

1 ☐ **Bioterrorism Act of 2002:**
**Food and Drug Administration Unified
Registration and Listing System (FURLS)**

2 ☐ **FDA Unified Registration and Listing System**

- As of December 12, 2003, all facilities that manufacture/process, pack or hold food for human or animal consumption in the United State must register with the FDA
- This includes all manufacturers of beverages
- (Yes, that means wineries, too)
- In order to protect the public from a possible terrorist attack on the U.S. food supply

3 ☐ **FDA Unified Registration and Listing System**

Online Registration procedures :

- www.access.fda.gov/
- click on **Login**
then **Create New Account**
- fill out **Form 3537**
- call 800.216.7331 or e-mail furls@fda.gov for assistance with electronic registration

4 ☐ **FDA Unified Registration and Listing System**

Other Registration procedures:

- **Mail** paper version of **Form 3537** to:
Food and Drug Administration
HFS-681
5600 Fishers Lane
Rockville, MD 20857
- **FAX** completed form to: 301.210.0247

5 ☐ **FDA Unified Registration and Listing System**

Who must register?

- 1) The owner, operator or agent in charge of a domestic facility
- 2) Prior to December 12, 2003
- 3) All domestic manufacturing facilities must register regardless of whether food from that facility enters interstate commerce

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What types of facilities do not have to register?

- Private residences of individuals
- Farms, as long as all food packaged or held on that farm is grown, raised or consumed on that farm or another farm under the same ownership.
- Farms that manufacture food only for consumption on that farm or another farm under the same ownership
- Restaurants or retail food establishments; non-profits; fishing vessels; facilities regulated exclusively and solely by the USDA

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What information is required?

- 1) A separate registration for each facility

- 2) Although multiple facilities can be registered with PDF version of **Form 3537** on a CD-ROM with one signed copy and mailed to the FDA
- 3) Name, address, phone number and e-mail for each facility and for its parent company, if applicable
- 4) Emergency contact information for each facility

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What information is required?

- 5) Name, address and phone number of the owner, operator or agent in charge (foreign manufacturers must designate an agent residing in the USA)
- 6) All trade name the facility uses
- 7) Applicable food product category:
(#1 Alcoholic Beverages)
- 8) Certification of accuracy and authorization of submitter to represent the facility

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Additional information

- Any changes to information submitted in the registration must be updated within 60 days (e.g.—name, location, contact, etc.)
- Upon a change of ownership or closure, the former owner must file a **Form 3537a** and the new owner must submit a new registration on **Form 3537**
- All registrations must be received no later than Dec. 12, 2003
- FDA estimates that it will take 1-2 hours to gather the necessary information and one hour to fill out the form
- Firms offering assistance with registration are not affiliated with the FDA

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What's Next, according to WineAmerica?

- All manufactures will be required to keep detailed records of all inputs used in the making of their products
- Including ingredients (fruit sources), additives (sulfur, fining agents) and packaging (corks, bottles)
- Name, address, phone, FAX and e-mail of every vendor inputs purchased from, date received, lot or ID# and trucking or transport firm
- Records can be kept in any format but must be available within 4-8 hours notice
- Companies with <10 employees will have 18 months to comply, Companies with <500 employees will have 12 months to comply after the publication of the final rule

11 ☐ **FDA Unified Registration and Listing System**

Your Federal Government at Work

- This is an Interim Final Rule
- Additional 30-day comment period begins in March 2004: visit www.fda.gov/oc/bioterrorism/bioact.html for updates
- It is prohibited not to register
- After the extensive outreach and educational activities conducted by the FDA, they will enforce this Interim Final Rule with a policy of assistance