

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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DDM

Food and Drug Administration

Food and Drug Administration's Transition to the Federal Dockets Management System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that effective January 15, 2008, the public will no longer be able to submit electronic comments to its Dockets through FDA's Web site. Electronic comments to FDA's Dockets may continue to be submitted through the Federal eRulemaking Portal. In recent months, FDA has alerted the public through our published **Federal Register** documents that after the transition date, electronic submissions will only be accepted by FDA through Federal Dockets Management System (FDMS). Please note that the process for submitting written comments to FDA's Dockets will remain the same.

FOR FURTHER INFORMATION CONTACT: The Division of Dockets Management Public Room (HFA-305), Food and Drug Administration, 5630 Fishers Lane, 1061, Rockville, MD 20852, 301-827-6860, or FAX: 301-827-6870.

SUPPLEMENTARY INFORMATION:

I. Background:

FDMS is a major component of the President's e-Rulemaking Initiative, which provides easy access to the public dockets maintained by Federal agencies, while streamlining and increasing the efficiency of the internal, regulatory procedures for agencies. FDMS is designed so that the public has

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a single point of access to the public dockets across the Federal government and agencies have a standard, online procedure to manage and process dockets, documents, and public comments/submissions. The Initiative reduces costs by eliminating duplicative information systems and technical infrastructures.

A. What is FDMS?

FDMS is a full-featured electronic docket management system that gives Federal personnel and docket managers the ability to better manage their rulemakings, adjudications, and other docketed program activities. FDMS also provides the public with a one-stop site to search, view and download documents, as well as post comments/submissions to federal agencies.

FDMS makes it easier for all segments of the public with access to a computer and the Internet—whether at home, at work, or at a local library—to submit comments to agency dockets. FDMS is accessible on the Internet at <http://www.Regulations.gov>.

B. How Can I Access and Use FDMS?

FDMS is accessible on the Internet at <http://www.Regulations.gov>. The public may use FDMS to access available public docket materials online, as well as submit electronic comments to a particular docket available in FDMS.

C. How Can I Search FDMS?

FDMS provides two basic methods of searching to retrieve dockets and docket materials that are available in the system: (1) Quick Search to search using a full-text search engine and Browsing options or (2) Advance Search which displays various indexed fields such as the docket name, docket identification number, agency, date of issuance, document title, document identification (ID) number, type of documents, etc. Each data field in the

advance search may be searched independently or in combination with other fields, as desired. Each search yields a simultaneous display of all available information found in FDMS that is relevant to the requested subject or topic.

D. How Can I Post Comments/Submissions to FDMS?

The public may post comments/submissions online to FDMS on the Internet at <http://www.Regulations.gov> when a particular docket is open for public comment/submissions. For each Docket, FDA will issue a **Federal Register** notice or other document that provides information and instructions on posting comments/submissions to FDMS.

II. Migration from the Division of Dockets Management (DDM) to FDMS

A. Phased Migration

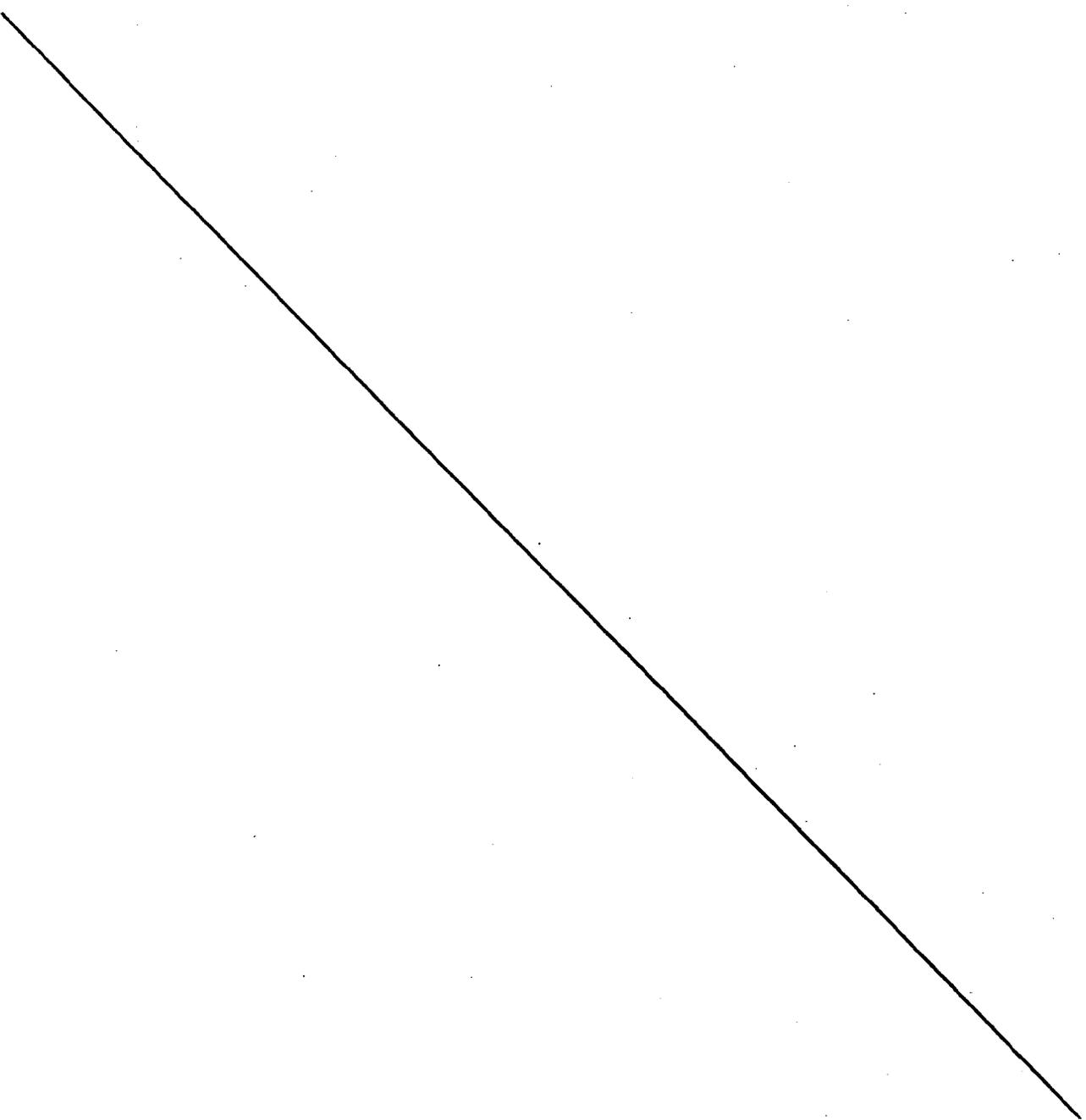
Using a phased approach, all dockets currently managed by FDA's DDM will be moved to FDMS. After the migration, the public will be able to access FDA Dockets at [Regulations.gov](http://www.Regulations.gov). On this Web site, the public will be able to read background dockets, public comments the agency has received, etc. Due to the tremendous amount of data to be transferred from FDA's DDM to FDMS, the migration will occur over the next few months. Until a Docket is migrated, the public will continue to be able to access it through FDA's Web Site at <http://www.fda.gov/ohrms/dockets>.

B. Docket ID Numbers

Any Docket created after January 15, 2008, will receive a docket ID established by FDMS. Any Docket created on or before January 15, 2008, and migrated to FDMS will receive a docket ID established by FDMS, but it will also include a reference to its original docket (identification) number that had been assigned by FDA (legacy numbers).

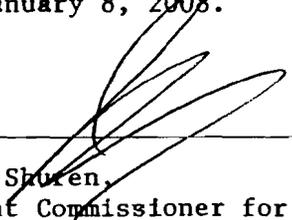
III. Additional Information

Additional details about FDMS, as well as detailed instructions and assistance for using the system, are available at <http://www.Regulations.gov>.



Dated: 1/8/08
January 8, 2008.

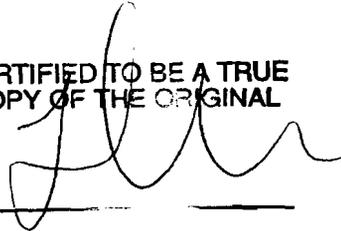
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