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

RE: Agency Information Collection; Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Docket No. FDA-2013-N-0065]

The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the extension of authority under the Paperwork Reduction Act (PRA) to collect food facility registrations [Docket No. FDA-2013-N-0065, 78 Fed. Reg. 4414 (Jan. 22, 2013)]. The PRA requires federal agencies to obtain approval from the Office of Management and Budget (OMB) before collecting information from the public. The purpose of PRA review is to "reduce, minimize and control burdens and maximize the practical utility and public benefit of the information… collected… by the Federal government."[1] The Food and Drug Administration (FDA) seeks comment on four issues,[2] but this comment only concerns the request for comment on ways to enhance the quality, utility, and clarity of the information to be collected.

Reducing unnecessary paperwork burdens is a valuable exercise, but weighing options under the PRA should not ignore the agency's primary responsibility to protect public health. Unfortunately, too many reviews seem to focus on reducing the burden on industry without adequate consideration for the utility and benefit to the public of the information collection. As a result, the information does not meet the needs of the agency and public safety suffers. For example, FDA did not consider annual registration in 2003 even though nothing in the Public Health Security and Bioterrorism Preparedness and Response Act prevented it from doing so. In the interim final rule, the agency noted but did not respond to a comment urging annual re-registration as it acted to reduce the burden of updating registration records.[3] While FDA was concerned about burdens on the food industry, the less burdensome one-time-registration adopted by the rule proved highly inefficient, undermining the value of the registration

[1] 5 C.F.R. § 1320.1, Purpose.
[2] Agency Information Collection; Registration of Food Facilities under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 78 Fed. Reg. 4414, 4415 (Jan. 22, 2013).
[3] Registration of Food Facilities under the Public Health Security and Bioterrorism Response Act of 2002, Interim Final Rule, 78 Fed. Reg. 58894, 58927 (Oct. 10, 2003).

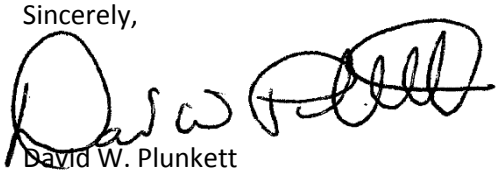
database.[4] It was largely because of problems caused by outdated and incorrect registrations that Congress included biennial registration in the Food Safety Modernization Act.[5]

While CSPI normally does not comment on PRA notices, we felt it was important to raise the issue of how OMB should weigh paperwork requirements in this case. We believe there were three additional information requests that should be included.

(1) FDA should improve the utility and public benefit of the registration by requiring facilities to note if they intend to claim qualified facility status or believe they are eligible for the very-small on-farm exemption. Such information would help the agency determine whether federal or state inspection is most appropriate. This could be done with a checkbox that would require little effort on the part of industry while assisting the agency in allocating its limited inspectional resources.
(2) FDA should require facility profile information to be reported as part of the biennial registration process.[6] This would ensure the agency has accurate information on a facility's type, size and operating schedule prior to and during inspections. The information would also provide the agency with more reliable data on industry practices and standards which would help define where there are industry-wide gaps or deficiencies, in order to better identify the areas where oversight and guidance would improve safety.
(3) FDA should also considered requiring facilities to submit their food safety plans during registration. This would permit the agency to target resources toward facilities with inadequate plans. It would also provide information on a facility's hazard analysis, preventive controls and employee training regimen, allowing the agency to appropriately target an inspection's focus.

Receiving adequate and appropriate information about the food industry is critical to FDA's management of its oversight responsibilities. As Congress mandated biennial registration, these additions to that reporting requirement are not burdensome and could improve the efficiency of inspections that better protect public health.

Sincerely,



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[4] Daniel R. Levinson, Inspector General, FDA's Food Facility Registry, Office of the Inspector General, Dec. 2009 (Recommending routine re-registration after finding 7% of facilities failed to register or failed to cancel registration, half had inaccurate information in their registrations, 23% failed to include necessary information, and 52% of managers were unaware of the registry requirements).
[5] *See*, 156 Cong. Rec. S8030 (daily ed. Nov. 18, 2010)(statement of Sen. Durbin); *see also* Enhancing Food Safety, 296 (Robert B. Wallace et al. eds., Nat'l Academies Press, 2010).
[6] Voluntary Submission of Food/Feed Facility Profile Information, 77 Fed. Reg. 27779 (May 11, 2012).