

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Independent Evaluation of the Food and Drug Administration's First Cycle Review Performance—Retrospective Analysis Final Report; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a report entitled “Independent Evaluation of FDA’s First Cycle Review Performance—Retrospective Analysis Final Report.” This report describes an independent evaluation of the issues associated with FDA’s conduct of first cycle reviews of new molecular entities for new drug applications (NMEs for NDAs), and biological license applications (BLAs). Applications covered by the report are those submitted to FDA in fiscal years 2002 to 2004. This independent study was conducted in relation to the Prescription Drug User Fee Amendments of 2002 (PDUFA III). This assessment includes a detailed evaluation of the events that occurred during the review process with a focus on identifying the best practices by FDA and industry that facilitated that process.

**ADDRESSES:** Submit written requests for single copies of this report to the Office of Planning (HFP-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit electronic requests to *Carolyn.Staples@fda.hhs.gov*. This report will be available on FDA’s Web site at a later date.

**FOR FURTHER INFORMATION CONTACT:** Carolyn Staples, Office of Planning (HFP-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5274, or William Hagan, Office of Planning (HFP-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-8816.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On June 12, 2002, the President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes PDUFA III. In conjunction with the passage of PDUFA III, FDA agreed to certain performance goals and procedures that were described in an enclosure to a June 4, 2002, letter from the Secretary of Health and Human Services, Tommy Thompson, to Congress entitled “PDUFA Reauthorization Performance Goals and Procedures” (PDUFA Goals and Procedures).

One of the goals relates to FDA’s performance of first cycle reviews of original NMEs for NDAs and BLAs (PDUFA Goals and Procedures, section 10). Related to this goal, FDA was to retain an independent expert consultant to undertake a study to evaluate issues associated with the agency’s conduct of first cycle reviews. The study was to assess the following objectives: (1) Current first cycle review performance and any changes that occur after FDA publishes guidance on Good Review Management Principles (GRMPs), (2) the first cycle review history of all NDAs for new molecular entities and all BLAs during PDUFA III, and (3) the effectiveness of FDA’s staff training regarding GRMPs. FDA awarded a contract to an independent expert to study these issues. The report referred to in this document covers the retrospective portion of objectives (1) and (2) listed previously.

In accordance with the PDUFA goal, the report is being made available to the public.

Dated: January 30, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

**BILLING CODE 4160-01-S**