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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Rm.1061)
Rockville, MD 20852

Attention: Document Control Room (HFA-305)

Subject: **Docket No. 81N-033P**
Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products; Establishment of a Monograph; Proposed Rules (ANPRM) 68 FR, No. 103, p. 32232 dated May 29, 2003

Additional Data to be Considered for Over-the-Counter Drug (OTC) Products for the Reduction or Prevention of Dental Plaque and Gingivitis

Dear Sir or Madam:

On December 4, 2000 and September 12, 2002 Colgate-Palmolive Company submitted additional data to be considered pursuant to 21 CFR 330.10 and requested that the Commissioner of Food and Drugs include zinc citrate as a Category I ingredient for safety and efficacy in the Final Monograph for Over-the-Counter Drug Products for the Reduction or Prevention of Dental Plaque and Gingivitis, Docket No. 81N-033P.

Those two submissions included the results of two (2) six-month plaque and gingivitis studies demonstrating the efficacy of zinc citrate in combination with sodium monofluorophosphate (MFP) in the reduction of plaque and gingivitis.

When the Advanced Notice of Proposed Rule Making (ANPRM) was published in the Federal Register on May 29, 2003 (Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products; Establishment

81N-033P

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of a Monograph; Proposed Rules (ANPRM) 68 FR, No. 103, p. 32232), it did not include discussion of these two submissions.

Colgate-Palmolive is now officially requesting that these 2 submissions sent to Docket No. 81N-033P on December 4, 2000 and September 12, 2002, respectively, be included in Docket No. 81N-033P during the currently open comment period.

If you have any questions regarding this request, please do not hesitate to contact me.

Respectfully,

Eugénie C. Acosta, RAC
Manager
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Colgate-Palmolive Company