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persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any 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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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: July 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–19020 Filed 7–25–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing the continuation of the Regulatory Project Manager Site Tours. This training program, initiated in 1999, gives CDER's regulatory project managers an opportunity to tour pharmaceutical facilities. The program provides regulatory project managers and their industry counterparts an opportunity to share their regulatory experiences. The program is intended to enhance review efficiency and quality by providing CDER staff with a better understanding of the pharmaceutical industry and its operation, and to improve communication and cooperation between CDER staff and industry. The purpose of this notice is to invite pharmaceutical companies interested in participating in these programs to contact CDER.

DATES: Pharmaceutical companies may submit proposed agendas by September 9, 2002.

FOR FURTHER INFORMATION CONTACT: Sean J. Belouin, Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2481, FAX 301–827–2523, e-mail: BELOUINS@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing the Regulatory Project Manager Site Tours to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide: (1) Firsthand exposure to industry's drug development processes, and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. Regulatory Project Manager Site Tours and Regulatory Interactions

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, may observe operations of pharmaceutical manufacturing, packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. The purpose of this tour, or any part of the program, is meant to improve mutual understanding and to provide an avenue for open dialogue.

During the site tours, regulatory project managers and their industry counterparts will also participate in daily workshops focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, project tracking mechanisms, and regulatory submission operations.

The overall benefit to regulatory project managers will be exposure to project management team techniques and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the site tours will be the responsibility of CDER, therefore, selection of potential facilities will be based on available resources for this program.

If your firm is interested in offering a site tour or learning more about this training opportunity, please submit a proposed agenda to Sean J. Belouin (see **FOR FURTHER INFORMATION CONTACT**).

Dated: July 17, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–19019 Filed 7–25–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

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 practitioner 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, 1999. 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 website. 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	Number of respondents	Responses per respondent	Hours per responses (in minutes)	Total burden hours
60.6(a), Errors & Omissions	400	4.625	15	462.5
60.6(b), Revisions to Actions	100	1.5	30	75
60.7(b), Medical Malpractice Payment Report	660	28.03	45	13,875
60.8(b), Adverse Action Reports—State Boards	[1] 0	0	0	0
60.9(a)3, Adverse Action Clinical Privileges & Professional Society	1,000	1.2	45	900
Requests for Hearings by Entities	1	1	480	8
60.10(a)(1), Queries by Hospital-Practitioner Applications	6,000	240,000	5	20,000
60.10(a)(2), (Queries by Hospitals-Two Yr. Cycle	6,000	960,000	5	80,000
60.11(a)(1), Disclosure to Hospitals	[2] 0	0	0	0
60.11(a)(2), Disclosure to Practitioners (Self Query)	[3] 0	0	0	0
60.11(a)(3), Disclosure to Licensure Boards	125	15,000	5	1,250
60.11(a)(4), Queries by Non-Hospital Health Care Entities	4,000	2,200,000	5	183,333
60.11(a)(5), Queries by Plaintiffs' Attorneys	5	5	30	2.5
60.11(a)(6), Queries by Non-Hospital Health Care Entities-Peer Review	[4] 0	0	0	0
60.11(a)(7), Requests by Researchers for Aggregated Data	100	100	30	50
60.14(b), Practitioner Places a Report in Disputed Status	1,000	1,000	15	250
60.14(b), Practitioner Statement	2,325	2,325	60	2,325
60.14(b), Practitioner Requests for Secretarial Review	110	110	480	880
60.3, Entity Registration-Initial	500	500	60	500
60.3, Entity Registration-Update	1,000	1,000	5	83
60.11(a), Authorized Agent Designation-Initial	500	500	15	125
60.11(a), Authorized Agent-Update	50	50	5	4.17
60.12(c), Account Discrepancy Report	300	300	5	75
60.12(c), Electronic Funds Transfer Authorization	400	400	15	100
60.3, Entity Reactivation	100	100	60	100
Total	.....	.....	.....	304,398

[1] Included in estimate for reporting adverse licensure actions to the HIPDB in 45 CFR part 61.
[2] Included in estimates for 60.10(a)(1).
[3] Included in estimate for self queries to the HIPDB in 45 CFR part 61.
[4] Included in estimate for hospital queries under 60.11(a)(4).

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 23, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02–19059 Filed 7–25–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director; Notice of Call for Applications for the Director's Council of Public Representatives

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH), the Federal government's primary agency for supporting and conducting medical research leading to the improvement in the nation's health, has established a national advisory council—the Director's Council of Public Representatives (COPR). The Chair of the COPR is the Director of the NIH. This notice describes the process for the selection of new members of the COPR that the NIH will use, as current members complete their terms.

DATES: The application deadline for the COPR is September 16, 2002—all applications must be postmarked on or before September 16, 2002; the notification of selection date is January 2003; the term start date is April 1, 2003; and the first COPR meeting date