DATE: February 2, 2004

NOTE TO: FDA Division of Dockets Management (HFA-305) 04 FEB -4 48:38

DOCKET NO.: 2002N-0278

SUBJECT: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 – Notice of Proposed Rulemaking

PUB DATE: February 3, 2003

The September 30, 1993, Executive Order 12866--Regulatory Planning and Review sets forth the Administration's principles and requirements for the Federal regulatory process. Under section 6(a)(3)(E) of the Executive Order, for "significant regulatory actions," Federal agencies must make certain information available to the public after publication of the regulatory action in the Federal Register.

Pursuant to the Executive Order, the Food and Drug Administration (FDA) has attached in this docket, for the subject significant regulatory action, the following information:

1) A copy of the draft regulatory action as submitted to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) for review, including any materials or assessments, required by the Executive Order, that accompanied the draft (TAB A);

2) The substantive changes between the draft submitted to OIRA for review and the regulatory action subsequently announced, including those changes that were made at the suggestion or recommendation of OIRA, and any other agency or governmental component to which this draft was submitted by OIRA for review, the Department of Health and Human Services (DHHS), or FDA, if any (see mark-ups, TABS B-1 to B-7); and

3) A copy of the final regulatory action as sent to the Office of the Federal Register for publication or as published in the Federal Register (TAB C).

Regulations Policy and
and Management Staff (HF-26)

Attachments

02N-0278

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