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Date: November 18, 2003

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

Re: Establishment of New OTC Monograph for Antigingivitis/Antiplaque Drug Products (21 CFR Part 356): Docket No. 81N-033P; RIN 0910-AA01

Dear Sir or Madam:

I write on behalf of Access Business Group (ABG), a wholly owned subsidiary of Alticor, Inc., to express our **support for the inclusion of triclosan as a safe and effective ingredient under the above-listed new monograph**. ABG serves the consumer and business-to-business market with a wide range of capabilities, including product development and formulation, manufacturing, private labeling, logistics services, packaging design, freight and warehousing. ABG is a sister company of Amway and Quixtar Inc. and is based in Ada, Michigan.

Triclosan has been approved for use and is currently being marketed in numerous over-the-counter Antigingivitis / Antiplaque products world-wide (including the U.S.) and should be included as an appropriate ingredient for such uses under this monograph.

It is our understanding that a manufacturer of triclosan, Ciba Specialty Chemicals Corporation, will be making a Time and Extent Application (TEA) to this docket supporting the Category I listing of triclosan under this monograph. Based on its long history of safe and efficacious use in this area, we support this TEA and urge the Agency to include triclosan as an acceptable Antigingivitis/Antiplaque ingredient under this monograph.

Sincerely,

A handwritten signature in black ink that reads "Thomas E. Hamernik". The signature is written in a cursive, flowing style.

Thomas E. Hamernik
Senior Research Regulatory Analyst
Technical Regulatory Affairs
Access Business Group

81N-033P

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