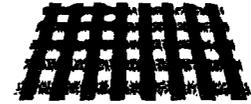


35 E Wacker Drive, Suite 2000
Chicago, IL 60601-2200
Phone: (312) 263-2303



America's Second Harvest
Ending Hunger

March 31, 2003

ATTN: Dockets Management Branch (HFA-305)
United States Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

RE: Notice of Proposed Rulemaking, Docket No. 02N-0276
Registration of Facilities under the *Public Health Security and Bioterrorism
Preparedness and Response Act of 2002*

On behalf of America's Second Harvest and 212 direct affiliate regional food banks and food rescue organizations, I am writing to provide comment to the proposed rule on the "Registration of Facilities under the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*," published in the Federal Register, Volume 68, Number 22, February 3, 2003.

America's Second Harvest is the nation's largest hunger relief charity. We are a national network of 212 regional affiliate food banks and food rescue organizations, subsidiary food banks, and approximately 50,000 local hunger relief charities including food pantries, food shelves, soup kitchens, women's and emergency shelters, and similar local agencies. Our affiliates and agencies provide food and grocery products to low-income people in all 50 states and Puerto Rico. According to a recent study of the emergency food assistance system by the United States Department of Agriculture's Economic Research Service, approximately 80 percent of all food banks in the United States are part of the America's Second Harvest network.

Pursuant to the proposed rule making on the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (P.L. 107-188), the Food and Drug Administration (FDA) is proposing that certain facilities register with the FDA. Among those facilities specifically exempted by the proposed rule from the registration requirement are food banks pursuant to Section 415(b)(1) of the Act. Section 1.226(e) of the proposed regulation would exempt certain nonprofit food facilities. Section 1.227(c)(7) defines a "Nonprofit food facility" as:

"...a charitable entity that prepares, serves, or otherwise provides food to the public. The term includes, but is not limited to, **food banks**, soup kitchens, and nonprofit food delivery services. To qualify as a nonprofit food facility, the entity must be exempt from paying federal income tax under the U.S. Internal Revenue Code." (emphasis added)

All America's Second Harvest food banks, food rescue organizations, and all local agencies of our affiliates, are required to be incorporated as nonprofit organizations that are exempt from paying income tax as defined by the Internal Revenue Code Section 501(c)(3) or the equivalent.

02N-0276

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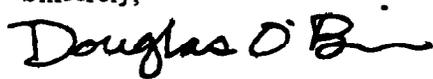
Come visit our website at
www.secondharvest.org

U.S. Food and Drug Administration letter
Page Two
March 31, 2003

Our certified affiliate food banks and food rescue organizations provide food to the public through direct distributions and through distributions to local nonprofit 501(c)(3), or equivalent nonprofit, agencies. As such, we understand the proposed rule exempts our affiliates and their agencies from the *Public Health Security and Bioterrorism Preparedness and Response Act* registration process.

Thank you for the opportunity to comment on this important proposed regulation.

Sincerely,



Douglas O'Brien
Vice President, Public Policy & Research
America's Second Harvest



**America's Second Harvest
Ending Hunger**

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FACSIMILE COVER PAGE

Date: March 31, 2003

To: Dockets Management Branch
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Phone: (301) 827-6860
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From: Eleanor Thompson
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Pages (including cover): 3

Notes: Please accept the following comments concerning Docket No. 02N-0276 re: *Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.*

Thank you very much for your consideration.