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An Association of California Table Wine Producers

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June 1, 2004

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Ref: Docket No. 2002N-2078
Alternative producer identification method for Prior Notices

Dear Sirs:

The Family Winemakers of California (FWC) submits the following comments in support of adopting a supplemental producer identification method to the registration number system specified in the interim final rule for Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. FWC's comments are intended to support the position advocated by the California Fine Wine Alliance in comments submitted on December 24, 2003.

FWC represents over 670 small and growing wineries, vineyards and supporting businesses. Its members grow grapes, make wine and are a key part of the state's \$33 billion wine industry. Selling fine wine in today's highly competitive marketplace is a challenge for small producers. Representation and presence in the marketplace are crucial. The FDA's Prior Notice rule making will negatively impact small producers by reducing the number of potential representatives and sales venues as secondary fine wine market importers disappear. FWC believes in an open marketplace and the current Prior Notice proposal will disrupt the free flow of goods between nations.

The fundamental intent of the Bioterrorism Act is to protect food safety. Producer registration was designed to give FDA critical response information when there is a question about a product's safety. The FDA's Prior Notice system would allow it to track imported food stuffs, including wine. Fine wine, however, is fundamentally different from typical short shelf life consumables. Because fine wine often passes through several ownerships and increases in age and value prior to importation into the U.S., the producer registration numbers lose their relevance. FDA's notice scheme should focus on what entity had possession of the fine wine shipment last. To require non-designated importers of fine wine on the secondary market to comply with the Prior Notice is to erect a meaningless trade barrier.

The maturing process and collectors' market for fine wines requires FDA to reevaluate the application of the prior notice requirements to these products. It is appropriate for FDA to consider applying, if only to fine wines, that the absence of a registration number would not prohibit importation of the product.

The FDA should provide an option for importers who can identify the manufacturer of the wine, but who do not have access to the facility's registration number. A potential mechanism to mitigate the disproportionately negative effect on wine importers and distributors would be to amend the prior notice requirement to allow

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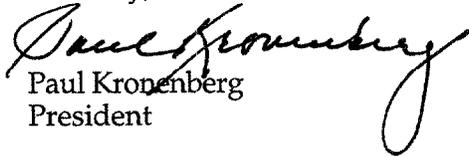
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the notifier to provide FDA with a reason for the absence of a registration number and furnish supplemental information that would be informative in providing for food safety. The supplemental information should be the name and address of the producer. In its evaluation of the prior notice, FDA may then choose to inspect the product based on the absence of the registration number or concern about the supplemental information. This approach will avoid situations where shipments are rejected while still preserving FDA's regulatory discretion.

By excluding a sizable percentage of fine wine imports, the prior notice regulations, as currently written, will have significant economic and trade consequences on the wine industry. Such impacts are clearly not the purpose of the Bioterrorism Act, nor are they consistent with the expressed intent of Congress to minimize trade barriers. For these reasons, Family Winemakers of California joins with the California Fine Wine Alliance in respectfully requesting FDA to consider an alternative to the use of registration numbers.

Sincerely,



Paul Kronenberg
President