THE WESTON A. PRICE FOUNDATION®
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Farm-to-Consumer Legal Defense Fund®

FARM&RANCH FREEDOM ALLIANCE℠

June 8, 2015

Submitted online at http://www.regulations.gov/#!submitComment;D=FDA-2002-N-0323-0168

Re: Docket No. FDA-2002-N-0323

Dear FDA staff:

The Weston A. Price Foundation (WAPF) is a nonprofit organization with members in every state and internationally. WAPF was founded in 1999 to disseminate the research of Dr. Weston Price, whose studies of isolated nonindustrialized peoples established the parameters of human health and determined the optimum characteristics of human diets. WAPF is dedicated to restoring nutrient-dense foods to the human diet through education, research and activism.

The Farm-to-Consumer Legal Defense Fund (FTCLDF) is a non-profit organization whose mission is to protect the constitutional right of the nation's family farms and artisan food producers to provide processed and unprocessed farm foods directly to consumers through any legal means, and to protect the constitutional right of consumers to obtain unprocessed and processed foods directly from family farms and artisan food producers.

The Farm and Ranch Freedom Alliance (FARFA) is a national nonprofit organization that supports independent family farmers and protects a healthy and productive food supply for American consumers. FARFA promotes common sense policies for local, diversified agricultural systems.

WAPF, FTCLDF, and FARFA jointly submit the following comments on the Amendments to Registration of Food Facilities, Docket No. FDA-2002-N-0323.

Issue 1: Definition of retail food establishment

The registration requirement for food facilities was first created under the 2002 Bioterrorism Act, and then amended by Congress under the Food Safety Modernization Act of 2010. The Bioterrorism Act exempted both "farms" and "retail food establishments" from the definition of "facilities" that had to register with FDA, but did not define the terms.

In the original regulations under the Bioterrorism Act, FDA defined "retail food establishment" to include any establishment whose primary function was to sell directly to consumers, defined as selling more than half of the products directly to individual consumers. However, since the

Bioterrorism Act focused on registration of **each location,** it was unclear whether the sales had to occur at the same location as the food processing in order to qualify. In other words, under the FDA's original regulation, a business that made jams in a commercial kitchen and then sold them at a farmers' market might not be classified as a "retail food establishment" even if more than half of its sales were direct to individual consumers.

The Tester-Hagan amendment of FSMA addressed this issue as follows:

> (1) Retail food establishment.--The Secretary shall amend the definition of the term "retail food establishment" in section in 1.227(b)(11) of title 21, Code of Federal Regulations to clarify that, in determining the primary function of an establishment or a retail food establishment under such section, the sale of food products directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include--
>
> (A) the sale of such food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed;
>
> (B) the sale and distribution of such food through a community supported agriculture program; and
>
> (C) the sale and distribution of such food at any other such direct sales platform as determined by the Secretary.

This language addresses **all** food businesses, not just those that are located on farms. Yet, in proposing regulations to implement this section, FDA is limiting it to only those operations that are located on farms. This is contrary to the clear language of the statute.

Indeed, if FSMA had intended only to address those businesses located on farms, it would have been far more logical to amend the definition of "farm" rather than "retail food establishment." By directing the agency to amend the definition of "retail food establishment," and *not* addressing the agency's definition of farms, the Tester-Hagan amendment's structure supports the clear language: whether or not the business is located on a farm is not relevant.

The agency must comply with the Tester-Hagan language of FSMA, and exempt <u>all</u> facilities that sell more than half of their products directly to consumers at roadside stands, farmers' markets, and similar locations.

Similarly, the FDA also improperly limited roadside stands and farmers' markets to only farmers. Roadside stands can be set up by both farmers and non-farmers. And while we agree that the **majority** of the vendors at a market should be farmers for it to be classified as a farmers' market, artisan food providers have an important role in these markets. There are very few farmers' markets in the country that have solely farmers, and the common understanding of the term includes locations that have both farmers and other food vendors.

FDA should amend section 1.227 as follows:

- Remove the phrase "located on a farm" in section (b)(11)
- Replace the phrase "at which a farmer sells food from his or her farm directly to consumers" with "at which a vendor sells food directly to consumers" in section (b)(11)(1)
- Replace the definition of farmers' market in section (b)(11)(1) with "a location where multiple farmers sell agricultural products produced on their farms directly to consumers, and which may include a smaller number of other food vendors selling products they produced directly to consumers."

We support the list of direct-to-consumer venues in section 1.227(b)(11)(iii), including door-to-door sales, mail, catalog and internet orders, nonprofit events, and fairs.

Issue 2: Electronic registration

FSMA left the issue of whether to require electronic registration to the FDA's discretion. We oppose the agency's decision to impose a general requirement for electronic registration. However, if the agency moves forward with such a requirement, at a minimum it should provide clear exemptions.

The agency has included a process for getting a waiver, but the proposed rule does **not** include any listing of the grounds for a waiver. In other words, a business can apply for a waiver but there is no guidance as to the basis for granting such a waiver.

The agency should clarify the process for getting a waiver from registering electronically under section 1.245. The regulation should specifically recognize religious objections and lack of reasonable access to the internet as reasons to grant a waiver, in addition to any other reasons that may be raised by applicants.

Issue 3: Email contact address

FSMA added "email address" to the list of information that should be submitted by a food facility in its registration. But just as many people do not have regular internet access for religious or practical reasons — a fact recognized by FDA in proposing the waiver from electronic registration — even more people either do not have an email address or do not check email regularly.

The FDA has attempted to address this problem in its proposed rule by providing that the registrant can list the email address of someone other than the owner or manager. While this is a partial solution, it still assumes that the owner of the food business has a trustworthy contact person who has an email address and reliable, regular access. That is not the case for many people who live in certain religious communities or in rural and low-income areas.

In the preamble to the proposed rule, the FDA indicates that it plans to use email communications in order to reach businesses quickly during an emergency. But if a facility owner or manager doesn't have their own email address, or if they only access email occasionally, then relying on email for communicating during an emergency is counter-productive; the agency will be acting on the assumption that the email notification will be received in a timely manner, which is false.

Section 1.232 of the proposed rule should be amended to provide an exemption for those who do not have email addresses. The proposed rule should also be amended so that food facilities can indicate their preferred means of contact in an emergency on the registration form, whether by email, phone, fax, or other. That is the only way to ensure that the FDA has the most reliable means for contacting the business in the event of an emergency.

Issue 4: D-U-N-S Number

The proposed rule would require a food facility to include a D-U-N-S number when registering with FDA; if the business does not already have such a number, it would have to register with Dun & Bradstreet first in order to complete the mandatory registration with FDA. FSMA made no reference at all to this system; the agency is proposing this new requirement on its own initiative.

In the preamble, the agency indicated that this new requirement will serve as a cross-check on the accuracy of the information submitted to FDA for the facility registration. But if a business only gets a D-U-N-S number for the purpose of registering with FDA, then there's no real purpose. It cannot serve as an effective way to prevent unauthorized agents or other inaccurate information from being submitted, if the same entity submits the same information at the same time to both the DUNS system and FDA's registration system. Rather, it serves only as an additional time-consuming step.

Moreover, some individuals will have religious objections to registering in the D-U-N-S system because it involves a mandatory universal numbering system.

For purposes of serving as a way to confirm the accuracy of the registration information, the DUNS number is only useful if it pre-dates the facility registration. FDA should therefore amend section 1.232 to provide that the registrant provide a D-U-N-S number **if** the facility has one. This would achieve FDA's stated objective without creating unnecessary burdens.

Issue 5: Deadlines

The agency is also proposing to shorten the time period for a food facility to update or cancel its registration from 60 calendar days to 30 calendars days. We oppose this change. Given that there are criminal penalties for failing to timely update or cancel a registration, the agency needs to provide a reasonable amount of time for compliance. Particularly for businesses that are being shut down or in the midst of major reorganizations, 30 days is an unreasonably short period of

time. FDA should amend the proposed sections 1.234 and 1.235 to re-instate the previous 60-day time limit.

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