DATE: September 20, 2007

NOTE TO: FDA Dockets Management Branch 0658 7 SEP 20 P3:08

DOCKET NO.: 2007N-0262

SUBJECT: OMB Changes

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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 are shown in track changes text; and

3) Likewise, changes in the regulatory action that were made at the suggestion or recommendation of OIRA, are shown in track changes text.

Diane Sullivan, B.S., J.D.
Regulatory Policy Analyst
FDA Regulations Policy and Management Staff
(HF-26)

Attachment(s)

2007N-0262

REF1