



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

APR 18 2005

Rec'd 4/18/05
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LaVada Watson
Worldwide Director, Regulatory Affairs
Colgate-Palmolive Company
909 River Road, P.O. Box 1343
Piscataway, New Jersey 08855-1343

Re: Docket No. 1981N-0033P
Comment No. EC4

Dear Ms. Watson:

This is in response to your letter dated September 17, 2004 to the Division of Dockets Management (formerly the Dockets Management Branch) filed as comment No. EC4 under Docket No. 1981N-0033P. Your letter requested a 45-day extension of the comment period for the safety and efficacy review of triclosan as an additional ingredient for antigingivitis, antiplaque use in the over-the-counter (OTC) oral health care drug products monograph.

In the FEDERAL REGISTER of July 6, 2004 (69 FR 40640), FDA published a call-for-data for safety and effectiveness information on triclosan as an antigingivitis/antiplaque ingredient in OTC dental pastes and oral rinses. This notice was based on FDA's review of a time and extent application (TEA) that supported triclosan's eligibility for consideration in the OTC drug monograph system. The notice stated that FDA will evaluate the submitted data and information to determine whether triclosan can be generally recognized as safe and effective (GRAS/E) for this proposed OTC indication.

The original closing date for the comment period was October 4, 2004. Your letter stated that Colgate-Palmolive requires additional time to evaluate the effectiveness data on triclosan in dental pastes and oral rinses in the context of the TEA procedure. This time was requested to allow for a "comprehensive submission addressing the formula-dependent efficacy of triclosan-containing dental pastes and mouth rinses" to meet the requirements of the OTC oral health care proposed monograph.

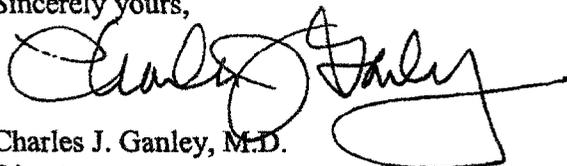
FDA has received your company's partial submission dated October 4, 2004, and filed as comment No. C26 under Docket No. 1981N-0033P. In that submission, Colgate-Palmolive notes that the second half of its comments will be submitted before or during any extension of the comment period. Because the requested extension time (45 days) has passed and because FDA has received no further requests for additional time, FDA does not intend to publish an extension of the comment period. FDA is aware that your original submission is incomplete and will accept the remainder of your comments, provided they are submitted prior to FDA's review of the data and information submitted

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during the original comment period. Please send three copies of the additional data and information directly to the Division of Dockets Management. Indicate in the cover letter that the information is a supplement to comment No. C26, dated October 4, 2004.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Charles J. Ganley". The signature is fluid and cursive, with a long horizontal stroke extending to the right from the bottom of the name.

Charles J. Ganley, M.D.
Director
Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: APR 18 2005

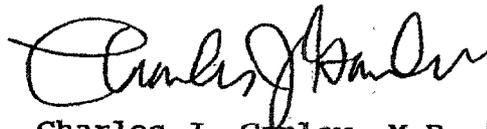
FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 1981N-0033P

TO: Dockets Management Branch, HFA-305

The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment No. EC4


Charles J. Ganley, M.D.

Attachment