DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 82N-0143]

Assessment of the Economic Impacts of the OTC Drug Review Process; Availability

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an assessment of the economic impacts of the over-the-counter (OTC) drug review process.

ADDRESS: Written comments and requests for a copy of the assessment to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFN-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: This document announces the availability of an assessment of the economic impacts of the OTC drug review process. The assessment has been prepared to determine whether the economic effects of the OTC drug review process, as a whole, are sufficient to warrant a Regulatory Impact Analysis (as specified in Executive Order 12291) or a Regulatory Flexibility Analysis (as required by the Regulatory Flexibility Act, Pub. L. 96-354).

In 1972, FDA established procedures for the conduct of the OTC drug review (21 CFR Part 330). In accordance with these procedures, as amended, the agency now is issuing proposed and final regulations to establish monographs for numerous individual therapeutic categories of the OTC drug products. These actions by the agency affect the marketability of thousands of OTC drug products. To determine the economic consequences of these actions, FDA has prepared a document entitled "Assessment of the Economic Impacts of the OTC Drug Review Process." This assessment evaluates the economic effects (costs) of any required labeling, reformulation, and/or testing of OTC drug products as a direct result of the OTC drug review process. The assessment examines the economic impact of the establishment of a monograph for any particular therapeutic class of OTC drugs. The assessment demonstrates that the review process in its entirety will not have a "major impact" as defined in Executive Order 12291, and probably will not have a "significant economic impact on a substantial number of small entities" as defined in the Regulatory Flexibility Act. The assessment concludes that any single monograph of the more than 60 planned over the next five years should be presumed to have neither kind of impact except in the event that interested persons present specific evidence to the contrary.

A copy of the assessment is available for public examination between 9 a.m. and 4 p.m., Monday through Friday, in the Dockets Management Branch. Requests for single copies of the assessment may be submitted to the Dockets Management Branch and should identify the assessment with the docket number found in brackets in the heading of this document.

Interested persons may, on or before June 8, 1983, submit written comments on the assessment to the Dockets Management Branch (address above). Interested persons will be given further opportunity to comment on the economic impacts of the OTC drug review in the context of each individual rule as it is published. Such comments will be considered in determining whether further amendments to, or revisions of, the assessment are warranted. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The assessment and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday, except holidays.

Dated: February 1, 1983.

Mark Novitch,

Deputy Commissioner of Food and Drugs.

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