GAO
Accountability * Integrity * Reliability

United States General Accounting Office
Washington, DC 20548

B-293038

October 23, 2003

The Honorable Judd Gregg
Chairman
The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable W.J. "Billy" Tauzin
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Food and Drug Administration (FDA), entitled "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (RIN: 0910-AC40). We received the rule on October 10, 2003. It was published in the Federal Register as an interim final rule on October 10, 2003. 68 Fed. Reg. 58894.

The interim final rule requires domestic and foreign facilities that manufacture/ process, pack, or hold food for human or animal consumption in the United States to register with the FDA by December 12, 2003. The interim final rule implements the Public Health Security and Bioterrorism Preparedness Act of 2002.

Enclosed is our assessment of the FDA's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review indicates that the FDA complied with the applicable requirements.

If you have any questions about this report, please contact James W. Vickers, Assistant General Counsel, at (202) 512-8210. The official responsible for GAO evaluation work relating to the subject matter of the rule is Robert Robinson,

Managing Director, Natural Resources and Environment. Mr. Robinson can be reached at (202) 512-3841.

signed

Kathleen E. Wannisky
Managing Associate General Counsel

Enclosure

cc: Ann Stallion
Regulations Coordinator
Department of Health and
Human Services

ENCLOSURE

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION
ENTITLED
"REGISTRATION OF FOOD FACILITIES UNDER THE
PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS
AND RESPONSE ACT OF 2002"
(RIN: 0910-AC40)

(i) Cost-benefit analysis

FDA estimates the first-year costs to be $23 million for domestic facilities, $306 million for foreign facilities, and FDA costs of $13.2 million for total first-year costs of $342.2 million.

(ii) Agency actions relevant to the Regulatory Flexibility Act, 5 U.S.C. §§ 603-605, 607, and 609

FDA performed a Final Regulatory Flexibility Analysis in connection with the interim final rule. It found that the interim final rule could have a significant economic impact on a substantial number of small entities because 99 percent of the 216,271 domestic facilities would be considered small. A discussion of the options considered was included in the proposed rule and in the regulatory impact analysis of the interim final rule. These include the change from the proposed rule's requirement of updating information within 30 days to the 60-day timeframe in the interim final rule.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

FDA has determined that the interim final rule does not impose either an intergovernmental or private sector mandate, as defined in title II, of more than $100 million ($113 million adjusted for inflation) in any one year and, therefore, is not a significant rule under the act.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

The interim final rule was issued using the notice and comment procedures found at 5 U.S.C. 553. On February 3, 2003, the FDA and the Department of the Treasury issued a proposed rule requiring registration with the FDA. 68 Fed. Reg. 5378. In

response, approximately 350 comments were received and are discussed in the preamble to the interim final rule. In addition, comments on the interim final rule may be submitted until December 24, 2003.

Paperwork Reduction Act, 44 U.S.C. §§ 3501-3520

The interim final rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. FDA has submitted the required information to OMB for review and approval--including the number of respondents (216,271 domestic and 205,405 foreign facilities) and the estimated annual burden. FDA estimates the annual reporting burden in the first year will be 2,477,426 hours and 521,830 hours in subsequent years.

Statutory authorization for the rule

The interim final rule was promulgated under the authority contained in section 305 of the Public Health Security and Bioterrorism Preparedness Act of 2002 (Pub. L. 107-188, June 12, 2002).

Executive Order No. 12866

The interim final rule was reviewed by OMB and found to be an "economically significant" regulatory action under the order.

Executive Order No. 13132 (Federalism)

FDA has determined that there are no sufficient federalism implications to warrant the preparation of a federalism assessment.