DATE: December 11, 2006

NOTE TO: FDA Dockets Management Branch

DOCKET NO.: 2006N-0416

SUBJECT: OMB Changes

PUBLISHED: December 7, 2006

The September 30, 1993, Executive Order 12866 (E.O.) --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 E.O., 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 E.O for significant regulatory actions, FDA has attached in this docket a copy of the rule showing the following information:

1) 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;

2) Substantive changes between the draft submitted to OIRA for review and the action subsequently published. There were none; and

3) Likewise, changes in the regulatory action that were made at the suggestion or recommendation of OIRA. There were none.

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(HF-26)

Attachment(s)

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