abbreviated application for a generic new animal drug, that has not been withdrawn by the applicant and for which approval has not been withdrawn by the Secretary of Health and Human Services, or has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive; and (2) had an abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(k)(7) and 379j–21(a)(3)). A generic new animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j–21(a)(3)(B)). Applicants with more than six approved abbreviated applications will pay 100 percent of the sponsor fee, applicants with two to six approved abbreviated applications will pay 75 percent of the sponsor fee, and applicants with one or fewer approved abbreviated applications will pay 50 percent of the sponsor fee (see 21 U.S.C. 379j–21(a)(3)(B)). The sponsor fees are to be set so that they will generate $1,691,000 in fee revenue for FY 2009. This is the amount set out in the statute and no adjustments are required for FY 2009.

To set generic new animal drug sponsor fees to realize $1,691,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2009. Based on the number of firms that would have met this definition in each of the past 5 years, FDA estimates that in FY 2009 11 sponsors will pay 100 percent (full) fees, 11 sponsors will pay 75 percent fees, and 28 sponsors will pay 50 percent fees. That totals the equivalent of 33.25 full sponsor fees (11 times 100 percent or 11, plus 11 times 75 percent or 8.25, plus 28 times 50 percent or 14).

FDA estimates that about 10 percent of all of these sponsors, or 3.25, may qualify for a minor use/minor species waiver or reduction.

Accordingly, the agency estimates that the equivalent of 30 full sponsor fees (33.25 minus 3.25) are likely to be paid in FY 2009.

B. Sponsor Fee Rates for FY 2009

FDA must set the fee rates for FY 2009 so that the estimated equivalent of 30 full sponsor fees will generate a total of $1,691,000. To generate this amount will require the 100-percent fee for a generic new animal drug sponsor, rounded to the nearest fifty dollars, to be $56,350. Accordingly, the fee for those paying 75 percent of the full sponsor fee, rounded to the nearest five dollars, will be $42,265, and the fee for those paying 50 percent of the full sponsor fee will be $28,175.

VI. Fee Schedule for FY 2009

The fee rates for FY 2009 are summarized in table 1 of this document.

TABLE 1—FY 2009 FEE RATES

Generic New Animal Drug User Fee Category	Fee Rate for FY 2009
Abbreviated Application for Generic New Animal Drug Fee	$41,400
Generic New Animal Drug Product Fee	$3,005
100 Percent Generic New Animal Drug Sponsor Fee*	$56,350
75 Percent Generic New Animal Drug Sponsor Fee*	$42,265
50 Percent Generic New Animal Drug Sponsor Fee*	$28,175

* An animal drug sponsor is subject to only one such fee each fiscal year

VII. Procedures for Paying FY 2009 Generic New Animal Drug User Fees

FDA may not collect user fees for abbreviated applications, for generic new animal drug products, and for generic new animal drug sponsors until an appropriation of fees is provided by Congress (see 21 U.S.C. 379j–21(g)(1)). For this reason FDA may not begin to collect these fees at this time.

Fees for generic new animal drug products and sponsors will be invoiced at the rates published in this notice on the later of December 31, 2008, or 30 days after appropriation of generic new animal drug user fees by Congress.

Invoices for fees for abbreviated applications for generic new animal drugs submitted on or after July 1, 2008, will be issued 30 days after appropriation of generic new animal drug user fees by Congress. After that time, FDA will not consider an abbreviated application for a generic abbreviated new animal drug complete unless the application fee for that application has been paid in advance. Within 30 days after appropriation of generic new animal drug user fees by Congress, FDA will publish another notice in the **Federal Register** providing payment instructions so that these fees may be paid in advance of the submission of such abbreviated applications from that time forward.

Dated: September 3, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21453 Filed 9–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Application of Platform Technologies for the Development of Therapeutics for Biodefense-A.

Date: October 16–17, 2008.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Alec Ritchie, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID/DHHS, 6700 B Rockledge Drive, MSC 7616,

Bethesda, MD 20892–7616, 301–435–1614, *aritchie@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases, Special Emphasis Panel, Application of Platform Technologies for the Development of Therapeutics for Biodefense-B.

Date: October 20–21, 2008.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: Washingtonian Center Courtyard, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Alec Ritchie, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID/DHHS, 6700 B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–435–1614, *aritchie@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases, Special Emphasis Panel, Application of Platform Technologies for the Development of Therapeutics for Biodefense-C.

Date: October 23–24, 2008.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Alec Ritchie, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID/DHHS, 6700 B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–435–1614, *aritchie@niaid.nih.gov.*

Name of Committee: Allergy, Immunology, and Transplantation Research Committee.

Date: October 29, 2008.

Time: 11 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge Drive, 3128, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Katrin Eichelberg, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, (301) 496–0818, *keichelberg@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 5, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–21169 Filed 9–12–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Cooperative Research Partnerships for Biodefense and Emerging Infectious Diseases SEP 6.

Date: October 3, 2008.

Time: 11 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, 3257, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Michelle M Timmerman, PhD, Scientific Review Officer, Scientific Review Program NIH/NIAID/DHHS, Room 3147, 6700B Rockledge Drive, MSC–7616, Bethesda, MD 20892–7616, 301–451–4573, *timmermanm@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; HIV Vaccines Research and Development (HIVRAD).

Date: October 6–8, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Washington DC/Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Eleazar Cohen, PhD, Scientific Review Officer, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, Room 3129, Bethesda, MD 20892, 301–435–3564, *ec17w@nih.gov.*

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group; Microbiology and Infectious Diseases Research Committee; Microbiology and Infectious Diseases Research Committee.

Date: October 9, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Crowne Plaza—Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: Annie Walker-Abbey, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIH/NIAID/DHHS, 6700B Rockledge Drive, RM. 3126, Bethesda, MD 20892–7616, 301–451–2671, *aabbey@niaidnih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Hematopoietic Cell Transplantation.

Date: October 16, 2008.

Time: 11 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Sujata Vijh, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, 301–594–0985, *vijhs@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 5, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–21170 Filed 9–12–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Services Subcommittee of the Interagency Autism Coordinating Committee (IACC).

The purpose of the Services Subcommittee is to review the current state of services and supports for individuals with Autism Spectrum Disorder (ASD) and their families in order to improve these services. The Subcommittee meeting will be conducted as a telephone conference call with presentations on the web. This meeting is open for the public to call in to listen and to access the web presentations. The Subcommittee will report on its meeting at the next meeting of the IACC on November 21, 2008.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of Meeting: Services Subcommittee Conference Call and Webinar.

Date: October 10, 2008.

Time: 9:30 a.m. to 11:30 a.m. Eastern Time.