



THE CHICAGO WINE COMPANY

Celebrating Our 28th Year as Fine Wine Merchants

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May 13, 2004

VIA FEDERAL EXPRESS

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

Re: Docket No. 2002N-0278 – Interim Final Regulation 21 C.F.R. Part 1,
Subpart I, Sections 1.276 through 1.285 (the “Prior Notice Regulation”)

Dear Ms. Fuller:

I am writing to you as the owner and President of The Chicago Wine Company, which is located at 5663 West Howard Street, Niles, Illinois 60714. The Chicago Wine Company has been in business for nearly thirty years and specializes in fine and rare wines, most of which are imported.

A provision of the FDA’s Prior Notice Regulation threatens to limit the wines that our company and hundreds of other small, fine wine merchants throughout the United States can import, substantially hurting our business. I am writing to ask that the FDA change the regulation in the narrow manner I propose below, in the final version of the regulation.

As you know, the Prior Notice Regulation requires that a “prior notice” form be submitted to the FDA whenever food or beverages (including wine) are to be imported into the United States. This prior-notice aspect of the regulation is not the problem. The problem is the requirement that for every wine that is imported for us by our importer/wholesaler, we must provide the FDA-issued facility registration number for the winery which produced the wine. It is virtually impossible for us and for many others affected to provide these registration numbers, because the numbers are not publicly available.

Many foreign wineries that deal only with a single, exclusive distributor or importer are not divulging their FDA registration numbers to anyone other than their exclusive distributor or importer. The rest of us, who obtain wine legally on the open market in Europe and elsewhere in order to import it into the U.S., are unable to obtain many of the numbers. Quantities of fine

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wine in the U.S. are thus being limited and prices can be expected to rise, just as the wineries and their exclusive distributors and importers would like. This is anti-competitive and a restraint on trade.

The FDA is not required under the Bioterrorism Act to make food and beverage producers' registration numbers a requirement of the prior notices. The Bioterrorism Act requires only that the prior notice provide the "identity" of the producer (referred to as the "manufacturer" under the Act and in the Prior Notice Regulation). (See Section 307 of the Bioterrorism Act, 107 P.L. 188.) When registering with the FDA, foreign producers are required to provide the FDA with their name, the street addresses of their facilities and the trade names under which they do business. (See Section 305 of the Bioterrorism Act.) The FDA then maintains this information in a database of registered producers. If importers were to provide only the name and address of the producer in their notices, this would be sufficient to identify the producer.

The change to the Prior Notice Regulation that I propose is simple. The first sentence of Section 1.281(a)(6), which is part of the list of required information in a prior notice, currently reads, "For an article of food that is no longer in its natural state, the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food." This sentence should be changed to read, "For an article of food that is no longer in its natural state, the name and address of the manufacturer of the article of food." Reading thus, the regulation would no longer require importers of food or beverages to include the registration number in prior notices of import.

The FDA has indicated that it wants the new facility registration requirement to be enforced through the prior notice regime. This can be accomplished without requiring that the facility registration numbers be included in the prior notice. With the name and address of the producer included, the FDA can look up the producer in its database of registered producers. If the producer has not registered, then the FDA would deny entry to the food or beverages in question. The producers therefore already have a strong incentive to register themselves with the FDA, since that is the only way their products can gain entry into the U.S.

I am asking that the FDA change the Prior Notice Regulation as I propose above. It is not only The Chicago Wine Company that is being hurt. Most smaller importers, wholesalers, retailers, restaurants, clubs or hotels that buy wine for import are also being negatively affected, as well as the extensive number of private individuals who ultimately purchase such wine. If the requirement that registration numbers be included in the prior notice remains in the final version of the regulation, all of us who import wine will be prevented from doing business in any wine whose winery's registration number we cannot obtain. It is reasonable to assume that there are other industries, in addition to the retail wine industry, that are being affected in the same way. Congress surely never intended these effects when enacting the Bioterrorism Act.

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I look forward to hearing from you as soon as possible. Thank you.

Very truly yours,

Philip H. Tenenbaum

Philip H. Tenenbaum,
President