approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 1271, subpart C have been approved under OMB Control No. 0910–0543. The collections of information in part 1271, subpart D have been approved under OMB Control No. 0910–0559.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance announced in this document. 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 the brackets in the heading of this document. A copy of 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.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm*or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 21, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–3445 Filed 2–27–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0021]

Draft Guidance for Industry on Advisory Committee Meetings: Preparation and Public Availability of Information Given to Advisory Committee Members; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Advisory Committee Meetings—Preparation and Public Availability of Information Given to Advisory Committee Members.'' This guidance is intended to provide information to industry sponsors, applicants, and petitioners on the development, preparation, or submission of briefing materials that will be given to advisory committee members as background information prior to open FDA advisory committee meetings. The guidance will help sponsors develop, organize, and submit advisory committee briefing materials for public release and should help minimize the time and resources spent in preparing these materials for public availability. The guidance also describes the process FDA intends to follow when we make briefing materials available to the public.

DATES: Submit written or electronic comments on the draft guidance document by April 30, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your request. Submit written comments on the draft guidance to 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Poppy Kendall, Food and Drug Administration (HF–11), 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, FAX: 301–594–6777, e-mail: *poppy.kendall@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Advisory Committee Meetings—Preparation and Public Availability of Information Given to Advisory Committee Members.'' This guidance will help sponsors develop, prepare, and submit advisory committee briefing materials and should help minimize the time and resources spent in preparing these materials for public availability. The guidance also describes the process FDA intends to follow when we make briefing materials available to the public. The term ''briefing materials'' is used to describe the package of information that we provide to advisory committee members before a meeting, and that usually contains information prepared by us and/or the sponsor (if the meeting involves an application or particular product). In addition, the Appendices to the draft guidance provide timelines for preparing and submitting briefing materials to FDA.

For open advisory committee meetings for which the briefing materials may contain information that under certain circumstances could be considered to be exempt from disclosure under the Freedom of Information Act (FOIA) (5 U.S.C. 552), we intend to post the publicly available version of the briefing materials on our Web site at least 2 full business days before the advisory committee meeting is scheduled to occur. With respect to meetings for which the briefing materials do not contain information that could be considered exempt from disclosure under FOIA, we will probably make the briefing materials available on our Web site more than 2 full business days before the advisory committee meeting is schedule to occur. In the latter case, we anticipate that meetings subject to this timeline will normally address general matters such as guidance documents and policy issues related to FDA-regulated products.

This draft guidance, which will harmonize the preparation and public availability of information given to advisory committee members for all products regulated by FDA, replaces three previously issued draft guidances: (1) ''Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000;'' (2) ''Disclosing Information Provided to Advisory Committees in Connection With Open Advisory Committee Meetings Related to the Testing or Approval of Biologic Products and Convened by the Center for Biologics Evaluation and Research;'' and (3) ''Availability of Information Given to Advisory Committee Members in Connection With the Center for Devices and Radiological Health Open Public Panel Meetings.'' An important goal of this guidance is to help ensure that briefing materials are made available to the public as provided under section 10(b) of the Federal

Advisory Committee Act (5 U.S.C. app. 2). The guidance includes recommendations on how to identify information that is exempt from public disclosure under the FOIA.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA'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 the 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 regarding this document. 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 draft guidance 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

Persons with access to the Internet may obtain the document at *http://www.fda.gov/opacom/morechoices/industry/guidedc.htm*.

Dated: January 24, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–887 Filed 2–26–07; 8:45 am]

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 (OMB) 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)—Extension

The National Practitioner Data Bank (NPDB) was established through Title IV of Public Law (P.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, Department of Health and Human Services (HHS). The NPDB began operation on September 1, 1990.

The intent of Title IV of P.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.

The reporting forms and the request for information forms (query forms) are accessed, completed, and submitted to the NPDB electronically through the NPDB Web site at *http://www.npdb-hipdb.hrsa.gov*. 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 Annualized Burden are as Follows:

Regulation citation	Number of respondents	Frequency of responses	Hours per response (minutes)	Total burden hours
60.6(a) Errors & Omissions	303	5	15	385
60.6(b) Revisions to Actions	115	1.1	30	64
60.7(b) Medical Malpractice Payment Report	485	39	45	14,236
60.8(b) Adverse Action Reports—State Boards	0	0	0	0
60.9(a)3 Adverse Action Clinical Privileges & Professional Society	686	1.5	45	785
Requests for Hearings by Entities	1	1	480	8
60.10(a)(1) Queries by Hospital—Practitioner Applications	6,000	37.3	5	18,615
60.10(a)(2) Queries by Hospitals—Two Yr. Cycle	6,000	149	5	74,461
60.11(a)(1) Disclosure to Hospitals	0	0	0	0
60.11(a)(2) Disclosure to Practitioners (Self-Query)	0	0	0	0
60.11(a)(3) Disclosure to Licensure Boards	80	225	5	1,499
60.11(a)(4) Queries by Non-Hospital Health Care Entities	4,938	437	5	179,673
60.11(a)(5) Queries by Plaintiffs' Attorneys	5	5	30	3.0
60.11(a)(6) Queries by Non-Hospital Health Care Entities—Peer Review	0	0	0	0