[FR Doc. 2015–18904 Filed 7–31–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Supplemental Nutrition Assistance Program (SNAP) State Agency Performance Reporting Tool.

OMB No.: New Collection.

Description: State agencies administering a Supplemental Nutrition Assistance Program (SNAP) are mandated to participate in a computer matching program with the federal Office of Child Support Enforcement (OCSE). The outcomes of the computerized comparisons with information maintained in the National Directory of New Hires (NDNH) provide the state SNAP agencies with information to help administer their programs and determine an individual's eligibility. State agencies must enter into a computer matching agreement and adhere to its terms and conditions, including providing OCSE with annual performance outcomes attributable to the use of NDNH information.

The Office of Management and Budget (OMB) requires OCSE to periodically report performance measurements demonstrating how NDNH information supports OCSE's strategic mission, goals, and objectives. OCSE will provide the annual SNAP performance outcomes to OMB.

The information collection activities for the SNAP performance reports are authorized by: (1) Subsection 453 (j)(10) of the Social Security Act (42 U.S.C. 653(j)(10)), which allows the Secretary of the U.S. Department of Health and Human Services to disclose information maintained in the NDNH to state agencies administering SNAP under the Nutrition Act of 2008, as amended by the Agriculture Act of 2014; (2) the Privacy Act of 1974, as amended by the Computer Matching and Privacy Protection Act of 1988 (5 U.S.C. 552a), which sets for the terms and conditions of a computer matching program; and (3) the Government Performance and Results Modernization Act of 2010 (Pub. L. 111–352), which requires agencies to report program performance outcomes to OMB and for the reports to be available to the public.

Respondents: State SNAP Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (SNAP agencies)	Number of responses per respondent	Average burden hours per response	Total burden hours
SNAP Agency Matching Program Performance Reporting Tool	52	1	1.625	84

Estimated Total Annual Burden Hours: 84.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–18952 Filed 7–31–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0007]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2016

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) 2016 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Drug User Fee Amendments of 2013 (ADUFA III), authorizes FDA to collect user fees for certain animal drug applications and supplements, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2016.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6888. For general questions, you may also email the Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the FD&C Act (21 U.S.C. 379j–12) establishes four different types 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 (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 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each fiscal year (21 U.S.C. 379j–12(b)(1)). Base revenue amounts established for years after FY 2014 are subject to adjustment for inflation and workload (21 U.S.C. 379j–12(c)). Fees for applications, establishments, products, and sponsors are to be established each year by FDA

so that the percentages of the total revenue that are derived from each type of user fee will be as follows: Revenue from application fees shall be 20 percent of total fee revenue; revenue from product fees shall be 27 percent of total fee revenue; revenue from establishment fees shall be 26 percent of total fee revenue; and revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379j–12(b)(2)).

For FY 2016, the animal drug user fee rates are: $351,100 for an animal drug application; $175,550 for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $7,790 for an annual product fee; $105,950 for an annual establishment fee; and $101,000 for an annual sponsor fee. FDA will issue invoices for FY 2016 product, establishment, and sponsor fees by December 31, 2015, and payment will be due by January 31, 2016. The application fee rates are effective for applications submitted on or after October 1, 2015, and will remain in effect through September 30, 2016. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under ADUFA.

II. Revenue Amount for FY 2016

A. Statutory Fee Revenue Amounts

ADUFA III (Title I of Pub. L. 113–14) specifies that the aggregate fee revenue amount for FY 2016 for all animal drug user fee categories is $21,600,000. (21 U.S.C. 379j–12(b)(1)(B).)

B. Inflation Adjustment to Fee Revenue Amount

The fee revenue amount established in ADUFA III for FY 2015 and subsequent fiscal years are subject to an inflation adjustment (21 U.S.C. 379j–12(c)(2)).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first three of the four preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs for the first three of the four preceding fiscal years (see 21 U.S.C. 379j–12(c)(2)(A) and (B)). The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes that actual cost and FTE data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first three of the four fiscal years preceding FY 2016. The 3-year average is 2.2328 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

Fiscal year	2012	2013	2014	3-Year average
Total PC&B	$1,824,703,000	$1,927,703,000	$2,054,937,000	
Total FTE	13,382	13,974	14,555	
PC&B per FTE	$136,355	$137,949	$141,184	
Percent Change from Previous Year	3.1843%	1.169%	2.3451%	2.2328%

The statute specifies that this 2.2328 percent should be multiplied by the proportion of PC&B costs to total FDA costs. Table 2 shows the amount of PC&B and the total amount obligated by FDA for the same 3 FYs.

TABLE 2—PC&B AS A PERCENT OF TOTAL COSTS AT FDA

Fiscal year	2012	2013	2014	3-Year average
Total PC&B	$1,824,703,000	$1,927,703,000	$2,054,937,000	
Total Costs	$3,550,496,000	$4,151,343,000	$4,298,476,000	
PC&B Percent	51.3929%	46.4356%	47.8062%	48.5449%

The payroll adjustment is 2.2328 percent multiplied by 48.5449 percent (or 1.0839 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs for FY 2016 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington–Baltimore, DC–MD–VA–WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total FDA costs (see 21 U.S.C. 379j–12(c)(2)(C)). Table 3 provides the summary data for the percent change in the specified CPI for the Baltimore-Washington area. The data from the Bureau of Labor Statistics is shown in table 3.

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN BALTIMORE-WASHINGTON AREA CPI LESS FOOD AND ENERGY

Year	2012	2013	2014	3-Year average
Annual CPI	144.413	146.953	149.581	
Annual Percent Change	2.4475%	1.7588%	1.7883%	1.9982%

To calculate the inflation adjustment for non-pay costs, we multiply the 1.9982 percent by the proportion of all costs other than PC&B to total FDA costs. Since 48.5449 percent was obligated for PC&B as shown in table 2, 51.4551 percent is the portion of costs other than PC&B (100 percent minus 48.5449 percent equals 51.4551

percent). The non-payroll adjustment is 1.9982 percent times 51.4551 percent, or 1.0282 percent.

Next, we add the payroll component (1.0839 percent) to the non-pay component (1.0282 percent), for a total inflation adjustment of 2.1121 percent for FY 2016.

ADUFA III provides for the inflation adjustment to be compounded each fiscal year after FY 2014 (see 21 U.S.C. 379j–12(c)(2)). The factor for FY 2016 (2.1121 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2015 (2.0201 percent), as published in the **Federal Register** of August 1, 2014 (79 FR 44787 to 44792), which equals 1.041749 (rounded) (1.021121 times 1.020201) for FY 2016. We then multiply the base revenue amount for FY 2016 ($21,600,000) by 1.041749, yielding an inflation adjusted amount of $22,501,778.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

A workload adjustment will be calculated to the inflation adjusted fee revenue amount established in ADUFA III for FY 2015 and subsequent fiscal years (21 U.S.C. 379j–12(c)(3)).

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 5-year period that ended on September 30, 2013 (the base years), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended June 30, 2015.

The results of these calculations are presented in the first two columns of table 4. Column 3 reflects the percent change in workload over the two 5-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 5 years. Column 5 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 of table 4 the sum of the values in column 5 is added, reflecting a total change in workload of 1.4066 percent for FY 2016. This is the workload adjuster for FY 2016.

TABLE 4—WORKLOAD ADJUSTER CALCULATION

[numbers may not add due to rounding]

Application type	Column 1 5-year average (base years)	Column 2 latest 5-year average	Column 3 percent change	Column 4 weighting factor	Column 5 weighted % change
New Animal Drug Applications (NADAs)	9.80	11.6	18.4%	0.0215	0.3945%
Supplemental NADAs with Safety or Efficacy Data	9.6	12.8	33.3%	0.0352	1.1749%
Manufacturing Supplements	361.0	345.8	−4.2%	0.1437	−0.6049%
Investigational Study Submissions	216.4	210.8	−2.6%	0.6254	−1.6184%
Investigational Protocol Submissions	133.6	149.4	11.8%	0.1742	2.0605%
FY 2016 Workload Adjuster					1.4066%

Over the last several years FDA has seen an increase in the number of animal drug sponsors requesting meetings to discuss new animal drug product development. These meeting requests come from both existing animal drug sponsors as well as sponsors new to the animal drug market. These factors have contributed to an increase in the number of protocol submissions and New Animal Drug Applications (NADAs) submitted for many novel drug classes and novel indications for both food-producing animals and companion animals. Additionally, FDA has seen an increase in the number of animal drug sponsors pursuing multiple changes to their existing NADAs (*e.g.,* new indications, new species, changes in dosage). For this reason we are seeing an increase in the number of supplemental NADAs with safety or effectiveness data. As a result, the statutory revenue amount after the inflation adjustment ($22,501,778) must now be increased by 1.4066 percent to reflect the changes in review workload (workload adjustment), for a total fee revenue target of $22,818,000 (rounded to the nearest thousand dollars).

D. FY 2016 Fee Revenue Amounts

ADUFA III specifies that the revenue amount of $22,818,000 for FY 2016 is to be divided as follows: 20 percent, or a total of $4,564,000 (rounded to the nearest thousand dollars), is to come from application fees; 27 percent, or a total of $6,161,000 (rounded to the nearest thousand dollars), is to come from product fees; 26 percent, or a total of $5,932,000 (rounded to the nearest thousand dollars), is to come from establishment fees; and 27 percent, or a total of $6,161,000 (rounded to the nearest thousand dollars), is to come from sponsor fees (21 U.S.C. 379j–12(b)).

III. Application Fee Calculations for FY 2016

The terms ''animal drug application'' and ''supplemental animal drug application'' are defined in section 739 of the FD&C Act (21 U.S.C. 379j–11(1) and (2)).

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 $4,564,000 in fee revenue for FY 2016, after workload adjustment ($4,500,000 times 1.014066, rounded to the nearest thousand dollars). The fee for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to criteria set forth in section 512(d)(4) of the FD&C Act is to be set at 50 percent of the animal drug application fee (21 U.S.C. 379j–12(a)(1)(A)(ii)).

To set animal drug application fees and supplemental animal drug application fees to realize $4,564,000 FDA must first make some assumptions about the number of fee-paying applications and supplements the Agency will receive in FY 2016.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates from year to year. In estimating the fee revenue to be generated by animal drug application fees in FY 2016, FDA is assuming that the number of applications that will pay fees in FY 2016 will equal the average number of submissions over the 5 most recent completed years of ADUFA (FY 2010 to FY 2014). FDA believes that this is a reasonable approach after 11 completed years of experience with this program.

Over the 5 most recent completed years, the average number of animal drug applications that would have been subject to the full fee was 6.8. Over this same period, the average number of supplemental applications and applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act that would have been subject to half of the full fee was 12.4.

B. Application Fee Rates for FY 2016

FDA must set the fee rates for FY 2016 so that the estimated 6.8 applications that pay the full fee and the estimated 12.4 supplemental applications and applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act that pay half of the full fee will generate a total of $4,564,000. To generate this amount, the fee for an animal drug application, rounded to the nearest $100, will have to be $351,100, and the fee for a supplemental animal drug application for which safety or effectiveness data are required and for applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act will have to be $175,550.

IV. Product Fee Calculations for FY 2016

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 a new animal drug application or supplemental new animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360), and 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'' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved (21 U.S.C. 379j–11(3)). The product fees are to be set so that they will generate $6,161,000 in fee revenue for FY 2016, after workload adjustment ($6,076,000 times 1.014066, rounded to the nearest thousand dollars).

To set animal drug product fees to realize $6,161,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2016. FDA developed data on all animal drug products that have been submitted for listing under section 510 of the FD&C 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 June 2015, FDA estimates that there are a total of 815 products submitted for listing by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA estimates that a total of 815 products will be subject to this fee in FY 2016.

In estimating the fee revenue to be generated by animal drug product fees in FY 2016, FDA is assuming that 3 percent of the products invoiced, or 24, will not pay fees in FY 2016 due to fee waivers and reductions. FDA has reduced the estimate of the percentage of products that will not pay fees from 4 percent to 3 percent this year, based on historical data over the past 5 completed years of the ADUFA program. Based on experience over the first 11 completed years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2016.

Accordingly, the Agency estimates that a total of 791 (815 minus 24) products will be subject to product fees in FY 2016.

B. Product Fee Rates for FY 2016

FDA must set the fee rates for FY 2016 so that the estimated 791 products that pay fees will generate a total of $6,161,000. To generate this amount will require the fee for an animal drug product, rounded to the nearest $5, to be $7,790.

V. Establishment Fee Calculations for FY 2016

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: (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 FD&C 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 fiscal year. (See 21 U.S.C. 379j–12(a)(3).) An establishment subject to animal drug establishment fees is assessed only one such fee per fiscal year. (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 $5,932,000 in fee revenue for FY 2016, after workload adjustment ($5,850,000 times 1.014066, rounded to the nearest thousand dollars).

To set animal drug establishment fees to realize $5,932,000, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2016. 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 June 2015, FDA estimates that there are a total of 64 establishments owned or operated by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA believes that 64 establishments will be subject to this fee in FY 2016.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2016, FDA is assuming that 12 percent of the establishments invoiced, or 8, will not pay fees in FY 2016 due to fee waivers and reductions. FDA has kept this estimate at 12 percent this year, based on historical data over the past 5 completed years. Based on experience over the past 11 completed years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying establishments in FY 2016.

Accordingly, the Agency estimates that a total of 56 establishments (64 minus 8) will be subject to establishment fees in FY 2016.

B. Establishment Fee Rates for FY 2016

FDA must set the fee rates for FY 2016 so that the estimated 56 establishments that pay fees will generate a total of $5,932,000. To generate this amount will require the fee for an animal drug

establishment, rounded to the nearest $50, to be $105,950.

VI. Sponsor Fee Calculations for FY 2016

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: (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 FD&C 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 fiscal year. (See 21 U.S.C. 379j–12(a)(4).) The sponsor fees are to be set so that they will generate $6,161,000 in fee revenue for FY 2016, after workload adjustment ($6,076,000 times 1.014066, rounded to the nearest thousand dollars).

To set animal drug sponsor fees to realize $6,161,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2016. Based on the number of firms that would have met this definition in each of the past 11 completed years of ADUFA, FDA estimates that a total of 173 sponsors will meet this definition in FY 2016.

Careful review indicates that 33 percent of these sponsors will qualify for minor use/minor species waiver or reduction (21 U.S.C. 379j–12(d)(1)(D)). Based on the Agency's experience to date with sponsor fees, FDA's current best estimate is that an additional 32 percent will qualify for other waivers or reductions, for a total of 65 percent of the sponsors invoiced, or 112, who will not pay fees in FY 2016 due to fee waivers and reductions. FDA has kept this estimate at 65 percent this year, based on historical data over the past 5 completed years of ADUFA. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in FY 2016.

Accordingly, the Agency estimates that a total of 61 sponsors (173 minus 112) will be subject to and pay sponsor fees in FY 2016.

B. Sponsor Fee Rates for FY 2016

FDA must set the fee rates for FY 2016 so that the estimated 61 sponsors that pay fees will generate a total of $6,161,000. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest $50, to be $101,000.

VII. Fee Schedule for FY 2016

The fee rates for FY 2016 are summarized in table 5.

TABLE 5—FY 2016 FEE RATES

Animal drug user fee category	Fee rate for FY 2016
Animal Drug Application Fees:	
Animal Drug Application	$351,100
Supplemental Animal Drug Application for which Safety or Effectiveness Data are Required or Animal Drug Application Subject to the Criteria Set Forth in Section 512(d)(4) of the FD&C Act	175,550
Animal Drug Product Fee	7,790
Animal Drug Establishment Fee [1]	105,950
Animal Drug Sponsor Fee [2]	101,000

[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.

VIII. Procedures for Paying the FY 2016 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 on or after October 1, 2015. 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, by wire transfer, or electronically using Pay.gov. (The Pay.gov payment option is available to you after you submit a cover sheet. Click the ''Pay Now'' button.) On your check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number (PIN), beginning with the letters AD, from the upper right-hand corner of your completed Animal Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 979033) 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 979033, St. Louis, MO 63197–9000.

If payment is made by wire transfer, send payment to: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, FDA Deposit Account Number: 75060099, U.S. Department of Treasury routing/transit number: 021030004, SWIFT Number: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., Silver Spring, MD 20993–0002. You are responsible for any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution about the fee and add it to your payment to ensure that your fee is fully paid.

If you prefer to send a check by a courier, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 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 314–418–4013. This telephone number is only for questions about courier delivery.)

The tax identification number of FDA is 53–0196965. (Note: In no case should the payment 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 two 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 payment in the full amount has been received, or when the U.S. Treasury notifies FDA of receipt of an electronic or wire transfer payment. U.S. Bank and the U.S. Treasury are required to notify FDA

within 1 working day, using the PIN described previously.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log on to the ADUFA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* and, under Tools and Resources, click ''The Animal Drug User Fee Cover Sheet'' and then click ''Create ADUFA 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.

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 PIN.

Step Three—Send the payment for your application as described in section VIII.A.

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 31, 2015, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2016 using this fee schedule. Payment will be due by January 31, 2016. FDA will issue invoices in November 2016 for any products, establishments, and sponsors subject to fees for FY 2016 that qualify for fees after the December 2015 billing.

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18913 Filed 7–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Sixth Annual Coalition Against Major Diseases/Food and Drug Administration Scientific Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the sixth annual scientific workshop co-sponsored by the Agency and the Coalition Against Major Diseases (CAMD) Consortium of the Critical Path Institute (C-Path). The purpose of this public workshop is to initiate constructive discussion among scientists from FDA, the CAMD Consortium, and other interested parties regarding ongoing efforts to develop tools and methods to facilitate drug development for Alzheimer's disease and Parkinson's disease.

DATES: The public scientific workshop will be held on October 15, 2015, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the public scientific workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

FOR FURTHER INFORMATION CONTACT: Jacqueline Brooks-Leighton, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 21, Rm. 4521, Silver Spring, MD 20993, 240–402–5292, FAX: 301–796–9907, *jacqueline.brooks-leighton@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA and C-Path seek to leverage their combined strengths to create new tools and methods to increase the efficiency of the drug development process and bring new treatments for Alzheimer's disease and Parkinson's disease. This annual public workshop brings together representatives from the pharmaceutical industry, the academic research community, patient advocacy groups, and governmental institutions; including, the National Institute of Aging, the National Institute of Neurological Disorders and Stroke, and the European Medicines Agency.

The objectives of the workshop include:

1. Understanding the accomplishments of CAMD scientific projects
2. Discussing how these tools are currently or will be applied in drug development
3. Obtaining commitment for sharing information/data to begin quantifying benefits of these tools
4. Facilitating robust and open discussion among all parties of drug development in Alzheimer's and Parkinson's diseases

II. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Individuals who wish to participate in the scientific workshop (in person or via the Internet) must register on or before October 1, 2015, by visiting *https://www.SignUp4.net/public/ap.aspx?EID=SIXT10E*.

Early registration is recommended; registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Onsite registration on the day of the scientific workshop will be based on space availability. The registration deadline is October 14, 2015. An agenda will be provided approximately 2 weeks before the scientific workshop at the FDA Meeting Information page, which is available online at: *http://www.fda.gov/Drugs/NewsEvents/ucm410863.htm*.

If you need special accommodations because of a disability, please contact Jacqueline Brooks-Leighton (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the scientific workshop.

A live webcast of this scientific workshop will be viewable at Adobe Connect Link: *https://collaboration.fda.gov/camd101515/* on the day of the scientific workshop. A video record of the scientific workshop will be available at the same Web address for 1 year.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript