



COLGATE-PALMOLIVE COMPANY

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 81N-033P – Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products: Notice of Eligibility; Request for Data and Information on Triclosan (69 Fed. Reg. 40640; July 6, 2004)

These comments are submitted on behalf of the Colgate-Palmolive Company (Colgate-Palmolive) in response to the captioned notice of eligibility and request for data and information. These comments supplement Colgate-Palmolive's submission of October 4, 2004, to the same docket. The October 4, 2004 submission was designated C26 by the Division of Dockets Management.

On October 4, 2004, Colgate-Palmolive submitted comments in response to FDA's July 6, 2004, notice. These comments demonstrated that there are inadequate data supporting GRAE status of triclosan alone for antiplaque and antigingivitis indications. In the accompanying cover letter, Colgate-Palmolive advised FDA that supplemental comments would be submitted later. By letter dated April 18, 2005, FDA advised Colgate-Palmolive that these additional comments would be accepted if submitted before FDA completed its review of the October 4, 2004 comments. We are now submitting supplemental comments.

Respectfully submitted,

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