



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

3479 04 MAY 17 2004

March 25, 2004

NOTE TO DOCKET NO. 1999D-0529

SUBJECT: Supplements and Other Changes to an Approved Application

PUBLICATION DATE:

Executive Order 12866 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 Executive Order 12866, FDA has attached, for the significant regulatory action 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 which includes changes to the regulatory action made at the request of OIRA (Tab A); and
- 2) The action as subsequently announced (Tab B).

Lisa Helmanis
Regulations Policy
and Management Staff (HF-26)

Attachments

99D-0529

REF 1