DATE: 10-31-03

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NOTE TO
DOCKET NO.: 02N-0417

SUBJECT: Application for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated....., Final Rule.

PUBLICATION DATE: 6-18-03

On September 30, 1993, President Clinton signed Executive Order 12866--Regulatory Planning and Review. This Executive Order 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 action subsequently announced, if any (TAB B); and

3) ✓ Those changes in the regulatory action that were made at the suggestion or recommendation of OIRA, if any (TAB B).

David F. Fishler
Regulations Policy and
Management Staff
(HF-26)

Attachment(s)

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