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INFORMATION

USA: BIENNIAL RE-REGISTRATION OF FOOD FACILITIES

Exporters to the USA are aware that all owners or operators in charge of facilities that manufacture, process, pack or hold wine exported for consumption in the US, are required to register their facilities with the FDA (Food and Drug Administration) under the so called Bioterrorism legislation.

Under the US Food Safety Modernisation Act 2011 all registered facilities 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.

The first cycle commenced on **1 October 2012**. However, we note that the re-registration form is not available as yet. We will let you know as soon as it is available online at www.fda.gov/furls.

For further information please see the attached memorandum from the New Zealand Ministry for Primary Industries. You can also visit: www.fda.gov/Food/FoodSafety/FSMA/ucm314178.htm.

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For Your Information: F50/12 United States of America: Food and Drug Administration Facility Registration Changes

Ministry for Primary Industries

Date: 26 September 2012 (1)

From: Janine Collier, Market Access Counsellor

1 Background

1.1 The US Food and Drug Administration (FDA) has introduced some changes which effect NZ exporters to the US. The FDA has new tools and authorities under the recent Food Safety Modernisation Act 2011 to make certain imported foods meet the same safety standards as food produced in the US.

2 New FDA Facility Registration Requirements

2.1 The US Food and Drug Administration (FDA) Food Safety Modernisation Act 2011 has mandated re-registration of facilities.

2.2 Re-registration of facilities that export or supply food or beverage products to the US, has now been implemented by FDA on a biennial basis. Facilities that are required to register with FDA will have to re-register every two years during the period beginning on 1 October and ending on 31 December in even numbered years.

2.3 This will first occur in October-December 2012.

2.4 Registration will now also require an e-mail address for the contact person of the facility or for the US agent of the facility and assurance that FDA will be permitted entry to inspect the facility.

2.5 Additionally, where determined necessary by FDA, further information may be required regarding the applicable food categories for foods manufactured/processed, packed or held at registered facilities.

2.6 FDA has also implemented registration suspension provisions to enable them to prevent adulterated food from entering US commerce.

2.7 MPI expects FDA to request facility inspections at a government-to-government level. If FDA does request to conduct an inspection of your facility, please forward that request to: Janine Collier, janine.collier@mpi.govt.nz.

2.8 Further information on Food Facility Registration can be found on FDA's Food Facility Registration web page: http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/default.htm

2.9 Part 10 of the US Overseas Market Access Requirements will be updated in due course. OMAR notification 11/19: "United States of America: Food and Drug Administration Prior Notice of Imported Food requirements" is a related notification on the prior notice of imported food required by FDA. This too will be updated in due course.

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