DATE: November 5, 2003

NOTE TO: FDA Division of Dockets Management (HFA-305) 03 NOV -6 A8:27

DOCKET NO.: 96N-0417

SUBJECT: Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements–Proposed Rule

PUB DATE: March 13, 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, FDA has attached, for significant regulatory actions, 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

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