

three year funding cycle. In addition, the Grant Application and Budget Instrument will be available on a data disk and can be transmitted

electronically to Regional offices. The Administration on Children, Youth and Families believes that, in promulgating this application document, the process

of applying for grants for the Head Start program will be more efficient for the applicants.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Head Start Grant Application and Budget Instrument	1,513	1	33	49,929

Estimated total Annual Burden Hours: 49,929.

Additional Information

ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by October 25, 1999. A copy of this information collection, with applicable supporting documentation, maybe obtained by calling the Administration for Children and Families, Reports Clearance Officer, Bob Sargis at (202) 690-7275.

Comments and questions about the information collection described above should be directed to the following address by October 25, 1999: Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paper Reduction Project, 725 17th Street, NW, Washington, DC 20503, (202) 395-7316.

Dated: September 21, 1999.

Bob Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Members on Public Advisory Panels or Committees; Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee (the Panel) in the Center for Devices and Radiological Health (CDRH). In this document, FDA is also requesting nominations for members to serve on the newly formed panel.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups. Final selection from among qualified candidates for each vacancy will be determined by the expertise required to meet specific agency needs and in a manner to ensure appropriate balance of membership.

DATES: Nominations should be received by October 27, 1999.

ADDRESSES: All nominations and curricula vitae, except for consumer-nominated and industry-nominated members, should be sent to Nancy J. Pluhowski (address below). All nominations and curricula vitae for the consumer-nominated members should be sent to Annette J. Funn (address below). All nominations for the industry-nominated members should be sent to Kathleen L. Walker (address below).

FOR FURTHER INFORMATION CONTACT:

Regarding all nominations for membership, except consumer-nominated and industry-nominated members: Nancy J. Pluhowski, Office of Device Evaluation (HFZ-400), CDRH, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2022.

Regarding all nominations for consumer-nominated members: Annette J. Funn, Office of Consumer Affairs (HFE-88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5006.

Regarding all nominations for industry-nominated members: Kathleen L. Walker, Office of Systems and Management (HFZ-17), CDRH, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1283, ext. 114.

SUPPLEMENTARY INFORMATION: The Panel was created on August 18, 1999. FDA is requesting nominations for members to serve on the new advisory panel.

Persons nominated for membership should have expertise in the activity of the Panel as identified below.

Functions

The functions of the medical devices panels of the Medical Devices Advisory Committee are to: (1) Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation; (2) advise the Commissioner of Food and Drugs regarding recommended classification or reclassification of these devices into one of three regulatory categories; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols; (5) review premarket approval applications for medical devices; (6) review guidelines and guidance documents; (7) recommend exemption to certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act (the act); (8) advise on the necessity to ban a device; (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices; and (10) make recommendations on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

Specifically, the function of the Molecular and Clinical Genetics Panel is to provide advice to the Commissioner on the appropriate scientific criteria to diagnostically test for human genes. In addition to the functions of the Medical Devices Advisory Committee, this panel shall review guidance and recommend criteria and classification of tests for human genes.

Criteria for Members

Persons nominated for membership on the Panel shall have expertise in human genetics and in the clinical management of patients with genetic disorders, e.g., pediatricians, obstetricians, and neonatologists. The agency is also interested in considering

candidates with training in inborn errors of metabolism, biochemical and/or molecular genetics, population genetics, epidemiology and related statistical training. Additionally, individuals with experience in genetic counseling, medical ethics as well as ancillary fields of study will be considered. The term of office is up to 4 years.

The Panel will also include technically qualified members who are identified with consumer interests and representatives of industry interests.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the Panel. Self-nominations are also accepted. Nominations shall include a complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude Panel membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

Criteria for Consumer-Nominated Members

Selection of members representing consumer interests is conducted through procedures that include use of a consortium of consumer organizations which has the responsibility for screening, interviewing and recommending candidates for the agency's selection. Candidates from this group, like all other candidates for membership on the Panel, should possess appropriate qualifications to understand and contribute to the Panel's work.

Industry Representatives

Regarding nominations for members representing industry interests, a letter will be sent to each person or organization that has made a nomination and to other organizations that have expressed an interest in participating in the selection process together with a complete list of all such organizations and the nominees. The letter will state that it is the responsibility of each nominator or organization that has expressed an interest in participating in the selection process to consult with the others to provide a consensus slate of possible members representing industry interests within 60 days. In the event that a slate

of nominees has not been provided within 60 days, the agency will select an industry representative for each such vacancy from the entire list of industry nominees to avoid delay or disruption of the work of the Panel. The agency is particularly interested in nominees that possess the essential scientific credentials needed to participate fully and knowledgeably in the Panel's deliberations. In addition to this expertise, the agency believes that it would be an advantage to the Panel's work if the individual had special insight and direct experience into specific industrywide issues, practices, and concerns that might not otherwise be available to others not similarly situated.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: September 17, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0969]

Antimicrobial Resistance in Food-Producing Animals; Notice of General Public Meeting and Public Workshops; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) will sponsor a general public meeting and two public workshops to discuss important issues related to antimicrobial resistance (AR) in food-producing animals. The agency is seeking public comment on the general public meeting in its further planning of the two public workshops. **DATES:** The general public meeting and the public workshops are scheduled as follows:

1. "General Public Meeting," Monday, October 4, 1999, 1 p.m. to 5 p.m.
2. "The Risk Assessment and the Establishment of Resistance Thresholds Workshop," Thursday and Friday, December 9 and 10, 1999, 9 a.m. to 5 p.m.
3. "Preapproval Studies in AR," Tuesday and Wednesday, February 22 and 23, 2000, 9 a.m. to 5 p.m.

ADDRESSES: The general public meeting and the public workshops will be held

at the DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD, 301-468-1100.

FOR FURTHER INFORMATION CONTACT:

For general information regarding the general public meeting and public workshops: Lynda W. Cowatch, Center for Veterinary Medicine (CVM) (HFV-150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5281, e-mail: lcowatch@cvm.fda.gov.

For information regarding technical inquiries: Sharon R. Thompson or Aleta M. Sindelar at 301-594-1798, FAX 301-594-1830.

Registration: The general public meeting and the public workshops are free, however, registration is required. Limited space is available and early registration is encouraged. Registration forms are available on CVM's home page at "<http://www.fda.gov/cvm/fda/mappqs/arregis1.doc>". If you need special accommodations for a disability, please contact the DoubleTree Hotel at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The agency believes it is essential to provide opportunities for public input regarding the following:

I. The General Public Meeting

The general public meeting is intended to provide an opportunity for stakeholders to give input to FDA on the appropriate issues, experts, and agenda items to be included in two subsequent scientific workshops related to AR. In general terms, the first scientific public workshop on December 9 and 10, 1999, is intended to focus on issues related to risk assessment and the establishment of resistance thresholds in food-producing animals. The second scientific public workshop on February 22 and 23, 2000, is intended to discuss the design of preapproval studies in food-producing animals to model the rate and extent of resistance development. FDA will consider comments received at the general public meeting in its further planning of the two scientific public workshops. We also encourage the submission of written comments at any time, but no later than 30 days after the date of publication of this notice to ensure time for full consideration in planning the December meeting. Comments should be identified with the docket number found in brackets in the heading of this document and submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.