terms and conditions of the award. The Financial Assistance Award will be signed by a Grants Officer and transmitted via postal mail.

ACF will notify unsuccessful applicants after the award is issued to the successful applicant.

2. Administrative and National Policy Requirements

Grantees are subject to 45 CFR Part 74 (non-governmental) or 45 CFR Part 92 (governmental)

3. Reporting

All grantees are required to submit semi-annual program reports with a final report due 90 days after the project end date. Grantees are also required to submit semi-annual financial status reports using the SF–269 with a final report due 90 days aftyer the project end date. A suggested format for the program report will be sent to the grantee after the award is made.

Special Reporting Requirements: None.

VII. Agency Contacts

Program Office Contact: Dr. Margaret Washnitzer, Department of Health and Human Services (HHS), Administration for Children and Families, Office of Community Services Operations Center, 1815 Fort Meyer Drive, Suite 300, Arlington, Virginia 22209, E-Mail: *OCS@lcgnet.com*, Phone: 1–800–281–9519.

Grants Management Office Contact: Barbara Ziegler Johnson, Team Leader, Office of Grants Management, Division of Discretionary Grants, Department of Health and Human Services (HHS), Administration for Children and Families, Office of Community Services Operations Center, 1815 Fort Meyer Drive, Suite 300, Arlington, Virginia 22209, E-Mail: *OCS@lcgnet.com*, Phone: 1–800–281–9519.

VIII. Other Information

Additional information about this program and its purpose can be located on the following Web site: *http://www.acf.hhs.gov/programs/ocs.*

Dated: April 16, 2004.

Clarence H. Carter,

Director, Office of Community Services.

[FR Doc. 04–9546 Filed 4–26–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Animal Drug User Fee Rates and Payment Procedures for Product, Establishment, and Sponsor Fees for Fiscal Year 2004

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for product, establishment, and sponsor fees for fiscal year (FY) 2004. 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 product, establishment, and sponsor fee rates for FY 2004. A separate notice was published establishing fee rates and payment procedures for animal drug application fees for FY 2004. For FY 2004, the product fee rate is $1,750, the establishment fee rate is $23,950, and the sponsor fee rate is $15,450. FDA will issue invoices for FY 2004 product, establishment, and sponsor fees on or about May 1, 2004. Those invoices will be due and payable within 30 days of the date of the invoice.

FOR FURTHER INFORMATION CONTACT: Visit the FDA Web site at *http://www.fda.gov/oc/adufa* or contact Robert Miller, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7529 Standish Pl., Rockville, MD 20855, 301–827–5436. For general questions, you may also e-mail the Center for Veterinary Medicine 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 FYs 2004 through 2008, the act establishes aggregate yearly revenue amounts for each of these fee categories. 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.

This notice establishes rates for FY 2004 for product, establishment, and sponsor fees. These fees are effective in FY 2004. FDA will publish a separate notice on or about August 1, 2004, providing rates for FY 2005, which begins October 1, 2004. In the **Federal Register** of February 18, 2004, FDA published a separate notice establishing fee rates and payment procedures for animal drug application fees for FY 2004 (69 FR 7646).

II. Product Fee Calculations for FY 2004

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 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 established so that they will generate the fee revenue amounts specified in the statute: $1,250,000 for FY 2004; $2,000,000 in FY 2005; and $2,500,000 in FYs 2006, 2007, and 2008 (see 21 U.S.C. 379j-12(b)(2)), adjusted for inflation and workload. Since FY 2004 is the first year of the program, there are no adjustments for workload or inflation. However, these adjustments will be made to the statutory revenue amounts each year after FY 2004 (see 21 U.S.C. 379j-12(c)(1) and (c)(2)).

To set animal drug product fees to realize $1,250,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2004. 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 April 1, 2004, FDA found a total of 774 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, will increase between April 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 76. FDA is assuming that 25 percent of these remaining products, or 19, will qualify for fees because their sponsors will submit an application between April 1, 2004, and the end of September 2004. Based on this, FDA believes that 793 products will be subject to this fee in FY 2004.

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 2004, FDA is assuming that 10 percent of the products invoiced, or 79, will not pay fees in FY 2004 due to fee waivers and reductions. Based on experience with other user fee programs, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in the first year of this program. FDA may further adjust this estimate in setting fees for future years based on actual experience with product fee waivers and reductions.

Accordingly, the agency estimates that a total of 714 products will be subject to product fees in FY 2004 (793 minus 79).

B. Product Fee Rates for FY 2004

FDA must set the fee rates for FY 2004 so that the estimated 714 products that pay fees will generate a total of $1,250,000. To generate this amount will require the fee for an animal drug product, rounded to the nearest $5, to be $1,750.

III. Establishment Fee Calculations for FY 2004

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 criteria: (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 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 the fee revenue amounts specified in the statute: $1,250,000 for FY 2004; $2,000,000 in FY 2005; and $2,500,000 in FYs 2006, 2007, and 2008 (see 21 U.S.C. 379j-12(b)(3)), adjusted for inflation and workload. Since FY 2004 is the first year of the program there are no adjustments for workload or inflation. However, these adjustments will be made to the statutory revenue amounts each year after FY 2004 (see 21 U.S.C. 379j-12(c)(1) and (c)(2)).

To set animal drug establishment fees to realize $1,250,000, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2004. 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 April 1, 2004, FDA found a total of 55 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, will increase between April 1, 2004, and the end of FY 2004, the number of establishments potentially subject to fees that have not already qualified for fees by April 1, 2004, is only 12. FDA is assuming that 25 percent of these remaining establishments, or 3, will qualify for fees because of additional applications submitted between April 1, 2004, and the end of September 2004. Based on this, FDA believes that 58 establishments will be subject to this fee in FY 2004.

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 2004, FDA is assuming that 10 percent of the establishments invoiced, or 6, will not pay fees in FY 2004 due to fee waivers and reductions. Based on experience with other user fee programs, FDA believes that this is a reasonable basis for estimating the number of fee-paying establishments in the first year of this program. FDA may further adjust this estimate in setting fees for future years based on actual experience with establishment fee waivers and reductions.

Accordingly, the agency estimates that a total of 52 establishments will be subject to establishment fees in FY 2004 (58 minus 6).

B. Establishment Fee Rates for FY 2004

FDA must set the fee rates for FY 2004 so that the estimated 52 establishments that pay fees will generate a total of $1,250,000. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest $50, to be $23,950.

IV. Sponsor Fee Calculations for FY 2004

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 criteria: (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 fiscal year (see 21 U.S.C. 379j-12(a)(4)). The sponsor fees are to be set so that they will generate the fee revenue amounts specified in the statute: $1,250,000 for FY 2004; $2,000,000 in FY 2005; and $2,500,000 in FYs 2006, 2007, and 2008 (see 21 U.S.C. 379j-12(b)(4)), adjusted for inflation and workload. Since FY 2004 is the first year of the program there are no adjustments for workload or inflation. However, these adjustments will be made to the statutory revenue amounts each year after FY 2004 (see 21 U.S.C. 379j-12(c)(1) and (c)(2)).

To set animal drug sponsor fees to realize $1,250,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2004. 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 142 sponsors will meet this definition in FY 2004.

Careful review indicates that about one third, or 33 percent, of all of these sponsors will qualify for a minor use/minor species exemption. While FDA's other user fee programs do not contain a fee similar to a sponsor fee, FDA's current best estimate is that an additional 10 percent will qualify for other waivers or reductions, for a total of 43 percent of the sponsors invoiced, or 61, who will not pay fees in FY 2004 due to fee waivers and reductions. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in the first year of this program. FDA may further adjust this estimate in setting fees for future years based on actual experience with sponsor fee waivers and reductions.

Accordingly, the agency estimates that a total of 81 sponsors will be subject to sponsor fees in FY 2004 (142 minus 61).

B. Sponsor Fee Rates for FY 2004

FDA must set the fee rates for FY 2004 so that the estimated 81 sponsors that pay fees will generate a total of $1,250,000. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest $50, to be $15,450.

V. Adjustment for Excess Collections

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 adjustments under this provision are required for fees assessed in FY 2004.

VI. Procedures for Paying Product, Establishment, and Sponsor Fees

FDA will issue invoices for product, establishment, and sponsor fees for FY 2004 on or about May 1, 2004. Invoices will be payable and due within 30 days of the date of the invoice. Complete payment instructions will be included with each invoice.

FDA will issue additional invoices after October 1, 2004, for any products, establishments, and sponsors that become subject to these fees after April 1, 2004, and these invoices will likewise include complete payment instructions.

Payment procedures and fee rates for FY 2004 application fees were provided separately on February 18, 2004 (69 FR 7646).

In early August 2004, FDA will establish animal drug user fee rates for FY 2005 for application, product, establishment, and sponsor fees. FDA intends to issue invoices for FY 2005 product, establishment, and sponsor fees in December 2004, with payments due on or before January 31, 2005 (see 21 U.S.C. 379j-12(a)(2), (a)(3), and (a)(4)). Application fees are due upon submission of the application (see 21 U.S.C. 379j-12(a)(1)(B)).

VII. May Some Animal Drug User Fees Be Waived or Reduced? How Do I Apply for Such Waivers or Reductions?

FDA will grant a waiver or reduction of one or more fees where the agency finds that:

- The assessment of the fee would present a significant barrier to innovation because of limited resources or other circumstances (see 21 U.S.C. 379j-12(d)(1)(A)).
- Fees exceed the costs (both anticipated present and future costs) of reviewing animal drug applications (see 21 U.S.C. 379j-12(d)(1)(B)).
- The animal drug is intended solely for use in either a type C free-choice medicated feed or a type B medicated feed intended for use in the manufacture of type C free-choice medicated feeds (see 21 U.S.C. 379j-12(d)(1)(C)).
- The animal drug application or supplement is intended solely to provide for a minor use or minor species indication (see 21 U.S.C. 379j-12(d)(1)(D)).
- The application is the first ever submitted by a qualifying small business (see 21 U.S.C. 379j-12(d)(1)(E) and (d)(3)).

Please note that all of the previously mentioned situations require the applicant to submit a written request to the agency for a waiver or reduction not later than 180 days after the fee is due (see 21 U.S.C. 379j-12(i)). Please refer to the ADUFA Web site at *http://www.fda.gov/oc/adufa* and click on the ''Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions'' link to find specific information on how to apply for any of the previously mentioned waivers or reductions. That document also discusses payment procedures for situations where FDA approves a waiver or reduction before the fee is due and situations where the fee waiver or reduction request is still pending when the fee is due.

VIII. Fee Schedule for FY 2004

The fee rates for FY 2004 are summarized in table 1 of this document.

TABLE 1.—FEE RATES FOR FY 2004

Animal Drug User Fee Category	Fee Rate for FY 2004
Animal drug application fee	
Animal drug application	$61,000
Supplemental animal drug application for which safety or effectiveness data are required	$30,500
Animal drug product fee	$1,750
Animal drug establishment fee[1]	$23,950
Animal drug sponsor fee[2]	$15,450

[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.

Dated: April 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–9565 Filed 4–22–04; 4:22 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Delegation of Authority

Notice is hereby given that I have delegated to Commissioner Food and Drugs, the authority vested in the Secretary of the Department of Health and Human Services, under Section 353 of the Public Health Service Act (42 U.S.C. 263a), as amended, to implement CLIA's complexity categorization provisions as they apply to commercially available tests to the Commissioner of Food and Drugs (FDA). This authority includes, but is not limited to the following:

(a) Interpreting the CLIA provisions related to complexity categorization;

(b) Holding public workshops and meetings on CLIA complexity categorization; and,

(c) Developing and issuing implementing rules and guidance for CLIA complexity categorization.

The Administrator of the Centers for Medicare & Medicaid Services (CMS) will provide funding to implement CLIA's complexity categorization provisions as set forth in the Agency Agreement between FDA and CMS (CMS IA–04–01, FDA 224–04–6052), as amended.

Except as provided above, the existing delegation of authority to the Administrator of CMS concerning CLIA is unaffected.

This delegation supersedes the delegation of authority memorandum dated October 31, 2003, from the Secretary to the Commissioner of Food and Drugs, titled ''Delegation of Authority for the Clinical Laboratory Improvements Amendments of 1988 (CLIA), Section 353 of the Public Health Service Act, as amended.''

This delegation shall be exercised under the Department's existing delegation and policy on regulations. In addition, I ratified and reaffirmed any actions taken by you or your subordinates which involved the exercise of this authorities prior to the effective date of this delegation.

This delegation was effective upon date of signature.

Tommy G. Thompson,

Secretary, Department of Health and Human Services

[FR Doc. 04–9527 Filed 4–26–04; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

HRSA–03–019 Fiscal Year 2004 Geriatric Academic Career Awards (GACA)—CFDA 93.250

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Extension of deadline date.

SUMMARY: The Health Resources and Services Administration previously announced in the HRSA Preview, Volume 7, Summer 2003, that the deadline for receipt of applications for Geriatric Academic Career Awards in Fiscal Year 2004 is February 2, 2004. This deadline has been extended to July 1, 2004. Applications must be sent to the Geriatric Academic Career Awards Program Office, Room 8–103, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857 and postmarked July 1, 2004, or earlier to be considered for Funding in Fiscal Year 2004.

Dated: April 13, 2004.

Elizabeth M. Duke,

Administrator.

[FR Doc. 04–9472 Filed 4–26–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

List of Recipients of Indian Health Scholarships Under the Indian Health Scholarship Program

The regulations governing Indian Health Care Improvement Act Programs (Pub. L. 94–437) provide at 42 CFR 36.334 that the Indian Health Service shall publish annually in the **Federal Register** a list of recipients of Indian Health Scholarships, including the name of each recipient, school and tribal affiliation, if applicable. These scholarships were awarded under the authority of Sections 103 and 104 of the Indian Health Care Improvement Act, 25 U.S.C. 1613–1613a, as amended by the Indian Health Care Amendments of 1988, Public Law 100–713.

The following is a list of Indian Health Scholarship Recipients funded under sections 103 and 104 for Fiscal Year 2003:

Abeita, Steven John, University of New Mexico-Albuquerque, Pueblo of Isleta, New Mexico

Acothley, Regina, University of New Mexico-Albuquerque, Navajo Nation, Arizona, New Mexico, & Utah

Adakai, Tamelyn Blythe, Arizona State University, Navajo Nation, Arizona, New Mexico, & Utah

Adams Moses, Cynthia Regina, Langston University, Muscogee (Creek) Nation, Oklahoma

Albers, Travis Alan, University of Maryland, Turtle Mountain Band of Chippewa Indians of North Dakota

Alcorn, Winter Dawn, Rogers State College, Cherokee Nation, Oklahoma

Alden-Littlelight, Roanne Gail, Pacific University College, Crow Tribe of Montana

Allery, Lonnie William, University of North Dakota, Turtle Mountain Band of Chippewa Indians of North Dakota

Allery, Rhea Neachet, University of North Dakota, Turtle Mountain Band of Chippewa Indians of North Dakota

Allick, Shannon Lynn, Minot State University, Turtle Mountain Band of Chippewa Indians of North Dakota

Allison, Amanda, University of New Mexico-Albuquerque, Navajo Nation, Arizona, New Mexico, & Utah

Allison, Carol Ann, Montana State University-Northern, Turtle Mountain Band of Chippewa Indians of North Dakota

Allison, Rochelle Jade, University of New Mexico-Albuquerque, Navajo Nation of Arizona, New Mexico, & Utah

Allison, Roselinda, University of Phoenix, Navajo Nation, Arizona, New Mexico, & Utah

Allison-Quick, Eunice Mary, University of Oregon, Blackfeet Tribe of the Blackfeet Indian Reservation of Montana

Anderson, Ella Mae, Gateway Community College, Navajo Nation, Arizona, New Mexico & Utah

Andis, Letetia Lynn, Bacone College, Cherokee Nation, Oklahoma

Antonio, Amber L., University of New Mexico-Albuquerque, Pueblo of Acoma, New Mexico

Armijo, Heather Denise, New Mexico State University, Pueblo of Jemez, New Mexico

Arnold, Carly Ellen, Northern Arizona University, Navajo Nation, Arizona, New Mexico & Utah

Arnold, Delphine, University of New Mexico, Navajo Nation, Arizona, New Mexico & Utah

Arredondo, LaDonna Leann, Southwestern Oklahoma State University, Choctaw Nation of Oklahoma

Arviso, Tennille Raye, Northern Arizona University, Navajo Nation, Arizona, New Mexico & Utah

Ashley, Natalie Lynn, Arizona State University, Navajo Nation, Arizona, New Mexico & Utah

Atene, Kathleen Cheryl, Northern Arizona University, Navajo Nation, Arizona, New Mexico & Utah