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December 8, 2003

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

RE: Comment on Prior Notice Rule

To Whom It May Concern:

The new October 10, 2003 Interim Final Rule for Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, requires prior notification of imported food as of December 12, 2003. The Rule requires the FDA Registration Number be identified to the FDA via ACS or OASIS on the prior notice form of any facility that manufactured a food or beverage item being imported for consumption into the United States as of December 12, 2003. The Rule does not address the situation whereby an importer or an overseas exporter does not know the FDA Registration Number of the facility that manufactured the item to be imported.

Specifically, the issue of what Customs and Border Protection describe as "U.S. Goods Returned" is not addressed by the Rule. Merchandise made in the United States by the first party is exported overseas and purchased by a second party, who then sells it to a wholesaler third party in the overseas country, which ships it back to the fourth party importer in the United States. The fourth party importer has had no contact with the first or second party, and the information about the manufacturer is not publicly available. Moreover, in the typical scenario, any attempt by the fourth party to the first party manufacturer inquiring about the FDA Registration Number will be rejected.

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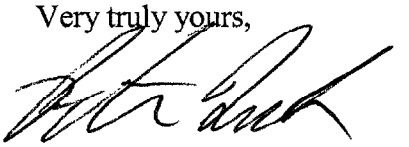
The Rule does not address the situation described above whereby the manufacturer refuses to provide its FDA Registration Number to the importer which purchases the food and beverage items overseas for importation and consumption in the
United States. Please amend the Rule to require, upon inquiry to the manufacturer, that the manufacturer must provide its FDA Registration Number.

Very truly yours,



Peter A. Quinter
For the Firm

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Cc: Clover Systems, Inc.