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## VIA ELECTRONIC SUBMISSION

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

### **Re: Docket No. FDA-2013-N-1425, Focused Mitigation Strategies To Protect Food Against Intentional Adulteration; 78 Fed. Reg. 78014-61 (December 24, 2013)**

The Consumer Healthcare Products Association (CHPA) welcomes the opportunity to comment on the above captioned request published in the December 24, 2013 Federal Register. CHPA is the 133-year-old trade association representing U.S. manufacturers and distributors of over-the-counter medicines and dietary supplements ([chpa.org](http://chpa.org)).

The agency has proposed to require domestic and foreign food facilities registering under the Federal Food, Drug, and Cosmetic Act to address hazards that may be intentionally introduced by acts of terrorism. Food facilities would be required to identify and implement mitigation strategies to significantly minimize or prevent vulnerabilities identified at various steps throughout a food operation. CHPA supports the agency's implementation of procedures under the Food Safety Modernization Act (FSMA) designed to safeguard the nation's food supply. As several CHPA member companies are involved in the manufacture/marketing of dietary supplements, we have an interest in the subject matter of the request for comments.

1. In Section §121.3, the agency has proposed to define "contaminant" as "*any biological, chemical, physical or radiological agent that may be intentionally added to food and that may cause illness, injury or death*". CHPA is concerned that the proposed definition could encompass ingredients intentionally added to food (dietary supplements) that are associated with an unintended consequence (e.g., an allergic or other adverse event response).

For the purpose of this regulation, to clarify the meaning to be an "intentional" contaminant, CHPA recommends amending the definition of "contaminant" to the following:

Contaminant means any biological, chemical, physical or radiological agent ~~that may be intentionally~~ added to food ~~and that may~~ to intentionally cause illness, injury or death.

2. Subpart D of the proposed rule provides requirements for records that must be established and maintained. Proposed Section §121.305(d) states that records must “[b]e created concurrently with performance of the activity documented.” While it is common for certain records to be created concurrently with performance of the activity (such as documenting a step executed in a batch record during production), the generation of other records would be more appropriately described as being prepared in a timely manner following performance of the activity (such as issuing plans and reports that require time for activities such as writing, reviewing, editing and approving).

As such, CHPA recommends changing proposed Section §121.305(d) to read as follows:

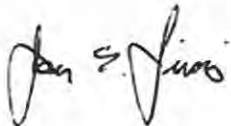
“Records must ... (d) Be created ~~concurrently with~~ in a timely manner following performance of the activity documented;”

3. Proposed Section §121.305(f)(2) states that records must include “[t]he date and time of the activity documented.” CHPA notes that for certain activities’ (e.g., when executing a batch record) recording of the time of activity is not necessary. Specific examples include equipment setup, verification of equipment setup, charging an ingredient into a blender, and weighing material for process yield and reconciliation purposes. In addition, some records are generated to document assessments or mitigation strategies where the name, location of the facility, the date and the signature will be present, but not the time.

As such, CHPA recommends that proposed Section §121.305(f)(2) be changed to read as follows: “The date and, where appropriate, the time of the activity documented;”

CHPA member companies thank the Agency for the opportunity to provide comments concerning these mitigation strategies to prevent the intentional adulteration of food. Please feel free to contact me should you have any questions.

Respectfully submitted,



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