



Australian Government

Wine Australia

US FDA Registration

OCTOBER 2012

Biennial FDA Registration

As you will be aware if you are already exporting to the USA, all owners or operators in charge of facilities that manufacture/process, pack, or hold wine that is exported for consumption in the US are required to register the facility with the Food and Drug Administration (FDA).

Wine Australia has been notified that facilities that are registered with the FDA will now have to re-register every two years during the period beginning on 1 October and ending on 31 December in even numbered years.

This will first occur from 1 October 2012. Therefore please ensure you have re-registered within the next three months.

In addition to previous requirements, registration will now request an e-mail address for the contact person of the facility and for the US agent of the facility and an assurance that the FDA will be permitted entry to inspect the facility.

Inspection by the FDA of Australian facilities is not expected to be routine and any requests for such inspection should be brought to the attention of Wine Australia.

Further information on the re-registration requirement can be found on the FDA's website:
www.fda.gov/Food/FoodSafety/FSMA/ucm314178.htm

We understand the re-registration form is still being developed, but it is expected to be available online at some stage during October 2012 at www.fda.gov/furls which operates during business hours from 7:00 am to 11:00 pm U.S. Eastern Standard Time. Effectively this means you should register in the morning, rather than the afternoon, Australian time. It is possible to register by mail and the forms can be downloaded from the FDA website although the FDA warn this is less efficient and likely to be subject to delay.

We have no information other than the material provided on the FDA website. Any questions should be directed to your US importer.