KELLER AND HECKMAN LLP

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WRITER'S DIRECT ACCESS

December 8, 2003

Jerome H. Heckman (202) 434-4110 heckman@khlaw.com

Via Electronic Submission and Regular Mail

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

Re: Pilot Program for Electronic Submissions of Food Contact Notifications;
Docket No. 2003N-0513

Dear Madam or Sir:

In response to the November 26, 2003 Federal Register Notice, Keller and Heckman respectfully requests to participate in the Food and Drug Administration's (FDA) pilot project to test the efficiency and practicality of a prototype procedure for filing Food Contact Notifications (FCNs) in electronic format (68 Federal Register 66448). Keller and Heckman has been pleased to work with FDA on the development of the FCN program since its inception, and we believe that, because of our representation of many of the stakeholders in the FCN process, we have a unique ability to assist the Agency in evaluating and commenting on the prototype electronic submission process. By offering to participate in the pilot program, Keller and Heckman represents that it intends to file at least four FCNs in electronic and written format during the pilot project.

We look forward to participating in this project with FDA and to improving the efficiency of the FCN process for the regulated community. If you should have any questions regarding our request to participate in this program, please do not hesitate to contact us.

Sincerely yours,

Jerome H. Heckman

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