IX. Procedures for Paying the FY 2005 Fees

A. Application Fees and Payment Instructions

The appropriate application fee established in the new fee schedule must be paid for an animal drug application or supplement subject to fees under ADUFA that is submitted after September 30, 2004. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. On your check, bank draft, or U.S. postal money order, please write your application's unique payment identification number, beginning with the letters ''AD,'' from the upper right-hand corner of your completed Animal Drug User Fee Cover Sheet. Also write FDA's post office box number (P.O. Box 953877) on the enclosed check, bank draft, or money order. Your payment and a copy of the completed Animal Drug User Fee Cover Sheet can be mailed to: Food and Drug Administration, P.O. Box 953877, St. Louis, MO, 63195–3877.

If you prefer to send a check by a courier such as Federal Express or United Parcel Service, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 953877, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314–418–4821. This telephone number is only for questions about courier delivery.)

The tax identification number of the FDA is 530 19 6965. (Note: In no case should the check for the fee be submitted to FDA with the application.)

It is helpful if the fee arrives at the bank at least a day or 2 before the application arrives at FDA's CVM. FDA records the official application receipt date as the later of the following: The date the application was received by FDA's CVM, or the date U.S. Bank notifies FDA that your check in the full amount of the payment due has been received. U.S. Bank is required to notify FDA within 1 working day, using the payment identification number described previously.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the ADUFA Web site at *http://www.fda.gov/oc/adufa* and, under the ''Forms'' heading, click on the link ''User Fee Cover Sheet.'' For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process. It may take a day or 2 to get the organization number and have the user account and password established.

Step Two—Create an Animal Drug User Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA, and you will be able to print a copy of your cover sheet showing your unique payment identification number.

Step Three—Send the payment for your application as described in section IX.A of this document.

Step Four—Please submit your application and a copy of the completed Animal Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product, Establishment, and Sponsor Fees

By December 30, 2004, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2005 using this fee schedule. Payment will be due and payable by January 31, 2005. FDA will issue invoices in October 2005 for any products, establishments, and sponsors subject to fees for FY 2005 that qualify for fees after the December 2004 billing.

Dated: July 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting and Nonvoting Members on a Public Advisory Committee; Pediatric Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Pediatric Advisory Committee in the Office of the Commissioner. Elsewhere in this issue of the **Federal Register**, FDA is publishing a document announcing the establishment of this committee.

FDA has 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.

DATES: Nominations received on or before August 17, 2004 will be given first consideration for membership on the Pediatric Advisory Committee. Nominations received after August 17, 2004 will be considered for nomination to the Pediatric Advisory Committee should nominees still be needed.

ADDRESSES: All nominations for membership, except for the consumer member, and the member from a patient or patient-family organization, should be sent to Jan Johannessen, Office of Science and Health Coordination (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, e-mail: *jjohannessen@fda.gov*.

All nominations for the consumer member should be sent to Michael F. Ortwerth, Office of the Commissioner (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville 20857, e-mail: *michael.ortwerth@fda.hhs.gov*.

All nominations for the patient or patient-family member should be sent to M. Lyvon Covington, Office of Special Health Issues (HF–12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, e-mail: *Magdalene.Covington@fda.hhs.gov*.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, the primary contact is Jan N. Johannessen, Office of Science and Health Coordination (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687 or FAX: 301–827–3042.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting and nonvoting members on the Pediatric Advisory Committee.

I. Function of the Pediatric Advisory Committee

The committee advises the Commissioner of Food and Drugs on pediatric therapeutics, pediatric research, and other matters involving pediatrics for which the Food and Drug Administration has regulatory responsibility. The Committee will also

advise and make recommendations to the Secretary of Health and Human Services pursuant to 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services.

II. Criteria for Voting Members

1. *Research and Clinical Scientists*: Persons nominated for membership shall have scientific expertise in one or more of the following disciplines: Pediatric research, pediatric subspecialties, pediatric therapeutics, statistics, and/or biomedical ethics.

2. *Consumer Member*: Persons nominated for membership on the committee as a consumer member shall have the following: (1) Ties to a consumer and/or community-based organization, (2) ability to analyze technical data, (3) understanding of research design, (4) ability to discuss benefits and risks, and (5) ability to evaluate the safety and efficacy of products under review. In their individual capacity, the consumer member will have the responsibility of representing the consumer perspective on issues and actions before the advisory committee; serving as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitating dialogue with the advisory committee on scientific issues that affect consumers.

3. *Patient or Patient-Family Organization Member*: Persons nominated for membership on the committee as a patient or patient-family organization member shall have the following: (1) Personal experience with a specific pediatric disease as a patient or patient care-giver; (2) experience in patient advocacy; (3) ability to communicate the interests and perspectives of patients; (4) ability to understand scientific data and technical information about research studies, and/or personal experience as a participant in clinical research; and (5) ability to disseminate information about the advisory committee experience to the patient community. As a member of the Pediatric Advisory Committee, the patient or patient-family organization member will serve in their individual capacity.

III. Criteria for Nonvoting Members

1. *Industry Representative*: Persons nominated for membership on the committee as a nonvoting industry representative shall have the following: (1) Professional experience in the medical product regulated industry, (2) ability to understand and analyze scientific data and issues related to pediatric product development, and (3) ability to communicate and disseminate information about the advisory committee experience to interested parties of industry.

2. *Pediatric Health Organization Representative*: Persons nominated for membership on the committee as a representative from a pediatric health organization shall have the following: (1) A direct affiliation with a recognized pediatric health organization and (2) the ability to understand and analyze scientific data and technical information.

IV. Nomination Procedures

1. *Research and Clinical Scientists*: Any interested person may nominate one or more qualified persons for membership on the advisory committee. Self-nominations are also accepted. Nominations shall include a current resume or curriculum vitae of each nominee, including 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 membership. FDA will ask the potential candidates to provide detailed information concerning matters related to financial holdings, employment, and research grants and/or contracts.

2. *Consumer Member*: Any interested person or organization may nominate one or more qualified persons for membership on the pediatric advisory committee to represent consumer interests. Self-nominations are also accepted.

All nominations must include a cover letter, a curriculum vitae or resume, including current business address and telephone number and a list of consumer or community-based organizations for which the candidate can demonstrate active participation. FDA will ask the potential candidates to provide detailed information concerning matters related to financial holdings, employment, and research grants and/or contracts.

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing public interest and consumer advocacy groups. The organizations have the responsibility of recommending candidates to the agency for selection.

3. *Patient or Patient-Family Organization Member*: Individuals, patient advocacy groups and organizations may submit nominations. Self-nominations will also be accepted.

Nominations shall include a current resume of the nominee (including current contact information), 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 membership. FDA will ask the potential candidates to provide detailed information concerning matters related to potential financial interests.

4. *Pediatric Health Organization Representative*: Individuals and pediatric organizations may submit nominations. Self-nominations will also be accepted.

All nominations must include a cover letter, a curriculum vitae or resume, information delineating the mission of the pediatric health organization and the relationship of the nominee to the pediatric health organization.

5. *Industry Representative*: Interested persons may nominate one or more qualified persons for membership. Self-nominations are also accepted.

Nominations shall include a current resume or curriculum vitae of each nominee, including current business address and telephone number, and shall state that the nominee is aware of the nomination, and is willing to serve as a nonvoting member. Nominees must have demonstrated first hand knowledge or work experience of the industry. Nominees must also demonstrate that they have the mechanisms to disseminate information from the advisory committee experience to their constituents.

Selection of the member representing industry interests will be made in accordance with 21 CFR 14.84(d). Any organization wishing to participate in the selection of a nonvoting member to represent industry on the Pediatric Advisory Committee should send a letter stating that interest to the FDA contact identified previously within 30 days of publication of this notice. Individuals who nominate themselves as industry representatives will not participate in the selection process.

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: July 27, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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