



May 12, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Submitted Electronically

Subject: Comments on FDA Food Safety Modernization Act: Focus on Implementation Strategy, Docket No. 2015-N-0797.

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP) appreciates the Food and Drug Administration's (FDA) continued work to implement the Food Safety Modernization Act and FDA's recent Public Meeting to seek comments.

USP would like to submit the following comments:

1. USP has consistently maintained that economically-motivated adulteration (EMA) would be misplaced under preventive controls and should be addressed as its own unique category of food adulteration, through a vulnerability assessment and control plan tailored specifically to EMA. We note that the Public Meeting did not appear to address EMA and we hope the issue was simply deferred for later discussion. **Any comprehensive food safety framework should address EMA. Food fraud/EMA is a significant public health concern, destroying markets, disrupting trade, eroding consumer confidence, and posing the threat of unspecified harm. We welcome continued dialog with FDA and industry in this area.**
2. Since FDA's call for information on appropriate EMA tools, USP has continued to engage stakeholders, including FDA, on a proposed [Guidance on Food Fraud Mitigation](#)—developed by USP's Expert Panel on Food Ingredients Intentional Adulterants—representing perspectives from industry, academia, and regulators. This common framework guides manufacturers and regulators in implementing effective mitigation approaches to safeguard the most fraud-vulnerable and impactful ingredients in the supply chain—supporting consumer protection and building added trust in the safety and integrity of food. **We are encouraged by the support we've received from industry and others to develop effective tools in this area.**

Thank you for considering our views. Should you require more information, our staff contact is Dr. Jeff Moore, Senior Scientific Liaison, at jm@usp.org, (301) 816-8288.

Sincerely,

Markus Lipp, Ph.D.
Senior Director, Food Standards