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December 24, 2003

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COURIER

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

Re: Comments to the Interim Final Rule; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Docket No. 02N-0278)

Dear Sir or Madam:

These comments are submitted on behalf of the California Fine Wine Alliance ("Fine Wine Alliance"), to the interim final rule for Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002[1] ("Bioterrorism Act"), published in the *Federal Register* of October 10, 2003.[2] These comments are supported by 64 members of the wine industry, which are individually listed beginning on the signature page.

The Fine Wine Alliance represents the entire spectrum of the foreign and domestic wine industry. Its members include consumers, retailers, wholesalers, importers, and wineries in addition to well formed relationships with similar organizations in other countries with prominent wine industries.

In sum, the Fine Wine Alliance believes that the FDA has misinterpreted the statutory language of the Bioterrorism Act by requiring the food facility registration number as part of the information for prior notice. This requirement may have unforeseen and

[1] Pub. L. No. 107-188, 116 Stat. 594 (2002).

[2] 68 Fed. Reg. 58974 (Oct. 10, 2003).

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unintended consequences that may severely impede the movement of fine wine from foreign producing countries into the United States without adding at all to the security of the food supply. In addition, when FDA developed the prior notice regulation, the Agency apparently assumed that foreign produced food products are ordinarily imported into the United States by a person with a direct relationship with the manufacturer. Although this may be true in the case of most foodstuffs, it is decidedly not the case for fine wine. Because fine wine improves with age, commerce in fine wine involves its acquisition of fine wine from persons other than the winery, which produced it (restaurants, private collectors, and estate sales, for example). Such transactions take place many years after the wine was initially produced. In all of these instances, the person importing the wine will not have access to the facility registration number of the winery where the wine was produced. Thus, under the interim final regulation, the importer will not be able to submit a complete prior notice.

This is not a result that the Congress intended nor is it a reasonable implementation of the Bioterrorism Act. By failing to consider the unique factors that relate to fine wine, FDA may be imposing burdensome, if not impossible, requirements on wine importers and distributors. FDA's actions may result in restraints on trade that may violate the World Trade Organization ("WTO") Treaty. Finally, the anticompetitive business environment created by FDA's interpretation of the prior notice provision of the Bioterrorism Act is contrary to the spirit of the Federal Trade Commission Act ("FTC Act"). Therefore, the Fine Wine Alliance respectfully requests that FDA recognize that the facility registration number may not always be available for inclusion in a prior notice where fine wine is concerned. 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. By doing so, the prior notice regulation can remain consistent with the Bioterrorism Act, but avoid the creation of legally impermissible barriers to trade.

I. Background on the Wine Industry

It is apparent that FDA did not consider major elements of the imported wine market when developing the prior notice requirement. While many wines (like most foods) can be produced in any quantity to meet consumer demand, *fine* wines cannot. Fine wines are carefully crafted products of particular vineyards or sets of vineyards that contribute distinctive qualities. Fine wines make up a small percentage of total world wine production, but they constitute a far greater percentage of the total U.S. wine market in

dollar value. It is this segment of the United States wine market that is threatened by the proposed prior notice requirement as it is currently written.

Fine wines are virtually always made from grapes grown in a single year. Because each year yields a wine of individual character, a wine's value and desirability in the market can vary dramatically depending on the vintage. The value of fine wines also varies, depending on their age, and many wines are aged for years, or even decades, to improve their quality and increase their value. The most desirable fine wines tend to be made in tiny quantities—from a few hundred to a few thousand cases a year—and are demand inelastic (i.e., they cannot be easily substituted). If demand is high and availability is limited, prices will rise until a balance of supply and demand is achieved.

The relationships between producers and importers tend to be long established and are based on allocations that vary little from year to year. Producers expect their foreign importers to accept their annual allocation regardless of economic conditions in their country. Even when faced with a downturn in demand, or unfavorable foreign exchange rates, importers are reluctant to turn down their annual allocation, knowing that they could easily be replaced. So they virtually always accept their allocation, and if selling the wine is a problem, they count on the secondary market and, ultimately, the American market to achieve market stability.

Today, demand for fine wine in the United States is, by far, the greatest in the world. This is a function not just of this country's size and purchasing power. It is also a reflection of a wine market that has come of age over the past twenty years. Today, Americans consume over 2 billion liters of wine each year, a vast increase over years past. Furthermore, tens of thousands of Americans would call their interest in food and wine their primary avocation, pumping hundreds of millions of dollars into local economies through restaurants and wine shops.

The wines to meet these consumers' needs are supplied in three ways: (1) domestic wineries, (2) direct-from-producer imports and (3) secondary-market imports. It is this last source that is threatened by the prior notice requirement.

Domestic wines meet approximately 70% of American wine demand. However, they are far less dominant within the fine wine market. While great progress has been made by American wine producers in recent years, a relatively small percentage of domestic wines have achieved the same stature in the market as the best European wines.

Direct-from-producer imports are the primary source of imported fine wines. Most fine wine producers have one or more designated American wine importers who receive an allocation of each year's production. Typically, a foreign producer will allocate about one-quarter of its total production to the United States. It will, in turn, allocate smaller quantities to other countries: for example, 10% the United Kingdom, 10% to Germany, 10% to France, 5% to Italy, etc.

For the most prestigious and desirable wines, the 25% allocation does not come close to meeting the demand of American consumers. In the meantime, the allocations that producers give other countries—particularly those experiencing unfavorable short-term economic conditions or unfavorable currency exchange rates—are often in excess of local demand. These imbalances are corrected by the scores of small specialist importers and private collectors who purchase wine on the foreign secondary market, particularly in Europe. The sources of these purchases include private wine collections, wine auctions, restaurant cellars and wine shops.

Currently, secondary market imports to the United States amount to approximately $200,000,000, or approximately 7.5% of the United States' $2.6 billion dollar imported wine market. However, within the context of fine wines, it is far more important—nearer to 20% of the total.

The requirement that all imported wines be accompanied by the facility registration number of the wine manufacturer overlooks the way in which the fine wine market functions. As proposed, the regulations would create instant trade monopolies. Early predictions that designated importers would discourage producers from giving their facility registration numbers to secondary importers have proven true. Already, many third-party requests for registration numbers from important European producers have been denied. In each case, the producer has said that their American importer has informed them that they cannot or should not give out this information.

More than any other segment of the wine market, the fine wine market is truly international, depending for its health on free trade among countries. The proposed prior notice requirement will not only create a significant trade barrier between the United States and other nations, but it will seriously disrupt the world market for fine wines. Global prices will be depressed while prices in the United States will rise; Americans will be robbed of their *only* source for imported old wines and the livelihoods of many small wine merchants and their employees will be placed in serious jeopardy.

II. FDA Misinterpreted the Bioterrorism Act

A. Background on the Prior Notice Regulation

The Bioterrorism Act was signed into law on June 12, 2002, with the intended purpose of providing FDA with the additional tools necessary to prevent a food-related bioterrorism event or other public health emergency. The Bioterrorism Act provides FDA with the authority to require, among other things, registration of food facilities and submission of prior notice for imported foods.

Accordingly, FDA initiated rulemaking to establish the requirements for prior notice. In the Notice of Proposed Rulemaking (NPR),[3] the Agency set forth the information that must be included in the prior notice, which included the identity of the manufacturer in the form of the name, address, phone number, fax number, e-mail address, and, if required to register, the food facility registration number.[4] Although FDA modified slightly the required information for proper identification of the manufacturer in the interim final rule by removing the requirement for the phone and fax number and e-mail address, the food facility registration number requirement remained.[5]

FDA stated that it does not believe that the Bioterrorism Act gives the Agency "the authority to waive the registration requirement for facilities that manufacture/process, pack or hold food for consumption in the United States."[6] FDA further stated that registration is "designed to work in concert with prior notice at the border as reflected in new section 801(l) of the [Federal Food Drug and Cosmetic Act ("FD&C Act")], which provides that food from facilities that must register may not be admitted into distribution for consumption in the United States unless the relevant facilities have been registered."[7]

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[3] 68 Fed. Reg. 5428 (Feb. 3, 2003).

[4] As provided for in the food facility registration regulations, certain facilities are exempt from registering with FDA. (Interim Rule 21 C.F.R. § 1.226) Additionally, for certain transshipments of imported foods that will not enter U.S. commerce, the registration number is not required. (Interim Rule 21 C.F.R. § 1.277)

[5] 68 Fed. Reg. 58974 (Oct. 10, 2003).

[6] Id. at 59001.

[7] Id.

An alternative approach, which was suggested by the comments, is to provide identifying information such as the name and complete address to allow FDA to independently verify that the manufacturer is properly registered.[8] However, FDA rejected this option by stating that it was unwilling to confirm registration without requiring that the number be submitted as part of the prior notice. The Agency's rationale for its denial was that there may be confusion with verifying such information because manufacturers may have the same or similar names and several may be located at a particular location. In addition, FDA believes that requiring the registration number, as part of the manufacturer's identity makes clear to foreign exporters and U.S. importers when registration is required for imported food. FDA was unwilling to alter its determination for requiring food registration numbers.

B. Plain Language of the Statute and Relevant Legislative History Does Not Support FDA's Broad Interpretation

To interpret properly the intent of Congress with respect to the provision that requires the "identity of the manufacturer," FDA must determine whether Congress has directly spoken on the precise question in the plain language of the statute, and, if so, the Agency must implement Congress's clearly expressed intent.[9] If the statutory language, on its face, does not clearly establish Congress's intent, it is appropriate to consider not only the particular language at issue, but also the language and design of the statute as a whole.[10]

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[8] Id.

[9] 68 Fed. Reg. 58984 (Oct. 10, 2003), citing Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837 (1984).

[10] 68 Fed. Reg. 58984 (Oct. 10, 2003), citing Martini v. Federal National Mortgage Association, 178 F.3d 1336 (D.C. Dir. 1999), citing Kmart Corp. v. Cartier, Inc., 486 U.S. 281 (1988).

For prior notice, § 307 of the Bioterrorism Act states that:

> "in the case of an article of food that is being imported or offered for import into the United States, [FDA] shall by regulation require, ***for the purpose of enabling such article to be inspected at ports of entry into the United States***, the submission to the [FDA] of a notice providing ***the identity of*** each of the following: the article, ***the manufacturer*** and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originated; the country from which the article is shipped; and the anticipated port of entry for the article."[11]

The statute clearly states that the "identity of the manufacturer" must be included for prior notice. It does not allude to or require the registration number. Moreover, identity is also used to describe the information necessary for the other elements enumerated by Congress in the statute, which includes article, shipper, grower, country of origination, country where the article is shipped from, and port of entry. Surely, identity cannot mean "registration number" for these terms as well. If Congress intended FDA to require the registration number, it would have specifically articulated this requirement as it did in § 321 of the Bioterrorism Act for drug and device imports.[12]

To justify FDA's broad interpretation of "identity" to mean registration number, evidence must exist elsewhere in the statute or legislative history. However, the legislative history repeatedly directs FDA to "minimize potential impacts on trade,"[13] that "neither the requirements of the notice nor the timing of the prior notice be more burdensome than necessary,"[14] and "that prior notice requirements never become a barrier to the smooth flow of commerce."[15] When the meaning of "identity of the manufacturer" is evaluated

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[11] Pub. L. No. 107-888, §307; 116 Stat. 594, 670 (2002) (emphasis added).

[12] Pub. L. No. 107-188, § 321, 116 Stat. 594, 675-676 (2002).

[13] 148 Cong. Rec. H2845-H2846 (May 22, 2002) (Statement of Rep. Tauzin).

[14] 148 Cong. Rec. H2858 (May 22, 2002) (The Bioterrorism Act conference report that was submitted for the record).

[15] Id.

in conjunction with these explicit instructions from Congress, FDA's interpretation is clearly erroneous. Congress unquestionably intended for FDA to take the least burdensome approach, which is not manifested in the prior notice requirements established by the Agency.

C. Consequences of FDA's Interpretation Directly Conflict with the Express Intent of Congress

By excluding a sizeable 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.

It is estimated that $200 million annually in imported wines will be barred access to the United States if the prior notice regulations remain as written. And for the American adult public, a quarter of whom are wine drinkers, the consequences are particularly far-reaching.

Producers' designated importers will have a monopoly on facility registration numbers, and faced with no competition for their particular wines, they will have a free hand to raise prices. Prices for the most desirable fine wines will inflate by as much as *50%*.[16] The oligopoly of large multi-state wine and spirit wholesalers, who have aggressively been buying up small distributors in many states, will become an even more dominant and oppressive force in the American wine market, leaving many residents of smaller states without *any* access to the fine wine market.

As the supply of many imported fine wines dries up, many of the small importers and wholesalers who breathe diversity into the American wine market will be forced to close. Small retailers will lose their ability to stock unique and hard-to-find wines, making it more difficult for them to compete with the large discount and chain stores. The closure of these small businesses will result in the potential loss of thousands of jobs.

The U.S.' thriving secondary market remains virtually the only source for Americans to purchase mature European wines. Under the proposed prior notice regulations, it would

[16] In the 28 states that have "primary source" laws, which do not allow any secondary market activity, wine prices are 50% higher, on average.

often be impossible to file complete prior notices for these wines and access to them will be shut down. This will starve American restaurants and retail shops of mature wines to sell.

The ability of small American importers to buy wines on the open market abroad is an established tradition dating back decades. This activity has long performed an important balancing function internationally, correcting poor producer allocations and preventing surpluses in foreign markets. Without the ability of demand from the U.S. to pick up the slack, wine inventories will pile up in many countries, leading to falling wine prices abroad. Not only will this have devastating implications for foreign wine markets; the United States' 20-year-old effort to build a vital export market for its wines will be severely set-back, as its products are unable to compete with a glut of lower-cost fine wines available in Europe and elsewhere.

Even the international wine auction market will be crippled. The major wine auctions in the United Kingdom and other European nations depend on American buyers (both private and trade). Without their participation, prices in auction rooms will collapse, sending a ripple through other segments of the fine wine market.

Finally, there is the threat of an emerging black market in fine wines. Licensed U.S. wine importers have long been required by the Alcohol, Tobacco, Tax and Trade Bureau ("Bureau") to provide detailed identifying information (including copies of all labels) for all wines imported. These requirements are reasonable and compliance is virtually 100%. Under the Prior Notice requirements as currently written, a black market is certain to be established, as licensed and unlicensed importers succumb to the incentive of low prices abroad and unmet demand at home. The FDA and Customs will have access to less complete information on wine imports than they have currently.

D. Review Process is an Efficient Means of Addressing Inadequate Prior Notices Due to Lack of a Registration Number

In the interim final rule, FDA attempts to explain that if a food is refused because of inadequate prior notice for failure to provide a registration number, review by the Agency may be requested.[17] FDA further explains that these instances will be limited to food

[17] 60 Fed. Reg. at 59001.

imports that are derived from food facilities that are no longer in business or have ceased making food within FDA's jurisdiction. To implement this review process, FDA established Interim Rule § 1.285, which specifically states that a request may be submitted to the Agency to review whether a facility is subject to the registration requirement. However, as the regulations state, the review process is not to be used for purposes of obtaining the food facilities' registration number.

The Agency's rationale and the review process completely disregard the procedures employed by the food industry and, in particular, the wine trade. Many within the food industry do not acquire food products directly from the manufacturer, and, therefore, do not have access to the food facility registration number. Moreover, FDA has ignored previous comments to the NPR informing the Agency of these methods of acquiring certain foods. For example, if a competing food product is found abroad and is imported into the United States for analysis, the importer may not have access to the product even though the food facility may be properly registered with FDA. There are other instances, such as trade shows and conventions, where food samples will require import into the United States, but the food facility registration number will be unavailable. The review process would be useless for the import of these food samples as it does not provide a remedy for situations where the importer has no way of obtaining the food facility registration number.

In addition, FDA does not understand that these situations will be frequent because the food industry is continually evaluating new products and sampling from various regions of the world. The effect of FDA's implementation of the review process for inadequate prior notices is that imported food will be barred from entry based on the single deficiency of a registration number although the food and its manufacturer may be in complete compliance with the provisions of the FD&C Act.

For the wine industry, the absence of a registration number in the prior notice will be a common and recurrent problem. As previously explained, the secondary market plays an enormous role in providing American consumers with fine wines. However, because the secondary market does not involve the original producing winery, obtaining registration numbers will be nearly impossible. Considering fine wines make up approximately $200 million dollars worth of imports, the numerous request for reviews of prior notices for wine imports will merely add to the volume of requests FDA will receive by other members of the food industry. Clearly, this is not an efficient or effective means of dealing with a situation that will repeatedly occur in light of the common practices of the

food industry and the difficulty of obtaining the registration numbers when wines are obtained through the secondary wine market. Accordingly, FDA should reevaluate the reasonableness of requiring the food facility registration number as part of the prior notice.

III. FDA's Rationale to Require the Registration Numbers is Seriously Flawed

In the interim final rule for prior notice, FDA reasoned that the Bioterrorism Act does not permit the Agency to waive the requirement for the food facility registration number as part of prior notice. The Agency explained that registration was designed to work in tandem with prior notice at the borders and that § 801(l) of the FD&C Act provides that food from facilities may not be admitted into distribution for consumption in the United States unless the relevant facilities have been registered. To enforce § 801(l) of the FD&C Act, FDA must review registration status as part of the prior notice, and the Agency contends that the registration information allows for crosschecking to determine if the facility is in compliance.

The rationale provided by FDA is unsubstantiated. The Bioterrorism Act states that prior notice shall be required "for the purpose of such article to be inspected at ports of entry into the United States."[18] The Act does not mandate that the registration and prior notice work in tandem for purposes of enforcing the registration requirement as suggested by FDA's interpretation. In fact, in the legislative history of the Bioterrorism Act, Congress often referenced both the registration and prior notice provisions, but never once stated or implied that the two were to be interpreted together, or that "identity" for prior notice purposes means registration number.[19]

FDA's attempt to enforce the registration requirement through the means of prior notice requirements, which affect persons that are completely unrelated to the party responsible

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[18] Pub. L. No. 107-188, § 307; 116 Stat. 594, 670 (2002) (emphasis added).

[19] 147 Cong. Rec. S13905 (Dec. 20, 2001) (Statement of Senator Frist); 147 Cong. Rec. E2388-E2389 (Dec. 20, 2001) (Statement of Rep. Shimkus); 148 Cong. Rec. S4780 (May 23, 2002) (Statement of Sen. Clinton); 148 Cong. Rec. H2845-H2846 (May 22, 2002) (Statement of Rep. Tauzin); 148 Cong. Rec. H2851 (May 22, 2002) (Statement of Rep. Waxman); 148 Cong. Rec. H2852 (may 22, 2002) (Statement of Rep. Bensten); 148 Cong. Rec. H2857-H2858 (may 22, 2002) (Statement of Rep. Shimkus); 148 Cong. Rec. E916 (may 24, 2002) (Statement of Rep. Shimkus); 148 Cong. Rec. E920 (May 24, 2002) (Statement of Rep. Dingell); and H.R. Conf. Rep. No. 107-481, at 76-77, 79-80, 132-137 (2002).

for registering the facility is inappropriate. Under the interim rule, any person may submit a prior notice for imported foods.[20] For the wine industry, secondary distributors and importers will likely be submitting prior notice. Under the Interim Rule, even when an importer determines that a facility is properly registered, the importer may be prevented from filing a complete prior notice. Confirmation that a facility is registered can be made without obtaining the registration number of the facility.

Congress specifically provided the Agency with additional enforcement tools to effectively implement the requirements of the Bioterrorism Act. The Bioterrorism Act explicitly states that the failure to register is a prohibited act under § 301 of the FD&C Act. As a prohibited act, FDA is permitted to use its enforcement powers to ensure that food intended for consumption in the United States was produced in a registered facility. In addition, the Bioterrorism Act authorized funds for FDA to increase inspection of foods offered for import,[21] administrative detention of food that the Agency deems a threat of serious adverse health consequences,[22] and the power to debar certain persons from importation of food into the United States.[23] With these newly authorized remedies, it was not the intent of Congress to enforce the registration requirement through prior notice and penalize third parties that are unable to compel registrants to disclose registration numbers.

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[20] Interim Rule 21 C.F.R. § 1.278.

[21] Pub. L. No. 107-188, § 302; 116 Stat. 594, 662 (2002).

[22] Pub. L. No. 107-188, §303; 116 Stat. 594, 663 (2002).

[23] Pub. L. No. 107-188, §304; 116 Stat. 594, 665 (2002).

IV. Unique Properties of Fine Wines Requires Modification of the Prior Notice Requirement

A. Lack of Continuity Between Winery and Consumer

Fine wines, unlike any other marketed food product, increase in value and desirability with age. Indeed, there is an emerging investment system known as wine futures that allows investors to speculate on the derivative price of wine from specific vintages and age. Fine wines initially produced at a specific winery may be aged for a limited amount of time at this facility before being distributed to importers for sale. From this point, fine wines may proceed down numerous paths before being purchased by the final consumer. Although some wines may be sold directly to consumers, often collectors obtain a substantial quantity and further age the wine for personal enjoyment, for exchange among other wine collectors, or to increase the value of their wine purchase. Therefore, because the aging process uniquely applies to fine wines, there is inherent in the system of acquiring these products a natural interruption between the final consumer and the original producing winery. It is common for fine wines to pass through multiple ownerships and increase in age and value before the products reenter commerce.

FDA did not consider the unique characteristics of fine wines when it developed and indiscriminately applied the registration number requirement as part of the prior notice. The maturing process and collectors' market for fine wines requires FDA to reevaluate the application of the prior notice requirements to these unusual 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.

B. Wines Do Not Present a Risk to the Public Health

The purpose of the Bioterrorism Act is to provide FDA with additional tools to help prevent a food-related bioterrorism event or other public health emergency. Of the food industries regulated by FDA, wines present the least risk to the public health. Because of the potential damage that may result if wine is exposed to air, bottles must be securely fastened with appropriate protective outer labels to ensure continued quality of the product and prevent any tampering after bottling. Wine is also regulated by the Tax & Trade Bureau.[24] As part of the Bureau's regulations, wine importers and distributors are

[24] 27 U.S.C. § 201 *et seq.*

required to hold a basic permit in addition to having all imported wine labels rigorously reviewed and kept on file with the Bureau.[25] Clearly, the nature of wine production and the Bureau's regulations both provide sufficient measures of security.

Major incidents of foodborne illnesses are most often associated with seafood and fresh produce.[26] More recently, the Center for Disease Control (CDC) concluded an investigation of an incident, which resulted in 3 people dead and approximately 555 people stricken with hepatitis A from ingesting green onions at a restaurant.[27] Despite these staggering figures, farms (for both produce and animals) are specifically exempt from registering; therefore, registration numbers are not required to appear on the prior notice of these goods.[28] Requiring registration numbers for wine producers is inversely correlated to the potential risk these products pose to the public health as compared to other potentially unsafe foods.

V. FDA's Actions May Violate the National Treatment Provision under the WTO Treaty

As a member of the WTO, the United States must abide by the provision of the WTO Treaty. The WTO Treaty includes the General Agreement on Tariffs and Trade ("GATT") as well as the Agreement on Technical Barriers to Trade ("TBT"), which specifically require National Treatment for all participating countries. The National Treatment provision is one of the most enshrined principles of the trade regime and specifically states in:

Article III of GATT,

> "The contracting parties recognize that internal taxes and other internal charges, and laws, regulations and requirements affecting the internal sale, offering for sale, purchase, transportation, distribution or use of products...should not be applied

[25] 27 C.F.R. Parts 1, 4, and 5.

[26] CSPI, Outbreak Alert, 2002.

[27] Morbidity and Mortality Weekly Report, 52(47); 1155-1157, November 28, 2003.

[28] Interim Rule 21 C.F.R. § 1.226.

> to imported or domestic products so as to afford protection to domestic production."[29]

Articles 2.1 and 2.2 of the TBT,

> "Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable [sic] than that accorded to like products of national origin and to like products originating in any other country,"[30] and

> "Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create."[31]

The National Treatment provisions of the WTO Treaty clearly state that members may not promulgate laws or regulations that serve as non-tariff technical barriers to trade and require equal treatment of products from all member countries. It appears that FDA, through promulgating the prior notice regulation, has effectively created a barrier to the international trade of wines by placing an onerous requirement on foreign wine and unfairly places foreign wine products at a severe disadvantage to domestic wines in the U.S. market.

As required by the interim final rule, the food facility registration number must be submitted as part of the mandatory information in the prior notice. As previously described, because of the unique procurement and distribution methods in the wine industry, secondary distributors and importers of foreign wine products may not be able to provide the registration number of the winery. Without the registration number, prior notice is considered inadequate and FDA may refuse the wine to enter United States commerce. Of course, domestic wines are not faced with this dilemma because they are

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[29] General Agreement on Tariffs and Trade, October 30, 1947, Article III.1.

[30] Agreement on Technical Barriers to Trade, Article 2.

[31] Id.

already within the borders of the United States, and there are no equivalent requirements to verify that domestic wines are produced at facilities that are properly register with FDA. By instituting the requirement for the food facility registration number, FDA has placed foreign wine products at a severe disadvantage to domestic wines, which results in the preferential treatment of domestic wines that may violate the National Treatment provisions.

Although strict regulations may be necessary for "legitimate objectives,"[32] the TBT specifically states that the "technical regulations shall not be more trade-restrictive than necessary." FDA may use other means, which are discussed later in these comments, to fulfill the laudable goals of the Bioterrorism Act without unnecessary negative ramifications on the trade of wine.

VI. FDA's Interpretation of the Prior Notice Provision is Inconsistent with the Spirit of the FTC Act

The purpose of the FTC Act is to protect the marketplace from unfair methods of competition and to prevent unfair or deceptive acts or practices that harm consumers. When these goals are achieved, it provides consumers with the freedom to choose goods and services in an open marketplace at a price and quality that fits their needs, and fosters opportunity for businesses by ensuring a level playing field among competitors. The mandates under the FTC Act embody the competitive nature of the American market.

However, the prior notice regulation established by FDA threatens to harm the spirit of the FTC Act. Requiring the food facility registration number as part of prior notice severely limits the potential importers and distributors that may provide product to the United States. Although wineries may be registered with the FDA to manufacture/process wine for consumption in the United States, only a limited number of distributors or importers may have access to this information because of the exclusive relationships that the wineries maintain. Properly obtained wine on the secondary market will not be eligible for import into the United States merely because of the limited access to the registration number. Additionally, the registration numbers will be held

[32] As identified in the TBT, legitimate objectives include, among other things, "national security requirements, the prevention of deceptive practices, protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia*: available scientific and technical information, related processing technology or intended end-uses of products." TBT Article 2.

confidentially by FDA, which further limits access to this information. FDA's action limits the number of participants in the wine market thereby limiting choice and supply for the American consumer. FDA's overly broad interpretation of the prior notice provision of the Bioterrorism Act results in an anticompetitive business environment that is contrary to the spirit of the FTC Act.

VII. Alternative for Providing the "Identity of the Manufacturer"

The Bioterrorism Act requires that the "identity of the manufacturer" be disclosed to FDA in the prior notice. FDA, through it rulemaking authority, has determined that the identity of the manufacturer may only be provided in the form of its food facility registration number along with the name and address. However, in light of the significant consequences associated with the prior notice requirement, as it is currently written, FDA should reevaluate its interpretation to minimize its impact.

The most appropriate solution is to remove the requirement for the food facility registration number as part of the prior notice requirement. Congress did not intend on requiring such information and provided FDA with adequate enforcement tools to ensure that facilities are in compliance. FDA has disregarded the intent of Congress by interpreting into the prior notice provision the requirement for the registration number. Therefore, modifying the prior notice regulation to remove the requirement for a registration number would be a more faithful interpretation of the statute and Congress's intent.

Alternatively, if FDA believes that such removal cannot be accommodated, the next mechanism to mitigate the disproportionately negative effect on wine importers and distributors would be to amend the prior notice requirement so as to allow the notifier to provide FDA with a reason for the absence of a registration number. The presumption would be that a registration number should be provided; however, if such number is unavailable, as is the case with many wine importers and distributors, an opportunity to provide a reason is permitted. Specifically, a drop down menu may be provided next to the space entry for registration numbers that allows the importer to explain the reason for the lack of a registration number. The drop down menu may list standard explanation such as "product was not obtained from manufacturer." After evaluating the prior notice, FDA may choose to inspect the product based on the absence of the registration number.

This optional approach allows FDA to continue to require registration numbers, but does not *per se* invalidate a prior notice based on the absence of this single piece of information. If necessary, FDA may require that the notifier submit a statement of "good faith belief" that the winery is properly registered with FDA. By instituting this option, the need for FDA review under 21 C.F.R. § 1.285 is bypassed, and opens up the Agency's limited resources and minimizes the delay of imported product.

VIII. Conclusion

Based on the foregoing, Fine Wine Alliance respectfully requests FDA to remove the requirement for the food facility registration number as a part of the information that must be submitted as part of the prior notice. Alternatively if FDA refuses to remove this requirement, the Fine Wine Alliance respectfully requests the FDA consider an alternative such as that outlined above.

Respectfully submitted,

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These comments are supported by:

Acker Merrall & Condit, New York, NY
Albany Vintners, London, UK
Armor Vins, Ploufragan, France
Atherton Imports, Menlo Park, CA
Aux Quatre Couleurs, Nantes, France
Ballantynes, Glamorgan, Wales, UK
Bloomsbury Wine & Spirits Co. Ltd., Dagenham, UK
Bordeaux Index, London, UK
Bordeaux Wine Investments, London, UK
Bordeaux Wine Locators, Ranier, WA

Brentwood Wine Co., Linn, OR
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Catovidex Management SA, Laurier Ste Foy, Québec
Caveau de La Tour, Meursault, France
Ciscoselections, Echuca, Victoria, Australia
Claret-e, London, UK
Comptoir des grands Crus, Melicocq, France
Crystle Ltd., Manchester, UK
Dapa Vins Rares, La Rochelle, France
David Feldstein, San Francisco, CA
Edinburgh Hotel & Cellars, Mitcham, Australia
Falcon Vintners, London, UK
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Farthinghoe Fine Wine Ltd., Brackley, UK
Fine & Rare Wines, London, UK
Gainsbridge Pty. Ltd., South Yarra, Australia
Gerald Whitwham Co., Altricham, UK
Grapes The Wine Company, Rye, NY
GW Wines Ltd., Knutsford, UK
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John Armit Wines, London, UK
Joshua Tree Imports, Pasadena, CA
K & L Wine Merchants, Redwood City, CA
Koppe & Partner Weinauktionen, Bremen, Germany
L'Assemblage, London, UK
La Loggia, Orvieto, Italy
Langton's Fine Wine Auctions, Melbourne, Australia
Liv-ex, London, UK
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Melodies en Sols, Villers sur Coudun, France
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Philip Poindexter, Spokane, WA
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Vénus Vins, Metz, France
Vino Veritas, Windsor, CA
Wine & Spirits Association, London, UK
Wine Cellars Ltd., Briarcliff Manor, NY