literature may be the basis for approval of an original application. The draft guidance is intended to provide specific advice on when FDA may be able to rely on published literature, with or without the submission of underlying data, to support new animal drug approval.

DATES: Submit written comments on the draft guidance for industry by July 18, 2000.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the draft guidance may be obtained on the Internet at http://www.fda.gov/cvm/fda/TOCs/guideline.html.

FOR FURTHER INFORMATION CONTACT: Gail L. Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20850, 301–594–1620, e-mail: gschmer1@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 403(b) of FDAMA (Public Law 105–115) requires FDA to issue guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for articles approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) or section 351 of the Public Health Service Act (42 U.S.C. 262). This provision includes a requirement that FDA publish guidance to clarify circumstances in which published matter may be the basis for approval of a supplemental application.

This draft guidance for industry clarifies the circumstances in which published literature may be the basis for approval of both original and supplemental new animal drug applications. Specifically, the draft guidance describes the circumstances under which FDA could rely on published literature without access to the underlying data and the circumstances under which the applicant should provide additional information about a published study.

II. Significance of Guidance

This draft guidance represents the agency's current thinking with regard to the use of published literature in support of new animal drug approval. 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 such approach satisfies the requirements of the applicable statute, regulations, or both. The agency has developed this draft guidance in accordance with the agency's good guidance practices (62 FR 8961, February 27, 1997), which set forth the policies and procedures for the development, issuance, and use of guidance documents.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by July 18, 2000. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of 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.

Dated: April 10, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–9713 Filed 4–18–00; 8:45 am]

BILLING CODE 4160–01–F

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 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 through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Donor Sabbath Organ Procurement Organization Survey—New

November 10–12, 2000, will mark the fifth annual National Donor Sabbath (NDS), a time for clergy throughout the Nation to help increase awareness about the critical need for organs and tissues. In support of the 1999 NDS, the Health Resources and Services Administration, Office of Special Programs, Division of Transplantation (DoT) distributed to 61 Organ Procurement Organizations (OPO) in the U.S. more than 300,000 organ donor awareness lapel pins attached to paper backings containing NDS information. The OPOs were asked to distribute the pins to their local clergy to be used for further distribution and education of their congregation. DoT plans to replicate this activity for 2000 NDS.

While DoT believed the 1999 pin distribution to be a positive educational tool there exists a need to properly investigate the efficacy of the pins as an aid in promoting NDS. The Division wishes to examine the pin distribution in 2000 NDS in order to plan the most effective, efficient, and cost effective role for DoT in subsequent observances of NDS. Investigation will consist of requesting each OPO to complete a short survey concerning usage, distribution, and impact of the pins. This is a one-time survey.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Subjects	Number of respondents	Responses per respondent	Total responses	Hrs. per response	Total hour burden
Organ Procurement Organizations	60	1	60	.33	20

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 13, 2000.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–9757 Filed 4–18–00; 8:45 am]

BILLING CODE 4160–15–P

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: Grants for Hospital Construction and Modernization—Federal Right of Recovery and Waiver of Recovery (42 CFR, Subpart H) (OMB No. 0915–0099)—Extension

The regulation known as ''Federal Right of Recovery and Waiver of Recovery,'' provides a means for the Federal Government to recover grant funds and a method of calculating interest when a grant-assisted facility under Titles VI and XVI is sold or leased, or there is a change in use of the facility. It also allows for a waiver of the right of recovery under certain circumstances. Facilities are required to provide written notice to the Federal Government when such a change occurs; and to provide copies of sales contracts, lease agreements, estimates of current assets and liabilities, value of equipment, expected value of land on the new owner's books and remaining depreciation for all fixed assets involved in the transactions, and other information and documents pertinent to the change of status.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Regulation	Number of respondents	Responses per respondent	Hours per response	Total burden hours
124.704(b) and 707	20	1	3	60

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

Dated: April 13, 2000.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–9756 Filed 4–18–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Early Therapeutics Development with Phase 2 Emphasis.

Date: May 8–9, 2000.

Time: 8 am to 5 pm.

Agenda: To review and evaluate contract proposals.

Place: Ramada Inn Rockville, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Lalita D. Palekar, Scientific Review Administrator, Special Review, Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 8066, Bethesda, MD 20892–7405, 301–496–7575.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology