



Date: October 1, 2023

Re: Final Rule on the Establishment and Maintenance of Records to Enhance the Security of the U.S. Food Supply Under the Bioterrorism Act.

Dear Valued Customer:

This letter confirms United Sugar Producers and Refiners (United) compliance with the final rule published on December 9, 2004 by the Food and Drug Administration regarding the final rule of the Bioterrorism Act.

This is the last of the four rulemakings implementing the Act. The effective date for implementation of this regulation is December 9, 2005. This regulation requires all persons who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records. These records identify the immediate previous source of all food received, as well as the immediate subsequent recipient of all food released.

The regulation also defines who must establish and maintain records, including the required retention time and availability of these records.

In addition, when FDA has a reasonable belief that an article of food is adulterated and poses a threat of serious adverse consequence, the FDA has the right to access all information pertinent to the threat. This information must be available to the FDA within 24 hours of the official request and must be available for photocopying.

Regards,

Janet A. W. Harriman
Director of Quality and Safety
United Sugar Producers and Refiners

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