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June 17, 2003

VIA FACSIMILE AND REGULAR MAIL

Dr. Michelle M. Jackson
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Over-the-Counter Drug Evaluation
Corporate 2, rm. S254 (HFD-560)
9201 Corporate Blvd.
Rockville, MD 20850

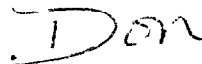
Re: Alcavis International, Inc. Citizen Petition (Docket No. 75N-183H, CP13)

Dear Dr. Jackson:

This letter follows up on questions that were raised by your office regarding the use of sodium hypochlorite for a material time and to a material extent as a healthcare antiseptic. For your convenience, we forwarded to you several documents that have been previously submitted to the Docket Management Branch. Among these documents is the original Citizen Petition by Alcavis that addresses, among other things, the use of sodium hypochlorite for a material time and to a material extent as a healthcare antiseptic. In particular, we would like to draw your attention to References 31, 33, 36, 37 and 40. The references indicate that the use of sodium hypochlorite preceded the Over-the-Counter ("OTC") Drug Review. Moreover, one of the references (i.e., Ref. 40) actually identifies a manufacturer of the product during the 1930's.

As we have previously stated, it does not appear that the Citizen Petition and subsequent correspondences have been given any meaningful review. The actions requested by Alcavis merits complete consideration and we request acknowledgement that such actions will be reconsidered. If you have any questions or require additional information, please feel free to contact us.

Very truly yours,



Donald E. Segal

75N-183H

cc: Dockets Management Branch
John M. Taylor
Tom Chin
Gerald Rachanow

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