

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2001D–0059 (formerly 01D–0059)]

### Guidance for Industry on Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees; Availability

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees.” The guidance describes the agency’s current policy on what should be contained in separate marketing applications and what should be combined into one application for purposes of assessing user fees and a definition of “clinical data” for user fee purposes.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance to the Division of Dockets

Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Beverly Friedman, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, or Rockville, MD 20857, 301–594–2041, FAX: 301–827–5562, or

Carla A. Vincent, Center for Biologics Evaluation and Research (HFM–110), 1401 Rockville Pike, Rockville, MD 20852, 301–827–3503, FAX: 301–827–2875.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled “Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees.” The guidance document describes FDA’s thinking on what will be considered separate marketing applications and what will constitute clinical data for purposes of assessing user fees under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h).

This guidance was issued in draft on February 22, 2001 (66 FR 11175) with comments due by March 26, 2001. No comments were received. In the meantime, Congress considered reauthorization of the user fee program. As a result, FDA delayed issuance of the guidance. Now that the program has been reauthorized without change to the relevant language, FDA is issuing the guidance. Other than minor editorial changes, only two changes of note have

been made to the guidance. We have reevaluated our policy on pharmacy bulk packages and products for prescription compounding and determined that a separate application is no longer needed for these products unless otherwise noted in the guidance document. Therefore, the subsection entitled “Pharmacy Bulk Packages and Products for Prescription Compounding” has been removed. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) may require a new application to be submitted because of a change to the reference listed drug. Therefore, a new subsection was added to clarify the user fee liability.

The guidance represents the agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of mailed 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 guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: December 16, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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