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TRANSMITTED VIA FAX TO (301) 210-0247 & BY U.S. MAIL

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

Re: Docket No. 02N-0278
Request for stay of enforcement of newly established regulations under the
Public Health Security and Bioterrorism Preparedness and Response Act of
2002.

To whom It May Concern:

Please be advised that this office is general counsel for Transat Trade Company, a
California and U.S. importer and distributor of fine wines.

I have reviewed the letter addressed to your office from attorney Stuart M. Pape of the
Law Firm of Patton Boggs dated July 12, 2004 written on behalf of his client, the California
Fine Wine Alliance. Although my client is not associated with nor a member of the
California Fine Wine Alliance, nevertheless, my client concurs with the comments made by
Mr. Pape on behalf of his client.

Without being repetitious to that argument and comments made by the California Fine
Wine Alliance the following comments and request are made on behalf of Transat Trade only
and are separate and distinct and do not necessary reflect the opinions or position of Mr. Pape
and his client.

Suffice it to say that if the new registration program affecting the importing of foreign
wines is put into effect the result will be disastrous for both the wine industry and the
consumer. Many importers of fine wines, like that of Transat Trade, depend upon the
secondary market for their importation and distribution. The effect of this new regulation
will be to entirely eliminate the importation of wines on the secondary market, and will
prevent the importation of fine vintage wines into this country. The enforcement of the

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newly established registration will cause irreparable harm to the wine industry and the consumer.

Based upon the registration requirements enacted by the FDA under the Bioterrorism Preparedness and Response Act of 2002 it is highly questionable that the newly established regulations are Constitutional and will most likely be challenged in the Federal Courts. Because of the popularity and demand for old wines of vintage quality it is also likely that flourishing black market may arise which circumvents the registration of the product.

By this letter I am hereby requesting a temporary stay of enforcement of the newly established regulations pertaining to registration by the bottler of foreign wines pending administrative hearings to determine the best methods of compliance with the Bioterrorism Act. I believe it was not the Congressional intent in the enactment of the Act to harm the wine industry and the consumer. There are alternative methods of regulation without compromising the safety and welfare of the public under the Bioterrorism Act of 2002.

In conclusion, it is respectfully requested that the FDA place into effect a temporary stay of enforcement pending administrative hearings to determine the best method of enforcement of the Act for the good of the wine industry and consumer without compromising the safety and welfare of the public as was intended by Congress in the enactment of the Bioterrorism Act of 2002.

Sincerely yours,

Bruce J. Guttman