrees with CDER's assertion that this Petition does not raise a significant and current public health issue that merits a formal FDA response.

The Petition requests FDA to apply the same new drug premarket clearance requirements to currently marketed root canal filling and sealing materials that the Agency has applied to the Petitioner's N2 Universal root canal filling material (which is the subject of a pending NDA mandated by CDER). Root canal filling and sealing materials containing drug ingredients are not safe for their intended use except when administered by licensed dental practitioners, are not generally recognized as safe and effective for their intended use, and hence are new drugs. 21 U.S.C. §§ 321(p), 353 (b)(1). To allow such materials to be marketed without NDA approval jeopardizes patient safety, and contravenes FDA's public health obligations under Section 505 of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 355; Hoffmann-La Roche, Inc. v. Weinberger, 425 F.Supp. 890 (D.D.C. 1975).

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In the subject Citizen Petition, the Petitioner has identified seven (7) root canal filling materials or sealers containing drug ingredients that are being marketed without approved NDA's, and as to which FDA has taken no enforcement action.¹

Further, singling out the Petitioner's root canal material for NDA premarket clearance while permitting these other root canal materials to be marketed without such clearance is a Constitutional violation, since the Fifth Amendment's due process clause requires FDA to apply even-handed regulatory standards to similarly-situated regulated products. United States v. Diapulse Corporation of America, 748 F.2d 56 (2d Cir. 1984); United States v. Undetermined Quantities of an Article of Drug ... "Exachol", 716 F. Supp. 787 (S.D.N.Y. 1989).

CDER routinely sends warning letters to manufacturers and distributors of unapproved new drugs, informing them that they must meet applicable NDA premarket clearance requirements. Surely this will not strain FDA's resources in this instance.

Accordingly, Petitioner N2 Products Corporation hereby requests that FDA grant its Citizen Petition, and take appropriate enforcement action the companies who are marketing these unapproved new drugs.²

Sincerely yours,



Charles J. Raubicheck

CJR:dmp

cc: N2 Products Corporation
Lana Ogram
Eric Latish

¹ The Petition also identifies 11 additional root canal materials that should be regulated as Class III medical devices requiring approved PMA's, because of their potential cytotoxicity.

² Please note that AH26, cited at pages 9-10 of the Citizen Petition, is now marketed in the U.S. under the brand name EndoSeal by L.D.Caulk Company.