

EXHIBIT 27

# FEDERAL REGISTER

Wednesday  
August 7, 1985

**Briefings on How To Use the Federal Register**  
For information on briefings in Washington, DC, see  
announcement on the inside cover of this issue.

## Selected Subjects

### Airports

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Federal Aviation Administration

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### Surface Mining

Surface Mining Reclamation and Enforcement Office

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Food and Drug Administration**

**28 CFR Ch. I**

**Docket No. 85N-0214]**

**Drug Price Competition and  
Patent Term Restoration Act of 1984;  
Reopening of Comment Period**

**AGENCY:** Food and Drug Administration.  
**ACTION:** Reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening for an unspecified period of time the period for public comment on interpretation of Title I of the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417). This action will allow the public additional time to submit comments.

**DATE:** Comments will be accepted for an unspecified period of time. FDA will announce the closing date for comments in a future issue of the Federal Register.

**ADDRESS:** Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-107, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Marilyn L. Watson, Center for Drugs and Biologics (HFN-360), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3640.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) was signed into law September 24, 1984. Title I of the new law amends section 305 of the Federal Food, Drug, and Cosmetic Act and codifies FDA's authority to accept abbreviated new drug applications (ANDA's) for generic versions of drug products first approved after 1962. Prior to the enactment of Pub. L. 98-417, ANDA's were permitted under FDA regulations for generic versions of drug products first approved between 1938 and 1962.

In the Federal Register of May 24, 1985 (50 FR 21460), FDA published a notice requesting public comments on Title I of Pub. L. 98-417. This notice also announced the establishment of a public file [Docket No. 85N-0214] for all comments, views, and other information submitted to FDA concerning Title I of Pub. L. 98-417. The purpose of the notice was to obtain public comment on interpretation of the new law for purpose of the agency's regulation-writing process. The notice gave interested persons an opportunity to submit written comments by July 8, 1985.

Because of the complexity of the statute's provisions, the agency is interested in continuing to receive questions, identification of policy issues, and suggested interpretations of the new law that will assist the agency in its efforts to develop regulations implementing Title I Pub. L. 98-417. Therefore, in an effort to encourage greater participation in the submission of comments, FDA is reopening the comment period for an unspecified time period.

The agency cautions, however, that it is proceeding expeditiously in developing implementing regulations and fully intends to issue a proposed rule in a timely manner. Interested persons are encouraged to submit comments on the new law as early as possible in order for FDA to evaluate and consider them in developing its regulations.

Interested persons may submit written comments on Title I of Pub. L. 98-417 to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. All comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 1, 1985

John R. Wessel.

Acting Associate Commissioner for  
Regulatory Affairs.

[FR Doc. 85-18203 Filed 8-2-85; 1:41 pm]

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**DEPARTMENT OF JUSTICE**

**28 CFR Part 16**

[AAG/A Order No. 14-85]

**Exemption of Records Systems Under  
the Privacy Act**

**AGENCY:** Department of Justice.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Justice, Antitrust Division, proposes to revise 28 CFR 16.88 to (1) exempt a system of records from certain provisions of the Privacy Act, (2) remove systems of records which are not operational, and (3) make editorial changes.

Specifically, the Antitrust Division proposes to exempt a system of records entitled "Freedom of Information/Privacy—Requester/Subject Index File (JUSTICE/ATR-008)" from subsections (c)(3), (d), (e)(4)(G) and (H), and (f) of the Privacy Act. This system is

exempted to the extent that the records reflect Antitrust Division law enforcement and investigative information. The exemption is needed to protect the integrity of law enforcement prosecutions and investigations, the privacy of third parties, and the identity of confidential sources. In addition, the Division proposes to remove from 28 CFR 16.88 notice of the exemption of two systems entitled, "Computerized Document Retrieval System—United States v. International Business Machines (CDRS—Tire Cases) (JUSTICE/ATR-002)," and "Computerized Document Retrieval System—Tire Cases (CDRS—Tire Cases) (JUSTICE/ATR-003)." Although these record systems have not been operational for many years, through administrative error they were never removed from 28 CFR 16.88. Thus, the removal of these systems is an editorial/administrative correction and has no effect on the public. Finally, and also for administrative reasons having no effect on the public, the Division proposes to change the identifying number of a system of records entitled "Antitrust Caseload Evaluation System (ACES)—Monthly Report (JUSTICE-ATR-009)" to "006."

**DATE:** Submit comments on or before September 6, 1985.

**ADDRESS:** Address all comments to Thomas F. O'Leary, Assistant Director, General Services Staff, Justice Management Division, Department of Justice, Room 6314, 10th and Constitution Avenue, NW., Washington, DC 20530.

**FOR FURTHER INFORMATION CONTACT:** Thomas F. O'Leary, 202-633-4414.

**SUPPLEMENTARY INFORMATION:** This order relates to individuals rather than small business entities. Nevertheless, pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601-612, it is hereby stated that the order will not have "a significant economic impact on a substantial number of small entities."

**List of Subjects in 28 CFR Part 16**

Administrative practice and procedure, Courts, Freedom of Information, Privacy, Sunshine Act.

Accordingly, pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order 793-78, it is proposed to revise 28 CFR 16.88 as set forth below.