DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0429]

Prescription Drug User Fee Act III Five-Year Plan; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an internal planning document entitled the ''PDUFA III Five-Year Plan'' (the plan). The plan to achieve PDUFA (Prescription Drug User Fee Act) III goals for the drug review process takes into account changes in the law under PDUFA III and projects revenue and spending in fiscal year (FY) 2003 through FY 2007.

DATES: Submit written or electronic comments on the plan at any time. These comments will be considered as the agency makes annual adjustments to the plan each fiscal year.

ADDRESSES: Submit written requests for single copies of this plan to the Office of Management and Systems, Attn: Frank Claunts (see **FOR FURTHER INFORMATION CONTACT**). Send a self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the plan 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 plan.

FOR FURTHER INFORMATION CONTACT: Frank Claunts, Office of Management and Systems (HF–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an internal planning document entitled ''PDUFA III Five-Year Plan.'' PDUFA was amended and extended through the year 2007 by the Prescription Drug User Fee Amendments of 2002 (PDUFA III). PDUFA III authorizes appropriations and fees that will provide FDA with resources to sustain the drug review staff developed through FY 2002 and to achieve the even more stringent new goals through FY 2007.

The plan begins with a statement of purpose, provides background information on PDUFA along with a summary of the new goals, and the plan documents the 10 major assumptions on which it is based. The plan summarizes individual plans of agency components with major PDUFA responsibilities and also provides a consolidated agency summary. The plan to achieve PDUFA III goals for the drug review process is based on projected revenue and spending projections through FY 2007. Appendix A of the plan is entitled the ''PDUFA III Information Technology Five-Year Plan.''

We (FDA) are making this plan available to interested individuals. We welcome comments, and we will consider all comments in the future as annual adjustments are made to the plan.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The plan and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of this document are available on the Internet at *http://www.fda.gov/oc/pdufa3/2003plan/default.htm*.

Dated: October 7, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25965 Filed 10–8–03; 4:06 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Proposed Project: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Regulations and Forms (OMB No. 0915–0126)—Revision

The National Practitioner Data Bank (NPDB) was established through Title IV of Pub. L. 99–660, the Health Care Quality Improvement Act of 1986, as amended. Final regulations governing the NPDB are codified at 45 CFR part 60. Responsibility for NPDB implementation and operation resides in the Bureau of Health Professions, Health Resources and Services Administration, U.S. Department of Health and Human Services (DHHS). The NPDB began operation on September 1, 1990.

The intent of Title IV of Pub. L. 99–660 is to improve the quality of health care by encouraging hospitals, State licensing boards, professional societies, and other entities providing health care services, to identify and discipline those who engage in unprofessional behavior; and to restrict the ability of incompetent physicians, dentists, and other health care practitioners to move from State to State without disclosure of the practitioner's previous damaging or incompetent performance.

The NPDB acts primarily as a flagging system; its principal purpose is to facilitate comprehensive review of practitioners' professional credentials and background. Information on medical malpractice payments, adverse licensure actions, adverse clinical privileging actions, adverse professional society actions, and Medicare/Medicaid exclusions is collected from, and disseminated to, eligible entities. It is intended that NPDB information should be considered with other relevant information in evaluating a practitioner's credentials.

This request is for a revision of reporting and querying forms previously approved on April 30, 2002. The reporting forms and the request for information forms (query forms) must be accessed, completed, and submitted to the NPDB electronically through the NPDB Web site at *http://www.npdb-hipdb.com*. All reporting and querying is performed through this secure Web site. Due to overlap in requirements for the Healthcare Integrity and Protection Data Bank (HIPDB), some of the NPDB's burden has been subsumed under the HIPDB.

Estimates of burden are as follows:

Regulation citation	No. of respondents	Frequency of responses	Hours per response	Total burden hours
60.6(a) Errors & Omissions	303	5	15 min.	[1]385
60.6(b) Revisions to Actions	115	1.1	30 min.	64
60.7(b) Medical Malpractice Payment Report	485	39	45 min.	14,236
60.8(b) Adverse Action Reports—State Boards	[2]0	0	0	0
60.9(a)3 Adverse Action Clinical Privileges & Professional Society	686	1.5	45 min.	785
Requests for Hearings by Entities	1	1	480 min.	8
60.10(a)(1) Queries by Hospital-Practitioner Applications	6,000	37.3	5 min.	18,615
60.10(a)(2) Queries by Hospitals-Two Yr. Cycle	6,000	149	5 min.	74,461
60.11(a)(1) Disclosure to Hospitals	[3]0	0	0	0
60.11(a)(2) Disclosure to Practitioners (Self Query)	[4]0	0	0	0
60.11(a)(3) Disclosure to Licensure Boards	80	225	5 min.	1,499
60.11(a)(4) Queries by Non-Hospital Health Care Entities	4,938	437	5 min.	179,673
60.11(a)(5) Queries by Plaintiffs' Attorneys	5	5	30 min.	3.0
60.11(a)(6) Queries by Non-Hospital Health Care Entities-Peer Review	[5]0	0	0	0
60.11(a)(7) Requests by Researchers for Aggregated Data	100	1	30 min.	50
60.14(b) Practitioner Places a Report in Disputed Status	666	1	5 min.	55
60.14(b) Practitioner Statement	2,563	1	45 min.	1,922
60.14(b) Practitioner Requests for Secretarial Review	117	1	480 min.	936
60.3 Entity Registration-Initial	500	1	60 min.	500
60.3 Entity Registration-Update	643	1	5 min.	54
60.11(a) Authorized Agent Designation-Initial	500	1	15 min.	125
60.11(a) Authorized Agent-Update	86	1	5 min.	7
60.12(c) Account Discrepancy Report	300	1	15 min.	75
60.12(c) Electronic Funds Transfer Authorization	363	1	15 min.	91
60.3 Entity Reactivation	100	1	60 min.	100
Total				293,644

[1] Estimates in this column that fall below or above a full hour are rounded to the nearest hour.
[2] Included in estimate for reporting adverse licensure actions to the HIPDB in 45 CFR part 61.
[3] Included in estimates for 60.10(a)(1).
[4] Included in estimate for self queries to the HIPDB in 45 CFR part 61.
[5] Included in estimate for hospital queries under 60.11(a)(4).

Send comments to Susan Queen, Ph.D., HRSA Reports Clearance Officer, Room 16C–17, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20852, (301) 443–1129. Written comments should be received within 60 days of this notice.

Dated: October 3, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–25843 Filed 10–10–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG 2003–16251]

Collection of Information under Review by Office of Management and Budget (OMB): OMB Control Number 1625–0086

AGENCY: Coast Guard, DHS.

ACTION: Request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Coast Guard intends to seek the approval of OMB for the renewal of one Information Collection Request (ICR). The ICR concerns Great Lakes Pilotage. Before submitting the ICR to OMB, the Coast Guard is inviting comments on it.

DATES: Comments must reach the Coast Guard on or before December 15, 2003.

ADDRESSES: To make sure that your comments and related material do not enter the docket [USCG 2003-16251] more than once, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL–401, 400 Seventh Street SW., Washington, DC 20590–0001.

(2) By delivery to room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.

(3) By fax to the Facility at (202) 493–2251.

(4) Electronically through the Web Site for the Docket Management System at *http://dms.dot.gov*.

(5) Electronically through Federal eRule Portal: *http://www.regulations.gov*.

The Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov*.

Copies of the complete ICR are available through this docket on the Internet at *http://dms.dot.gov*, and also from Commandant (G–CIM–2), U.S.