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July 12, 2004

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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 Reopening of the Comment Period for the Interim Final Rule on Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Docket No. 2002N-0278)

Dear Sir or Madam:

In response to the Food and Drug Administration's ("FDA" or the "Agency") reopening of the comment period for the Interim Final Rule on Prior Notice of Imported Food<sup>1</sup> (hereinafter referred to as the "Prior Notice IFR"), these comments are submitted on behalf of the California Fine Wine Alliance ("Fine Wine Alliance") to elaborate on the comments it previously submitted to this docket.

To properly carry out its mandate under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002<sup>2</sup> ("Bioterrorism Act"), the Agency must reconsider the prior notice requirement as it applies to fine wines. Fine wines possess unique intrinsic properties. Unlike any other food, fine wines are produced in limited quantities, undergo a considerable aging process that increases their value, have an extended chain of custody by multiple owners, and are subject to comprehensive regulatory oversight by the Alcohol and Tobacco Tax and Trade Bureau ("TTB") and the individual states.

<sup>1</sup> 69 Fed. Reg. 19763 (April 14, 2004). The comment period was extended for an additional 60 days in response to a request from the Canadian government. (69 Fed. Reg. 28060 (May 18, 2004)).

<sup>2</sup> Pub. L. No. 107-188, 116 Stat. 594 (2002).

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These distinct characteristics require that the Agency reconsider the information that must be submitted in the prior notice for fine wines. Specifically, it is appropriate for the Agency to modify prior notice for imported fine wine shipments by eliminating the food facility registration number as part of the required information. Accommodating the unusual circumstances associated with fine wines will prevent unintended consequences that may result from limiting the sources of these products. Eliminating the requirement for the facility registration number will not impede FDA's ability to maintain its oversight of the wine industry and continue to safeguard the nation's food supply.

**I. What are Fine Wines?**

**A. Unique Intrinsic Properties of Fine Wines**

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 are virtually always made from grapes grown in a single year. Because each year yields a wine of individual character, wine's value and desirability in the market can vary dramatically depending on the vintage. The most desirable fine wines tend to be made in tiny quantities and, therefore, only a very limited supply exists.

Fine wines, unlike any other food product marketed, increase in value and desirability with age. The aging process is seen as an extension of the manufacturing process. Many wines are aged for years, or even decades, to improve their quality and increase their value. Fine wines initially produced at a specific winery may be aged for a limited amount of time at the 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.

Some fine wines may be sold directly to consumers. Often, however, fine wines are sold to investors, merchants, restaurants and private collectors, who age the wines for later consumption or sale. Because the aging process uniquely applies to fine wines, there is inherent in the system of acquiring these products a natural interruption between the importer and the original producing winery. It is common for fine wines to pass through multiple owners and increase in age and value before reentering commerce.

Although the ownership of fine wines may change several times, the safety and quality of the wine is never jeopardized. The high cost of fine wines, as well as the potential

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additional value that may be obtained from aging the wine, provides a powerful economic incentive for the owner to protect its investment. Although the wine has left the producer's cellar, it is received by another individual or proprietor (serious private collector or professionally manned, special purpose wine warehouse, for example) that is equally knowledgeable and professional about the fine wine trade and has a strong financial interest in preserving the wine's quality and safety.

### **B. Strict Regulation of Fine Wines by TTB**

The food sector is generally regarded as a highly regulated industry. However, the level of regulatory scrutiny experienced by the wine trade far surpasses that of the food industry generally. Under the Federal Alcohol Administration Act<sup>3</sup> ("FAAA"), fine wines and other alcoholic beverage products are subject to an elaborate system of federal requirements.

TTB requires that anyone importing alcoholic beverage products into the United States must: (1) hold an approved Importer's Basic Permit,<sup>4</sup> (2) have all imported wine labels rigorously reviewed for compliance with labeling guidelines,<sup>5</sup> and (3) fulfill various record-keeping<sup>6</sup> and other requirements.<sup>7</sup> These requirements are not completed easily. On the contrary, TTB carefully reviews the submissions and has great discretion to require additional information to determine compliance with its requirements. In addition, TTB has ongoing authority to maintain oversight of the wine trade through facility and records inspection.

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<sup>3</sup> 27 U.S.C. § 201 *et seq.*

<sup>4</sup> 27 U.S.C. § 203. (Among other things, the FAAA provides that "it shall be unlawful, except pursuant to a basic permit issued under this subchapter by the Secretary of Treasury – (1) to engage in the business of importing into the United States distilled spirits, wine, or malt beverages; or (2) for any person so engaged to sell, offer or deliver for sale, contract to sell, or ship, in interstate or foreign commerce, directly or indirectly through an affiliate, distilled spirits, wine, or malt beverages so imported").

<sup>5</sup> 27 C.F.R Part 4.

<sup>6</sup> 27 C.F.R. §§ 27.133, 27.136, and 27.137.

<sup>7</sup> Alcoholic beverages are also subject to taxation requirements under 27 CFR § 27.30. Although these requirements are extensive and subject wine importers to additional oversight by the U.S. Treasury, it is not discussed in these comments.

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## **1. Requirements for an Importer's Basic Permit**

To engage in the business of importing alcohol, an Importer's Basic Permit must be completed and approved by TTB. A Basic Permit is issued only after a complete disclosure of investors and a thorough background check of officers.

To obtain a Basic Permit requires, among other things, that the applicant disclose their: (1) full name; (2) address of the premises; (3) telephone number; (4) employer identification number ("EIN"); (5) operating name; (6) labeling trade name; (7) mailing address; (8) business to be conducted at the facility; and (9) reason for the application. The applicant must also verify by an oath or affirmation, under penalties of perjury, that the information submitted in the application is correct.

As part of the permit process, TTB may require the applicant to produce any other information (e.g., affidavits, documents, and other supporting data) that it deems necessary to fully evaluate the application.<sup>8</sup> For example, the applicant is required to provide an extensive list or other information about its corporate owners such as their names, titles, percent voting interest (if applicable), investment in business, and the source of the funds invested. Each of these listed persons must also furnish his or her full name, nickname, date and place of birth, social security number or employer identification number, gender, citizenship, and residences over the last five years.

The applicant also must disclose whether the applicant or any owner listed on the application has: (1) ever been arrested, charged with, or convicted of any crime; and (2) if they have ever been denied a permit, license, or other authorization to engage in any business to manufacture, distribute, import, sell, or use alcohol products or had such authorization revoked or otherwise terminated.<sup>9</sup> When considering the application, TTB performs background checks, verifies the source of funds, and inspects the business premises. Clearly, TTB conducts a more substantial and thorough evaluation than the level that is required for food importers or manufacturers.

After the basic permit is approved, TTB continues to monitor the activities of the importer. For instance, TTB must be notified of any change in ownership, management,

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<sup>8</sup> 27 C.F.R. § 1.25.

<sup>9</sup> TTB Form 5100.24 (4/2004).

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or control of the business.<sup>10</sup> In the event of a name change or change of address, an application must be filed to amend the basic permit and provide the new information.<sup>11</sup> TTB may also take action against importers that do not comply with the necessary requirements and revoke or suspend a permit.<sup>12</sup> The regulations require that the TTB officer maintain information related to each application for public inspection for a period of up to one year following the final action on the application.<sup>13</sup>

## 2. Labeling Requirements

TTB also strictly regulates the information that must appear on wine labels. In addition to its own requirements, all wines imported into the United States must also meet the requirements of the country of origin. As a consequence, labels for alcoholic beverages must include brand name of the wine, the class or type of wine, the alcohol content, and, in certain instances, the percentage of foreign wine.<sup>14</sup> The label may also—and because of the regulations of the producing country usually does—state the name and address of the principal place of business of the foreign producer.<sup>15</sup> Each container of imported wine also must include the statement “imported by” or a similar phrase, followed immediately by the name of the importer, agent, sole distributor, or other person responsible for the importation, along with the address of the principal place of business in the United States of the named person.<sup>16</sup> Additionally, if the wine is “blended, bottled, or packed in a foreign country other than the country of origin” the regulations require that the label identifies the country of origin, the name of the blender, bottler or packer, and the place where the wine was blended, bottled, or packed.<sup>17</sup>

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<sup>10</sup> 27 C.F.R. § 1.42.

<sup>11</sup> 27 C.F.R. § 1.40.

<sup>12</sup> 27 C.F.R. § 1.50.

<sup>13</sup> 27 C.F.R. § 1.59.

<sup>14</sup> 27 C.F.R. § 4.32(a).

<sup>15</sup> 27 C.F.R. § 4.35a (b)(2).

<sup>16</sup> 27 C.F.R. § 4.35a (b)(1)(i).

<sup>17</sup> 27 C.F.R. § 4.35a (b)(1)(iii).

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For an imported wine shipment to be released from the custody of the U.S. Customs and Border Protection (“Customs” or “CBP”) and allowed to enter U.S. commerce, the importers must produce an approved certificate of label approval or certificate of exemption from label approval (“COLA”).<sup>18</sup> The COLA ensures that the wine labels comply with the applicable TTB requirement and provide identifying information about the importer and product of import such as name and address, vendor code, serial number, class and type of wine, fanciful name (if any), plant registry/basic permit number, formula number (if any), net contents, alcohol content, vintage, phone and fax numbers, and any wording appearing on materials affixed to the container. In addition, if a certificate of origin is required to be issued by the appropriate foreign government, no imported wine can be released from Customs’ custody unless the invoice is accompanied by this certificate.<sup>19</sup>

### 3. Recordkeeping Requirements

To maintain constant oversight of importers’ activities and the location of alcohol products, TTB regulations require that every importer of distilled spirits, wines, or beer keep records and render reports of the physical receipt and disposition of the liquors.<sup>20</sup> In the event of a terrorist act, these mandated records would allow a wine to be easily traced to its foreign source.

These records must be maintained separately, by transaction or reporting date at the importer’s place of business.<sup>21</sup> Supporting documents (or copies of supporting documents), such as consignors’ invoices, delivery receipts, and bills of lading may be filed in accordance with the importer’s regular accounting and record keeping practices.<sup>22</sup>

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<sup>18</sup> 27 U.S.C. § 205(e).

<sup>19</sup> 27 C.F.R. § 4.45.

<sup>20</sup> 27 C.F.R. § 27.133.

<sup>21</sup> 27 C.F.R. § 27.136(a).

<sup>22</sup> 27 C.F.R. § 27.136(d).

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For importers that conduct wholesale operations<sup>23</sup> or retail only operations,<sup>24</sup> additional requirements must be complied with that relate to daily recordkeeping and maintenance.

Finally, the regulations explicitly require the retention of these documents for review by TTB. These records, supporting documents, and reports must be retained for at least three years, and made available for inspection and copying by appropriate TTB or Customs officers during regular business hours.<sup>25</sup> In addition, the appropriate TTB officer may require these records to be kept for an additional period of up to three years and made available for inspection and copying in any case where the TTB officer determines retention necessary and advisable.

### **C. Additional Regulatory Oversight of Fine Wines by the States**

In addition to federal alcohol requirements, importers are highly regulated by the states in which they do business. Although these regulations vary, most states have a comprehensive licensing regime to control the importation and distribution of alcohol within and through their borders.

For example, in the state of Maryland, the Alcohol and Tobacco Tax Bureau (“ATTB”) is responsible for monitoring the manufacture, storage, transportation, sale and distribution of alcoholic beverages. Among other things, it issues licenses and permits to retailers and wholesalers of alcoholic beverages. Similar to TTB, the licensing by the Maryland ATTB requires the submission of extensive identifying information (e.g., date of birth, place of birth, social security number, contact information).<sup>26</sup> Applicants must answer a variety of questions relating to any past violations of law, revocation of permits, workers’ compensation compliance, and conforming to all the laws and regulations of the state of

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<sup>23</sup> 21 C.F.R. § 27.136(b).

<sup>24</sup> 21 C.F.R. § 27.136(c).

<sup>25</sup> 27 C.F.R. § 27.137.

<sup>26</sup> Maryland Form ATTB 007.

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Maryland as well as provide financial statements. In addition, all applicants must sign an affidavit (under penalty of perjury) that the contents of the document are true.<sup>27</sup>

Similarly, the Alcohol Beverage Regulation Administration (“ABRA”) regulates alcoholic beverage wholesalers, retailers, and manufacturers in the District of Columbia. Among other things, ABRA issues licenses to establishments that manufacture, sell, or serve alcoholic beverages, and also inspects license holders to ensure their compliance with regulations. To obtain a wholesaler’s license, applicants must complete an “Application for Alcoholic Beverage Control (ABC) License,” file for a District of Columbia business tax number and submit a stamped copy of the tax certification with the application, and pay appropriate processing charges. The applicant must also obtain a police clearance from the DC Metropolitan Police Department in addition to a police clearance for the applicant’s current residence and from each state in which the applicant has resided in the last five years. All persons with a misdemeanor conviction during the last five years or felony conviction during the last ten years must submit a copy of the court’s disposition.<sup>28</sup>

Wines, even more so than foods, must undergo critical evaluation by regulators. To import wine into the United States, importers must comply with multiple levels of rigorous regulatory scrutiny beginning at the federal level and continuing onto each state, in which the wine is to be imported. This highly intensive oversight further distinguishes fine wines from any other food product.

## **II. Fine Wines Should be Exempt from Providing the Registration Number on the Prior Notice**

Fine wines are uniquely situated food products that should not be required to include the registration number of the original producing winery on the prior notice. Unlike other food products, fine wines are produced in limited quantities with the understanding that it will be aged further to enhance its quality and desirability. Indeed, even within the wine industry, fine wines represent an exclusive segment of the market that is distinct from ordinary drinking wines. Ordinary drinking wines are not intended to undergo the aging process and, thus, do not improve with age.

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<sup>27</sup> Maryland Form ATTB-007.

<sup>28</sup> ABC Application - Instructions for Filing Application for Alcoholic Beverage Control License Application.

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Fine wines specifically are aged to further refine the product and, consequently, increase the value of the product. The aging process may be extensive. During this time, the wine may be held by various owners (collectors or investors, for example), which further distances the product from its original producing winery. By the time the fine wine reenters the market, it may not be possible for the current owner to have access to the wineries food facility registration number for import into the United States. In some instances, the aging process may extend beyond that of the winery, and the winery may no longer exist.<sup>29</sup> The unique lifecycle of fine wines frustrates the ability of importers, particularly importers specializing in fine and old wines, to comply with FDA's prior notice requirement because, in many instances, the wine is not being obtained from the original producing winery. As described in detail in the comments previously submitted by the Fine Wine Alliance, secondary distributors play a critical role in importing fine wines into the United States.<sup>30</sup>

Fine wines are further distinguished from typical food product because they are subject to an elaborate system of federal and state regulatory requirements. At the federal level, TTB strictly regulates the entry of alcoholic beverage products into the United States. Importers must be licensed, labels must be approved and records must be properly maintained in order to obtain the necessary regulatory approval to engage in the wine trade. Licensing by TTB requires a rigorous review of the applicants' history and personal information including a criminal background check and financial disclosures. The TTB requirements represent an extensive system of controls to ensure proper federal government oversight. The wine industry must undergo an added layer of regulatory scrutiny by the states, which enforce their own specific local requirements.

The inherent characteristics of fine wine as well as the extensive government oversight distinguish fine wines from any other food product currently marketed including other wine products. The unusual circumstances of fine wine require that FDA reevaluate the required information that must appear in a prior notice for these products. Clearly,

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<sup>29</sup> In the Prior Notice IFR, FDA specifically provided that a registration may be absent from a prior notice when the manufacturer is out of business or no longer manufactures products that fall within FDA's jurisdiction. Although, this issue is not being contended, it illustrates that the aging process is substantial and it is not uncommon for it to extend beyond the life of the winery.

<sup>30</sup> See, Comments to the Interim Final Rule for Prior Notice of Imported Food submitted by Patton Boggs on behalf of the Fine Wine Alliance on December 24, 2003. (C274)

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including the registration number in the prior notice is an unnecessary requirement that should be removed in light of the distinct properties associated solely with fine wines.

**III. Requiring Registration Numbers for Prior Notice of Imported Fine Wine Shipments Will Have Unintended Adverse Consequences.**

**A. Potential for the Development of an Illegitimate Wine Trade**

By requiring the registration numbers as part of the prior notice for fine wine shipments, FDA is discouraging legitimate importers from conducting business and encouraging the development of unwanted and potentially unlawful activities. The United States has become one of the largest consumers of fine wine. Today, Americans consume over 2 billion liters of wine each year. By maintaining that the registration number must appear on the prior notice, the ability for legitimate importers to ship wine to the United States will be significantly hindered. However, American consumers will continue to demand the wide selection of fine wines that currently exist in the market. The inability of credible fine wine importers to satisfy consumer demand will open up the market for illegitimate entities to satisfy the unmet demand for fine wines. The creation of a black market for fine wine is a likely result if registration numbers continue to be required for prior notice.

As a consequence of opening up the fine wine market to potentially illicit importers, the government will no longer maintain its strict control over the wine industry. Through TTB, the states and, recently, FDA's authority, the government has an accurate accounting of wine imports. Access to this information equips the government with the necessary information to trace-back, if necessary, the importer, producer, and other identifying information. This information also permits federal agencies to assess the possibility of a terrorist threat or other inappropriate activity. However, the development of a black market for fine wines will circumvent regulatory oversight and eliminate information about wine shipments. Without a well-informed government, the ability to conduct adequate surveillance will make the nation's food supply less safe and vulnerable to attack.

**B. Inappropriate Disclosure of Registration Numbers**

FDA has stated the importance of limiting access to registration numbers and preventing this information from being obtained by inappropriate users or potential terrorists.

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However, it is fallacious to believe that registration numbers will not be inadvertently or advertently disclosed. Registration numbers must appear on prior notice, Customs documents, as well as, communications between food companies and brokers. Numerous individuals have access to these documents, and it is impossible to guarantee that a registration number that a manufacturer will have for the life of the company will remain confidential.

Moreover, if maintaining the confidentiality of registration numbers is truly an objective of the Agency, it must reevaluate immediately the prior notice requirement. The fine wine market has already begun to adjust for the prior notice requirement by making freely available the registration numbers for certain wineries. For example, Bordeaux is a wine that is more commonly sold in the open market rather than through designated importers. To facilitate trade, these wineries have already provided ready access to their FDA registration numbers. Within the wine industry, a list comprised of hundreds of registration numbers is now circulating through the market.

The fine wine market will continue to adjust to compensate for the impractical requirements that are placed upon it. Whether it is through the development of an inappropriate trade of fine wines that circumvent regulatory oversight or direct conflict of the intended results of the FDA, supply of fine wines will continue to meet consumer demands. To prevent the adverse consequences these activities may have on the safety of the nation's food supply, FDA must reconsider the prior notice requirement as it applies to fine wines.

#### **IV. Invalid Assumptions by FDA**

##### **A. Registration Numbers Do Not Ensure the Legitimacy of the Shipment**

It appears that the Agency has made a broad assumption that including the food facility registration number on the prior notice somehow ensures the legitimacy of the food shipment. This conclusion is completely erroneous as it may be applied to fine wines. Indeed, there is no basis to conclude that the registration number is *prima facie* evidence that there is a relationship between the importer and producer.

The purpose of registration numbers is not unlike social security numbers. Similar to registration numbers, social security numbers are used to assist the government in

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identification and maintaining records. Social security numbers appear on numerous documents including drivers' licenses. Contrary to FDA, however, no one would assume that the mere possession of a social security number confirms that the holder is or has a relationship with the actual owner of the social security number.

Moreover, the attacks of September 11<sup>th</sup> demonstrate the capabilities of a committed terrorist. It is clear that producing a registration number of a food facility presents a diminutive obstacle for a motivated individual or terrorist group if the target is the U.S. food supply. Registration numbers may be easily obtained by registering a phony food facility, bribery, or other means. To operate under the assumption that registration numbers provide assurances that the food product being shipped may lawfully enter the country or does not present a bioterrorist threat is illusory. It is deceptive to believe that a meaningless requirement such as the inclusion of a registration number will provide any additional level of security. The elaborate regulatory regime of TTB and the individual states provides far greater assurance of the legitimacy of the imported fine wine shipment than supplying a registration number.

**B. Inclusion of Registration Numbers in Prior Notice Will Not Enforce the Requirements of the Bioterrorism Act**

FDA has inappropriately interpreted the prior notice provision of the Bioterrorism Act. 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. If Congress intended FDA to require the registration number, surely it would have specifically articulated this requirement. Indeed, the mere absence of statutory language requiring such information provides powerful evidence that it was not the intent of the Congress.

FDA's incorrect interpretation has led the Agency to rely heavily on the requirement for registration numbers as part of prior notice to ensure compliance with the Bioterrorism Act. Although registration numbers initially may provide some reassurances, it cannot be maintained in the long term and is detrimental for the Agency to assume that facilities have met the requirements based on this simple factor. As discussed earlier in these comments, numerous factors may contribute to the unintentional and intentional disclosure of these numbers. Eventually, the value of the registration number will be diluted. More appropriately, FDA should actively enforce the requirements of the Bioterrorism Act.

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**V. Alternative to Supplying the Registration Number for Prior Notice of Imported Fine Wine Shipments**

Prior notice plays an important role in safeguarding the nation's food supply. The Bioterrorism Act was signed into law to provide FDA with additional tools and authority to ensure the public health and safety is maintained. These laudable goals are strongly supported by the fine wine industry. However, by requiring the registration number on prior notice for fine wine shipments, FDA has completely misinterpreted the Bioterrorism Act and, in doing so, has severely restricted the common practices of the fine wine trade.

As discussed earlier in these comments, fine wines possess unique properties that limit the ability of importers to supply the registration number of the producing winery. It has become almost impossible for importers to comply with the Agency's prior notice regulations. These unrealistic requirements have forced the industry to respond in a manner that is inconsistent with the goals of the Bioterrorism Act and FDA's objectives to protect the nation's food supply. Moreover, unlike other food products, fine wines are subject to extensive federal and state regulatory scrutiny. These additional levels of rigorous review provide far greater assurance of the legitimacy of a shipment than the mere presence of a registration number. Accordingly, it is completely appropriate for FDA to exempt fine wines from the single requirement of registration numbers.

**A. Standard for Fine Wines**

To assist the FDA in determining whether a wine meets the standard of a "fine wine," the Fine Wine Alliance recommends that the Agency establish a minimum invoice value to distinguish these products. Wines that declare at least a \$10 value per 750 ml (the standard bottle size) at the time of import may be categorized as a "fine wine" and therefore exempt from including the registration number in the prior notice. A \$10 invoice value will command a retail price of approximately \$20, which is the threshold for fine wines.

To verify the value of the wine shipment, FDA may review the documentation that accompanies a wine shipment. The invoice is always included with the shipment. Therefore, FDA may readily determine the value of the wines without disrupting the flow of commerce and only nominally increasing the review process.

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**B. FDA Enforcement of Prior Notice Will Not Be Hindered By Exempting Fine Wines**

In lieu of the registration number, prior notices for fine wines will include the name and address of the winery, as well as an affirmation that the importer believes, to the best of its knowledge, that the producer is registered with FDA. From this information, FDA may verify the identity and registration information. These additional steps are minimal and do not overly burden the regulatory system.

Wines from sources outside of the direct producer-importer-consumer supply chain generally enter the United States through a small number of ports (Baltimore, MD; Los Angeles and Oakland, CA; New York, NY; and New Jersey) and therefore limit the extent to which FDA may be required to process fine wine prior notices. In addition, the Fine Wine Alliance recognizes that it may require additional time for the Agency to process fine wine shipments if the registration number is absent from the prior notice. Wines generally arrive at the port of entry by water and there is a lapse of time between the shipment departure and arrival with this mode of transportation. To accommodate the exemption requested for fine wines, it is appropriate for FDA to extend the period of time between the filing of prior notice and the actual arrival of the shipment at the port of entry to 48-72 hours.

Additionally, because of the strenuous evaluation and subsequent approval process by federal and state authorities, there are fewer than three or four dozen specialist fine and old wine importers in the United States. This small pool of companies allows FDA to readily identify importers and their shipments. Further, the difficult regulatory process deters importers from engaging in inappropriate behavior and risk revocation of their license. As a practical business matter, importers must maintain the integrity of the products they sell and ensure the products' origin.

Exempting fine wines from including the registration number of the producing winery will not impede FDA's ability to enforce the Bioterrorism Act. In fact, by establishing this exemption, FDA is more accurately implementing the statutes prior notice provision.

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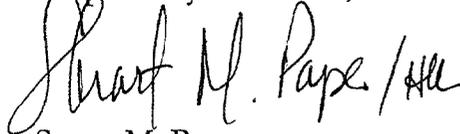
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**VI. Conclusion**

Therefore, based on the foregoing, the Fine Wine Alliance respectfully requests that FDA remove the requirement for the food facility registration number as part of the required information in the prior notice for fine wine shipments.

Respectfully submitted,



Stuart M. Pape

Counsel to the California Fine Wine Alliance