maltreated during the study reference period and to provide information about those children. Children identified by sentinels and those who alleged maltreatment is investigated by CPS during the same period are evaluated against standardized definitions and only children who meet the study standards are used to develop the study estimates. The study estimates are couched in terms of numbers of maltreated children, with data unduplicated so a given child is counted only once. Confidentiality of all participants is carefully protected.

A nationally representative sample of 120 counties will be selected and all local child protective service (CPS) agencies serving the selected counties will be identified. Plans will be developed to obtain data on cases investigated during the study reference period, September 4 to December 3, 2005. Sentinels in the selected counties will be identified through samples of agencies in 11 categories: county juvenile probation departments, sheriff (and/or state police) departments, public health departments, public housing departments, municipal police departments, hospitals, schools, day care centers, social service agencies, mental health agencies, and shelters for battered women or runaway/homeless youth. A total of approximately 1,600 sentinel agencies will be sampled. Plans will be developed to identify staff in these agencies who have direct contact with children to serve as sentinels during the study by submitting data on maltreated children they encounter during the study referenced period. in preparation for the study, letters will be sent to the directors of the selected agencies asking them to permit their agencies to participate in the NIS–4, and describing the general nature of the data collection effort. DHHS will issue subsequent notice of proposed data collection for this study after data collection plans are developed.

Respondents:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Letters to CPS Agencies	120	1	.20	24
Letter to Sentinel Agencies	1600	1	.20	320
Letter to Sentinels	12000	1	.20	2400
Estimated Total Annual Burden Hours:	.....	.....	.20	2744

Additional Information: ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by August 15, 2004. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Mary Bruce Webb at (202) 205–8628. In addition, a request may be made by sending an e-mail request to: *mbwebb@acf.hhs.gov.*

Comments and questions about the information collection described above should be directed to the following address by August 15, 2004: 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. E-mail address: *Katherine _T._Astrich@omb. eop. gov.*

Dated: July 26, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–17453 Filed 7–30–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2005

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2005 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Drug User Fee Act of 2003 (ADUFA), Public Law 108–130, authorizes FDA to collect user fees for certain animal drug applications, on certain animal drug products, on certain establishments where such products are made, and on certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2005.

For FY 2005, the animal drug user fee rates are: $119,300 for an animal drug application; $59,650 for a supplemental animal drug application for which safety or effectiveness data is required; $3,085 for an annual product fee; $42,600 for an annual establishment fee; and $32,150 for an annual sponsor fee. FDA will issue invoices for FY 2005 product, establishment and sponsor fees by December 30, 2004, and these invoices will be due and payable by January 31, 2005.

The application fee rates are effective for applications submitted on or after October 1, 2004, and will remain in effect through September 30, 2005. Applications will not be accepted to review until FDA has received full payment of application fees and any other animal drug user fees owed.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at: *http://www.fda.gov/oc/adufa* or contact Robert Miller, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–5436. For general questions, you may also e-mail the Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the act (21 U.S.C. 379j–12) establishes four different kinds of user fees: (1) Fees for certain types of animal drug applications and supplements, (2) annual fees for certain animal drug products, (3) annual fees for certain establishments where such products are made, and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions. (See 21 U.S.C.

379j–12(a).) When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j–12(d)).

For FY 2004 through FY 2008, the act establishes aggregate yearly base revenue amounts for each of these fee categories. Base revenue amounts established for years after FY 2004 are subject to adjustment for inflation and workload. Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the revenue for each fee category will approximate the level established in the statute, after the level has been adjusted for inflation and workload.

II. Revenue Amount for FY 2005 and Adjustments for Inflation and Workload

A. Statutory Fee Revenue Amounts

ADUFA specifies that the aggregate revenue amount for FY 2005 for each of the four animal drug user fee categories is $2,000,000, before any adjustments for inflation or workload are made. (See 21 U.S.C. 379j–12(b)(1)–(b)(4).)

B. Inflation Adjustment to Fee Revenue Amount

ADUFA provides that fee revenue amounts for each FY after 2004 shall be adjusted for inflation. (See 21 U.S.C. 379j–12(c)(1).) The adjustment must reflect the greater of: (1) The total percentage change that occurred in the consumer price index (CPI) for all urban consumers (all items; U.S. city average) during the 12-month period ending June 30 preceding the FY for which fees are being set or (2) the total percentage pay change for the previous FY for Federal employees stationed in Washington, DC. ADUFA provides for this annual adjustment to be cumulative and compounded annually after FY 2004. (See 21 U.S.C. 379j–12(c)(1).)

The inflation adjustment for FY 2005 is 4.42 percent. This is the greater of the CPI increase during the 12-month period ending June 30, 2004 (3.27 percent) or the increase in pay for FY 2004 for Federal employees stationed in Washington, DC (4.42 percent). No compounding is applied to this amount because there was no inflation increase applied in FY 2004.

The inflation-adjusted revenue amount for each category of fees for FY 2005 is the statutory fee amount ($2,000,000) increased by 4.42 percent, the inflation adjuster for FY 2005. The inflation-adjusted revenue amount is $2,088,400 for each category of fee, for a total inflation-adjusted fee revenue amount of $8,353,600 for all four categories of fees in FY 2005.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

For each FY beginning in FY 2005, ADUFA provides that fee revenue amounts, after they have been adjusted for inflation, shall be further adjusted to reflect changes in review workload (21 U.S.C. 379j–12(c)(2)).

FDA calculated the average number of each of the five types of applications and submissions specified in the workload adjustment provision (animal drug applications, supplemental animal drug applications for which data with respect to safety or efficacy are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions) received over the 3-year period that ended on September 30, 2002, (the base years). The agency also calculated the average number of each of these types of applications and submissions over the most recent 3-year period that ended May 31, 2004.

The results of these calculations are presented in the first two columns of table 1 of this document. Column 3 reflects the percent change in workload over the two 3-year periods. Column 4 shows the weighting factor for each type of application, reflecting how much of the total FDA animal drug review workload was accounted for by each type of application or submission in the table during the most recent 3 years. Column 5 of table 1 of this document is the weighted percent change in each category of workload and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right in table 1 of this document, the sum of the values in column 5 is added, reflecting a total change in workload of -4 percent for FY 2005. This is the workload adjuster for FY 2005.

TABLE 1.—WORKLOAD ADJUSTER CALCULATION

Application Type	Column 1 3-Year Average (Base Years)	Column 2 Latest 3-Year Average	Column 3 Percent Change	Column 4 Weighting Factor	Column 5 Weighted Percent Change
New Animal Drug Applications (NADAs)	23	20	-13%	3%	-0.4%
Supplemental NADAs with Safety or Efficacy Data	31	20	-35%	12%	-4.2%
Manufacturing Supplements	368	417	+13%	25%	+3.3%
Investigational Study Submissions	272	270	-0.7%	46%	-0.3%
Investigational Protocol Submissions	283	235	-17%	14%	-2.4%
FY 2005 Workload Adjuster					-4.0%

ADUFA specifies that the workload adjuster may not result in fees that are less than the inflation-adjusted revenue amount (21 U.S.C. 379j–12(c)(2)(B)). For this reason, the workload adjustment will not be applied in FY 2005, and the inflation-adjusted revenue amount for each category of fees for FY 2005 ($2,088,400) becomes the revenue target for fees in FY 2005, for a total inflation-adjusted fee revenue target in FY 2005 of $8,353,600 for fees from all four categories.

III. Application Fee Calculations for FY 2005

The terms ''animal drug applications'' and ''supplemental animal drug applications'' are defined in section 739 of the act (21 U.S.C. 379j–11(1).

A. Application Fee Revenues and Numbers of Fee-Paying Applications

The application fee must be paid for any animal drug application or supplemental animal drug application that is subject to fees under ADUFA and that is submitted on or after September 1, 2003. The application fees are to be set so that they will generate $2,088,400 in fee revenue for FY 2005. This is the amount set out in the statute after it has been adjusted for inflation and workload, as previously discussed in section II of this document. The fee for a supplemental animal drug application for which safety or effectiveness data are required is to be set at 50 percent of the animal drug application fee. (See 21 U.S.C. 379j–12(a)(1)(A)(ii).)

To set animal drug application fees and supplemental animal drug application fees to realize $2,088,400, FDA must first make some assumptions about the number of fee-paying applications and supplements the agency will receive in FY 2005.

The agency knows the number of applications that have been submitted in previous years. That number fluctuates significantly from year to year. Further, it is possible that the user fee program will affect the number of applications submitted, exacerbating the kinds of fluctuation in applications that is normally experienced. In addition, the agency does not have data on the number of waivers and reductions that will be granted, though this number will reduce the revenues that the agency will realize. For these reasons, in estimating the fee revenue to be generated by animal drug application fees in FY 2005, FDA is assuming that the number of applications that will pay fees in FY 2005 will be only 80 percent of the lower of the average number of submissions over the past 3 years or the number in the most recent year. This should account both for the effect of fluctuations in the numbers of applications submitted and for the effect of fee waivers or reductions that FDA estimates will be granted. Based on experience with other application user fee programs and the experience with ADUFA fees in FY 2004, FDA believes that this is a reasonable basis for estimating the number of fee-paying applications for the second year of this program.

Over the past 3 years, the average number of animal drug applications that would have been subject to the full fee was 14.3, and the number for the most recent year is estimated at 15. Over this same period, the average number of supplemental applications that would have been subject to half of the full fee was 15.3, and the number for the most recent year is estimated at 15.

Thus, for FY 2005, FDA estimates receipt of 11.5 fee paying original applications (80 percent of the 3-year average of 14.3) and 12 fee-paying supplemental animal drug applications (80 percent of the 15 estimated for the most recent years).

B. Fee Rates for FY 2005

FDA must set the fee rates for FY 2005 so that the estimated 11.5 applications that pay the full fee and the estimated 12 supplements that pay half of the full fee will generate a total of $2,088,400. To generate this amount, the fee for an animal drug application, rounded to the nearest $100, will have to be $119,300. The fee for a supplemental animal drug application, for which safety or effectiveness data, are required will have to be $59,650.

IV. Product Fee Calculations for FY 2005

A. Product Fee Revenues and Numbers of Fee-Paying Products

The animal drug product fee (also referred to as the product fee) must be paid annually by the person named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product submitted for listing under section 510 of the act (21 U.S.C. 360) and by the person who had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003. (See 21 U.S.C. 379j–12(a)(2).) The term ''animal drug product'' is defined in 21 U.S.C. 379j–11(3). The product fees are to be set so that they will generate $2,088,400 in fee revenue for FY 2005. This is the amount set out in the statute after it has been adjusted for inflation and workload, as previously discussed in section II of this document.

To set animal drug product fees to realize $2,088,400, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2005. FDA developed data on all animal drug products that have been submitted for listing under section 510 of the act and matched this to the list of all persons who had an animal drug application or supplement pending after September 1, 2003. As of July 1, 2004, FDA found a total of 752 products submitted for listing by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. While the number of applications pending after September 1, 2003, could increase between July 1, 2004, and the end of FY 2004, the number of products potentially subject to fees that have not already qualified for fees by April 1, 2004, is only 75. Based on experience over the past several months, FDA is assuming that none of these remaining products will qualify for fees because their sponsors will submit an application between July 1, 2004, and the end of September 2004. Based on this information, FDA believes that a total of 752 products will be subject to this fee in FY 2005.

The agency does not have data on the number of waivers and reductions that will be granted, though this number will reduce the revenues that the agency will realize. In estimating the fee revenue to be generated by animal drug product fees in FY 2005, FDA is assuming that 10 percent of the products invoiced, or 75, will not pay fees in FY 2005 due to fee waivers and reductions. Based on experience with other user fee programs and the first year of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in the first year of this program.

Accordingly, the agency estimates that a total of 677 products will be subject to product fees in FY 2005 (752 minus 75).

B. Product Fee Rates for FY 2005

FDA must set the fee rates for FY 2005 so that the estimated 677 products that pay fees will generate a total of $2,088,400. To generate this amount, the agency will require the fee for an animal drug product, rounded to the nearest $5, to be $3,085.

V. Establishment Fee Calculations for FY 2005

A. Establishment Fee Revenues and Numbers of Fee-Paying Establishments

The animal drug establishment fee (also referred to as the establishment fee) must be paid annually by the person who meets the following qualifications: (1) Owns or operates, directly or through an affiliate, an animal drug establishment; (2) is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product submitted for listing under section 510 of the act; (3) had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003; and (4) whose establishment engaged in the manufacture of the animal drug product during the FY. (See 21 U.S.C. 379j–12(a)(3).) An establishment subject to animal drug establishment fees is assessed only one such fee per FY. (See

21 U.S.C. 379j–12(a)(3).) The term ''animal drug establishment'' is defined in 21 U.S.C. 379j–11(4). The establishment fees are to be set so that they will generate $2,088,400 in fee revenue for FY 2005. This is the amount set out in the statute after it has been adjusted for inflation and workload, as previously discussed in section II of this document.

To set animal drug establishment fees to realize $2,088,400, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2005. FDA developed data on all animal drug establishments and matched this to the list of all persons who had an animal drug application or supplement pending after September 1, 2003. As of July 1, 2004, FDA found a total of 54 establishments owned or operated by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. While the number of applications pending after September 1, 2003, could increase between July 1, 2004, and the end of FY 2004, the number of establishments potentially subject to fees that have not already qualified for fees by July 1, 2004, is only 10. Based on experience over the last several months, FDA is assuming that none of these remaining establishments will qualify for fees because of additional applications submitted between July 1, 2004, and the end of FY 2004. Based on this information, FDA believes that 54 establishments will be subject to this fee in FY 2005.

The agency does not have data on the number of waivers and reductions that will be granted, though this number will reduce the revenues that the agency will realize. In estimating the fee revenue to be generated by animal drug establishment fees in FY 2005, FDA is assuming that 10 percent of the establishments invoiced, or five, will not pay fees in FY 2005 due to fee waivers and reductions. Based on experience with other user fee programs and the first year of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying establishments in the second year of this program.

Accordingly, the agency estimates that a total of 49 establishments will be subject to establishment fees in FY 2005 (54 minus 5).

B. Establishment Fee Rates for FY 2005

FDA must set the fee rates for FY 2005 so that the estimated 49 establishments that pay fees will generate a total of $2,088,400. To generate this amount, the agency will require the fee for an animal drug establishment, rounded to the nearest $50, to be $42,600.

VI. Sponsor Fee Calculations for FY 2005

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The animal drug sponsor fee (also referred to as the sponsor fee) must be paid annually by each person who meets the following qualifications: (1) Is named as the applicant in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 510 of the act or has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive and (2) had an animal drug application, supplemental animal drug application, or investigational animal drug submission pending at FDA after September 1, 2003. (See 21 U.S.C. 379j–11(6) and 379j–12(a)(4).) An animal drug sponsor is subject to only one such fee each FY. (See 21 U.S.C. 379j–12(a)(4).) The sponsor fees are to be set so that they will generate $2,088,400 in fee revenue for FY 2005. This is the amount set out in the statute after it has been adjusted for inflation and workload, as previously discussed in section II of this document.

To set animal drug sponsor fees to realize $2,088,400, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2005. Based on the number of firms that would have met this definition in each of the past 3 years, FDA estimates that a total of 138 sponsors will meet this definition in FY 2005.

Careful review indicates that about one third or 33 percent of all of these sponsors will qualify for minor use/minor species exemption. Based on the agency's experience with sponsor fees in FY 2004, FDA's current best estimate is that an additional 20 percent will qualify for other waivers or reductions, for a total of 53 percent of the sponsors invoiced, or 73, who will not pay fees in FY 2005 due to fee waivers and reductions. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in the second year of this program.

Accordingly, the agency estimates that a total of 65 sponsors will be subject to sponsor fees in FY 2005 (138 minus 73).

B. Sponsor Fee Rates for FY 2005

FDA must set the fee rates for FY 2005 so that the estimated 65 sponsors that pay fees will generate a total of $2,088,400. To generate this amount, the agency will require the fee for an animal drug sponsor, rounded to the nearest $50, to be $32,150.

VII. Adjustment for Excess Collections

Under the provisions of ADUFA, if the agency collects more fees than were provided for in appropriations in any year, FDA is required to reduce the adjusted aggregate revenue amount in a subsequent year by that excess amount (21 U.S.C. 379j–12(g)(4)). No adjustment under this provision is required for fees assessed in FY 2005 because FDA has not collected animal drug user fees in excess of amounts provided in appropriations in any previous year.

VIII. Fee Schedule for FY 2005

The fee rates for FY 2005 are summarized in table 2 of this document.

TABLE 2.—FY 2005 FEE RATES

Animal Drug User Fee Category	Fee Rate for FY 2005
Animal Drug Application Fee	
Animal Drug Application	$119,300
Supplemental Animal Drug Application for which Safety or Effectiveness Data are Required	$59,650
Animal Drug Product Fee	$3,085
Animal Drug Establishment Fee[1]	$42,600
Animal Drug Sponsor Fee[2]	$32,150

[1] An animal drug establishment is subject to only one such fee each fiscal year.
[2] An animal drug sponsor is subject to only one such fee each fiscal year.

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.

[FR Doc. 04–17441 Filed 7–30–04; 8:45 am]

BILLING CODE 4160–01–S

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