DATE: February 25, 2004

NOTE TO: FDA Division of Dockets Management (HFA-305)

DOCKET NOS.: 1991N-384H and 1996P-0500

SUBJECT: Food Labeling: Nutrient Content Claims, Definition of Sodium Levels for the Term "Healthy" – Proposed Rule

PUB DATE: February 20, 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 for significant regulatory actions, FDA has attached, in this docket, 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, if any (see mark-ups, TAB B); and

3) A copy of the final regulatory action as published in the Federal Register (TAB C).

Regulations Policy and
and Management Staff (HF-26)

Attachments

91N-384H

REF 1