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## MEMORANDUM

October 20, 2006

### BY ELECTRONIC MAIL

FROM: Olsson, Frank and Weeda, P.C.

RE: Bioterrorism Act: FDA Lacks Accurate Emergency Contact Information for Many Registered Food Facilities

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The Food and Drug Administration (FDA) has conducted an initial test of emergency contact information in the agency's Food Facilities Registration Database and has found a high error rate. A summary report is available at <http://www.cfsan.fda.gov/~furls/ffregacc.html>.

FDA is urging owners, operators, and agents in charge of all food facilities registered with FDA (and the U.S. Agents of all foreign facilities registered with FDA) to review all of the data in their facility registration(s) to ensure it is correct.

### Background

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), any facility that manufactures/processes, packs, or holds food intended for human or animal consumption in the United States must register with FDA, unless the facility qualifies for an exemption.<sup>1</sup>

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<sup>1</sup> FDA implementing regulations can be found at 21 C.F.R. part 1, subpart H.

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FDA's implementing regulations require that the registration information include the telephone number of an Emergency Contact accessible at all times.<sup>2</sup> In the case of foreign facilities that register with FDA, the U.S. Agent will be considered the Emergency Contact unless the registration specifies a different Emergency Contact.<sup>3</sup> FDA intends to use this information to quickly notify food facilities that might be affected by an outbreak of food-borne illness or other threat to the food supply. According to the agency, "the facility must ensure that the information it provides will enable FDA to contact a live person representing the facility 24 hours a day, 7 days a week."<sup>4</sup>

### Initial Test of Emergency Contact Information

From July 10, 2006 to August 2, 2006, FDA conducted an initial test to verify the accuracy of the Emergency Contact information in the agency's Food Facility Registration Database. The test was intended to determine whether FDA could establish contact with the true Emergency Contact/U.S. Agent for the registered facility using the primary mode of contact.<sup>5</sup> The test involved a statistically representative sample of 800 facilities (400 domestic facilities and 400 foreign facilities).

The test found serious gaps in FDA's Emergency Contact/U.S. Agent data for registered facilities. Among the specific findings were the following:

- For domestic facilities, 39 out of 400 facilities (9.8%) had provided an Emergency Contact telephone number that was not correctly formed or was for a line that was non-existent or out of service. Another 72 facilities (18%) had provided an accurate Emergency Contact telephone number, but FDA did not receive a response to the voicemail message it left requesting return confirmation. At another 41 facilities (10.2%), the person contacted stated that they were not the Emergency Contact for the facility.

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<sup>2</sup> An E-mail address for the Emergency Contact may also be optionally provided.

<sup>3</sup> An E-mail address and/or fax number for the U.S. Agent may also optionally be provided.

<sup>4</sup> 68 Fed. Reg. 58894, 58923 (Oct. 10, 2003).

<sup>5</sup> FDA selected E-mail as the primary mode of contact if the facility provided an E-mail address for its Emergency Contact. FDA considered telephone the primary mode of contact if the facility did not provide an E-mail address for its Emergency Contact. If a foreign facility designated its U.S. Agent as its Emergency Contact and did not provide an E-mail address for the U.S. Agent, FDA considered fax the primary mode of contact (or, if a fax number was not provided, FDA considered telephone the primary mode of contact). If FDA received no response to an E-mail or fax notification within 14 days, FDA attempted contact by telephone.

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- For foreign facilities, 48 out of 400 facilities (12%) had provided an Emergency Contact/U.S. Agent telephone number that was not correctly formed or was for a line that was non-existent or out of service. Another 70 facilities had provided an accurate phone number, but FDA did not receive a response to its voicemail message. At another 43 facilities (10.8%), the person contacted stated that they were not the Emergency Contact/U.S. Agent for the facility. At another 37 facilities (9.2%), the person contacted did not speak English.<sup>6</sup>
- Many facilities re-register when registration information changes instead of updating the existing registration. This results in duplicate or triplicate registrations for the same facility.
- A coding error in FDA's registration system allowed some domestic facility registrations (1.4% of all domestic registered facilities) to be accepted by FDA without Emergency Contact information. FDA has corrected this coding error.

Based on these results, FDA estimates that, in the event of an emergency, FDA would be unable to contact 20% to 30% of registered facilities. FDA estimates with 95% confidence that the primary mode of contact is accurate for about 75% to 85% of all registered domestic facilities (78% to 88% of all registered foreign facilities). FDA also estimates with 95% confidence that both the primary mode of contact and the identity of the Emergency Contact are accurate for 52% to 62% of all registered domestic facilities (38% to 48% of all registered foreign facilities).

#### FDA Recommendations and Follow-Up Action Plan

FDA plans to take a number of follow-up steps, including notifying by mail all domestic and foreign test facilities found to have inaccurate information in their registrations. FDA also intends to conduct a second test in 2007 to determine whether the accuracy of Emergency Contact information has improved.

FDA is also urging all owners, operators, and agents in charge of registered facilities (and U.S. Agents of foreign registered facilities) to review all of the data in their registrations to ensure it is accurate.

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<sup>6</sup> We are not aware of any requirement that the Emergency Contact or U.S. Agent speak English, but this reasonably would facilitate communication of an outbreak of food-borne illness or other threat to the food supply and FDA apparently is taking that position.

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Additional Recommendations

Given the political sensitivity of food security issues, it is possible that FDA might declare registrations that lack accurate Emergency Contact/U.S. Agent information to be invalid, and take appropriate enforcement action.

We recommend that companies that have facilities registered with FDA review their registrations to ensure that all information, especially Emergency Contact/U.S. Agent information, is accurate and up-to-date. In addition, companies may wish to notify their foreign suppliers and request that they also review the registration information for their FDA-registered facilities. Finally, if a company is acting as U.S. Agent for a registered foreign facility, it may wish to confirm with that foreign facility that its registration information, especially its Emergency Contact/U.S. Agent information, is accurate and up-to-date.

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We trust this information is useful. If you have any questions, please contact Bob Hahn at (202) 518-6388 or [rhahn@ofwlaw.com](mailto:rhahn@ofwlaw.com).

OFW:jdm