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DHHS and DHS Issue Bioterrorism Act Food Facilities Registration Final Rule

The U.S. Department of Health and Human Services (DHHS) is joining with the U.S. Department of Homeland Security (DHS) today to announce the issuance of a final rule implementing the food facilities registration provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). The final rule confirms the interim final rule on food facility registration that DHHS and DHS issued in October 2003. The rule requires domestic and foreign facilities that manufacture, process, pack, or hold food for consumption in the United States to register with the U.S. Food and Drug Administration (FDA) by December 12, 2003.

Information provided to FDA under this final rule will help the Agency identify and locate promptly food processors and other establishments, in the event of deliberate or accidental contamination of the food supply. Except for specific exemptions, the registration requirements apply to all facilities that manufacture, process, pack, or hold food, including animal feed, dietary supplements, infant formula, beverages (including alcoholic beverages and bottled water), and food additives.

"This rule is one of our critical tools for safeguarding the American food supply," said Acting FDA Commissioner Andrew C. von Eschenbach, MD. "By finalizing this rule, we now have another important safeguard in our ongoing efforts to make sure that human and animal foods are protected from a deliberate or accidental act of contamination."

The final rule announced today is one of five regulations issued by the Agency to implement the Bioterrorism Act. In October 2003, DHHS and DHS also jointly issued an interim final rule for prior notice of imported food shipments, which requires that FDA receive advance notice of human and animal food that is imported or offered for import into the United States.

In June 2004, FDA published a final rule that specifies procedures that FDA would use to administratively detain food when the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. In December 2004, FDA published a final rule requiring food firms to establish and maintain records that would allow FDA to conduct an effective and efficient traceback investigation to protect the U.S. human food and animal feed supply, in the event the agency has a reasonable belief that an article of food is adulterated and poses a threat of serious adverse health consequences or death to humans or animals.

Together, these regulations increase the safety and security of the U.S. human and animal food supply and better protect Americans from a deliberate act of contamination of the food supply (such as a terrorist act) or an incident of unintentional contamination that could lead to a serious outbreak of food-borne illness. More information about each rule may be found on FDA's website at www.fda.gov under the "Bioterrorism Act" link.

FDA had previously indicated its plan to publish the Prior Notice Final Rule along with the registration final rule. Publication of the registration final rule is being announced today, and FDA and DHS/Customs and Border Protection continue to develop as expeditiously as possible a final rule that responds to the numerous comments the agencies received on the Prior Notice Interim Final Rule.