



THE CHICAGO WINE COMPANY

Celebrating Our 28th Year as Fine Wine Merchants

5663 West Howard Street • Niles, Illinois 60714 U.S.A.

(847) 647-8789 • Fax (847) 647-7265 • tcwc@aol.com • www.tcwc.com

2289 '03 OCT 31 AM 36

October 30, 2003

VIA FEDERAL EXPRESS

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

Re: Food and Drug Administration Interim Final Regulation 21 CFR Part 1,
Subpart I, Sections 1.276 through 1.285 (the "Prior Notice Regulation")

Ladies and Gentlemen:

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 FDA's Prior Notice Regulation was published under the Bioterrorism Act on October 10, 2003 and is scheduled to become effective December 12, 2003. This regulation requires that prior notice be submitted to the FDA whenever food or beverages (including wine) are to be imported into the United States. A small, and I believe unnecessary, provision threatens to force our company and hundreds of other small, fine wine merchants throughout the United States out of business.

The Chicago Wine Company has been in business for almost thirty years, and we specialize in fine and rare wines, most of which are imported. The wines we buy are imported for us by a licensed Importer/Wholesaler with all of the required label approvals, etc.

The prior notice aspect of the Prior Notice Regulation is not the problem. The problem is the requirement that for every single wine that is imported for us by our Importer/Wholesaler, we must provide a registration number for the winery which produced the wine. That will be virtually impossible to comply with for many of those affected, because the registration numbers will not be publicly available.

It is not only The Chicago Wine Company that will be negatively impacted. Most importers, wholesalers, retailers, restaurants, clubs or hotels that buy wine for import will also be affected, as well as the extensive number of private individuals who ultimately purchase such wine. This could also have a huge negative effect on the entire wine trade of the United Kingdom, home of the world's largest wine trading center (London). Much of the wine being

02N-0278

C 234

offered for sale by the U.K. wine trade is already in the U.K., and now the U.K. wine merchants won't be able to sell it to their U.S. customers, since they will be unable to provide the registration numbers that the FDA is requiring.

We buy wine in Europe and elsewhere from a variety of different sources:

1. Wholesalers
2. Retailers
3. At auction
4. From private individuals

It is virtually impossible for us to buy wines directly from the wineries that produce the wine. Those producing wineries are the entities which must obtain the registration numbers from the F.D.A. Most wholesalers, retailers, auction companies and private individuals will not have the registration numbers, and without those numbers, the wines we buy abroad will not be allowed into the United States as the regulation now reads.

Many such wineries deal only with a single, preferred distributor or importer. These wineries can be expected to refuse to divulge their FDA registration numbers to anyone other than their preferred distributor or importer. The rest of us, who obtain wine legally on the open market in Europe and elsewhere in order to import it to the U.S., will be unable to obtain the numbers. Quantities of fine wine in the U.S. will thus be limited and prices higher, just the way the wineries and their preferred distributors/importers like it. This is uncompetitive and un-American.

The FDA is required under the Bioterrorism Act to write and implement regulations concerning prior notice of imported food and beverages, including wine. The Bioterrorism Act requires that the prior notice "identify" the producer. However, the FDA is not required under this Act to make the wineries' registration numbers a requirement of the prior notices. All wineries producing wine for consumption in the U.S. will be required under other provisions of the Bioterrorism Act to provide to the FDA their name, the street addresses of their facilities and the trade names under which they do business. Therefore, so long as the importer provides the name and address of the producer of the wine, this will be sufficient for the FDA to identify whether the producer is registered with the FDA. Additionally requiring the importer to furnish an identification number is unnecessary to implement the Act.

Further, in the case of wine and other alcohols, the usefulness of registration numbers in prior notices is made even smaller by the existence of the label-approval system that currently exists involving the Bureau of Alcohol, Tobacco and Firearms (BATF). Under this system, importers must obtain label approval from the BATF for each wine imported. After these

Division of Dockets Management (HFA-305)
Food and Drug Administration
October 30, 2003
Page 3

approvals have been obtained, the FDA then reviews the label-approval forms as it clears the wine for entry into the U.S. Considered together with the new prior-notice process, these label approvals should provide the FDA with a greater degree of certainty that the wine being imported is actually from the winery indicated in the prior notice. In addition, the label approvals would give the FDA greater opportunity to detect discrepancies in a given winery's registration – for example, a winery using a trade name that was not furnished in its registration. Also, if a winery has been given a registration number by the FDA and a wine importer receives a label approval from the BATF for that winery's wine, it would seem logical that the FDA should allow the importer to import that wine even though the importer might not know the winery's registration number (which would be on file at the FDA).

Although the requirement of registration numbers is therefore a redundant and seemingly small detail of the regulation, it will have drastic negative effects on the ability of wine retailers like The Chicago Wine Company to import fine wines. Congress surely never intended these effects when enacting the law.

I am primarily (and urgently) asking you to change the Prior Notice Regulation to eliminate the requirement that the registration numbers be included in notices of imported wine and that only the name and address of the producer be required.

Finally, we did not know about the Prior Notice Regulation until relatively recently, or we would have voiced our concerns much sooner. Hundreds or thousands of other U.S. firms were also late in finding out. If the registration number provision for wine is not eliminated, at the least the FDA should permit a six-to-nine-month grace period for compliance with the registration number requirement, so that the many firms unfairly caught off guard are given time to import the wine that they have already purchased before learning about the requirement. I therefore secondarily ask you to allow a six-to-nine-month grace period to comply if the registration number provision is not eliminated.

I look forward to hearing from you as soon as possible, since the December 12, 2003 effective date is fast approaching.

Sincerely,

Philip H. Tenenbaum
by J. B.

Philip H. Tenenbaum
President

PHT:mr