



E. & J. GALLO WINERY

COMPLIANCE DEPARTMENT — TELEPHONE 209-341-7521; FAX 209-341-6959

April 3, 2003

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

Docket No.: R 02N-0276

Ladies and Gentlemen:

E. & J. Gallo Winery respectfully submits that the proposed plant registration requirements, as applied to alcohol beverage production (wineries, breweries, distilled spirits plants) are redundant with existing requirements. As such, they merely add to the already profuse amount of paperwork and recordkeeping that impacts much of our business, without contributing anything to Homeland security. We would like to seriously urge your reconsideration of the comments made by the Bureau of Alcohol, Tobacco and Firearms on August 30, 2002, with regard to duplicate plant registrations.

As you are aware the Bureau of Alcohol Tobacco and Firearms has been split between Department of Justice and the Department of Treasury. The relevant functions for this discussion are within the newly-formed Alcohol and Tobacco Tax and Trade Bureau (TTB), which remains in the Department of Treasury. There has been no change in the position of TTB regarding registration under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Our registrations with the TTB meet all the requirements of the Act of 2002, as outlined in their letter and the Internal Revenue Code. We operate under the requirements of the Federal Alcohol Administration Act, which stipulate that we must have a Basic Permit allowing us to engage in the business of producing and selling wine and brandy and a plant registration to produce malt beverages (beer). As part of the permit and registration process, we are required to provide background information allowing the TTB to verify the personal integrity of our officers and directors and the validity of our business structure, confirming (among other things) that there is no hidden ownership.

In addition, TTB regulations impose detailed recordkeeping requirements. These enable the TTB or, if the need arises, the Food and Drug Administration to track all of our products throughout distribution—beginning with the source materials from which they

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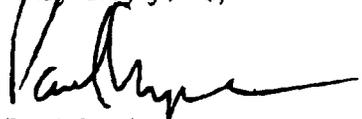
were produced and including any treatment materials that may have been used during the course of their production.

We urge you to accept the invitation of the TTB to further discuss the extent to which the proposed plant registration requirement would essentially duplicate information already contained in TTB's files.

Whether or not you consider TTB's databases sufficient for your purposes under the Act, we request that you also provide an alternate means of on-line registration wherein the registrant would be allowed to submit the data in the form of a spreadsheet file, a flat file, an XML document, or some other file format that would simplify the process of registering multiple facilities. Even if you do not require us to re-register our four (4) winery locations, there will be additional locations we will be required to register by virtue of our processing of waste materials for animal feed and other uses. We also operate a number of distribution points that might require registrations, depending on how the final regulations define registered facilities. This would also facilitate processing changes in registration information by allowing batch-mode entry instead of time-consuming, interactive, on-line entry of the information.

You are faced with a gargantuan task to develop a system of registration under the Act. Once again, we urge that you accept registration of members of the industries regulated by the TTB in lieu of a duplicate registration with the FDA. While there would still be some facilities that E. & J. Gallo Winery might need to register, as noted above, you would find the bulk of our registrations already on file by virtue of the requirements of the Federal Alcohol Administration Act and the Internal Revenue Code.

Very truly yours,



Paul C. Thorpe
Director of Compliance

PCT/lss

**E. & J. GALLO WINERY**

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FAX

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Re: Response to Docket No. R 02N-0276	

PLEASE DELIVER IMMEDIATELY UPON RECEIPT. THANK YOU.

If you have problems receiving this fax, please phone Linda Segal at 209-341-3392.