and whether the information in a previously approved application is sufficient or new information would be needed. Comments provide additional information to assist the sponsor. In this way, the draft guidance specifies data requirements that will avoid duplication of previously submitted data. It also refers drug sponsors to related guidance documents that will aid them in the preparation of supplemental NADA's.

This draft guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public.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 requirement of the applicable statute, regulations, or both.

IV. Section 403(b)(3): Define Supplemental Applications That Are Eligible for Priority Review

When CVM determines that a product represents an important advance in animal health, it may expedite the review of original and supplemental applications. The circumstances in which CVM may make such a determination are outlined in an existing guidance entitled ''CVM Program Policy and Procedures Guide 1240.3135,'' available at the address above.

V. Section 403(c): Responsibilities of Centers

FDA has designated the following individual within CVM to be responsible for encouraging prompt review of supplemental applications for approved articles and for working with sponsors to facilitate the development and submission of data to support the approval of supplemental applications in accordance with section 403(c) of FDAMA:

Director, Office of New Animal Drug Evaluation (ONADE), Center for Veterinary Medicine, (HFV–100), Food and Drug Administration, 7500 Standish Place, Rockville MD 20855, 301–594–1620.

VI. Section 403(d): Collaboration to Identify Published and Unpublished Studies

CVM currently collaborates with the U.S. Department of Agriculture (USDA) National Research Support Project #7 (NRSP–7) and others, including state agencies, extension agents, universities, the National Coordinator for Aquaculture NADA's, and other USDA agencies, to encourage sponsors to make supplemental applications for minor use new animal drugs by encouraging development of Public Master Files (PMF's). Minor use new animal drugs are drugs used in minor animal species or drugs used in any animal species for the control of a disease that occurs infrequently or occurs in limited geographic areas. Minor species are defined in 21 CFR 514.1(d). PMF's contain public data from unpublished and published studies that can be used in conjunction with data already available in a major use product's original NADA to support a supplemental NADA. The majority of approved minor use drugs have been approved as supplements to products approved for use in major species.

In a notice entitled ''Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses; Availability'' published in the **Federal Register** (63 FR 58056, October 29, 1998), CVM proposed other methods of collaboration to make data available for minor use supplemental applications.

In addition, CVM frequently participates in discussions with animal industry trade associations to help clarify the new animal drug approval process. These discussions encourage university researchers and others to identify or initiate studies that may be used to support supplemental applications.

VII. Comments

The draft guidance discussed in section III of this document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Written comments may be submitted at any time, however, comments should be submitted by May 8, 2000, to ensure adequate consideration in preparation of the final document. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document 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: January 24, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–2767 Filed 2–7–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel.

Date: February 28, 2000.

Time: 1:30 pm to 6 pm.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Joyce A. Hunter, PHD, NIH, NHLBI, DEA, Rockledge Center, II, 6701 Rockledge Drive, Suite 7192, Bethesda, MD 20892–7924, (301) 435–0287.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 31, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–2757 Filed 2–7–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

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 meetings.

The meetings 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