implicated in a number of CNS disorders, including psychostimulant abuse, psychosis and Parkinson's disease. Compounds that bind with high affinity and selectivity to D3 receptors can not only provide important tools with which to study the structure and function of this receptor subtype, but may also have therapeutic potential in the treatment of numerous psychiatric and neurologic disorders.

The 4-phenylpiperazine derivatives are an important class of dopamine D3 selective ligands. However, due to their highly lipophilic nature, these compounds suffer from solubility problems in aqueous media and reduced bioavailability. To address this problem, a process was designed to introduce functionality into the carbon chain linker of these compounds. Compared to currently available dopamine D3 receptor ligands, the resulting compounds show improved pharmacological properties and D3 selectivities but due to their more hydrophilic nature, these derivatives are predicted to have improved water solubility and bioavailability.

Applications:

• Therapeutics for a variety of psychiatric and neurologic disorders

• Research tools to study D3 receptor structure and function

Advantages:

• Improved pharmacological properties and selectivity over existing dopamine D3 receptor ligands

• Hydrophilic nature likely to lead to improved water solubility and bioavailability

Development Status: Pre-clinical discovery.

Further R&D Needed:

• Evaluate selected compounds in animal models of drug abuse, psychosis, obesity and Parkinson's disease.

• Design and synthesize novel, functionalized analogs using both classical and computational drug design to improve D3 receptor affinity and selectivity.

• Evaluate compounds for binding in D3 and D2 receptor expressing cell lines and in in vitro functional assays.

• Correlate in vitro binding affinities with in vivo function in rats and monkeys and evaluate compounds in knockout mice models.

• Pursue PET and SPECT imaging agents by radiolabel of D3 ligands and evaluation in rats and non-human primates.

Inventors: Amy H. Newman (NIDA), Peter Grundt (NIDA), Jianjing Cao (NIDA), *et al.*

Patent Status: PCT Application No. Pct/US2007/71412 filed 15 Jun 2007, which published as WO 2008/153573 on 18 Dec 2008 (HHS Reference No. E–128–2006/0–PCT–01).

Licensing Status: Available for licensing.

Licensing Contact: Charlene Sydnor, PhD; 301–435–4689; *sydnorc@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute on Drug Abuse's Medications Discovery Research Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize 4-phenylpiperazine derivatives as dopamine D3 selective ligands. Please contact Vio Conley, MS at 301–435–2031 or *conleyv@mail.nih.gov* for additional information.

High-Yield Methods of Producing Biliverdin

Description of the Technology: This invention describes methods of making high yields of biliverdin, the pharmaceutical compositions of biliverdin made using that process, and methods of using the compositions therapeutically.

In reaction to a wide range of cellular stresses, hemoglobin is naturally metabolized to biliverdin, which is then quickly metabolized to bilirubin, a bile pigment, through a highly conserved set of enzymes. Both bilirubin and biliverdin are normally processed for rapid excretion, and excessive serum levels of bilirubin have known toxic effects (most notably jaundice). Surprisingly, research in the past decade has shown that decreasing serum levels correlate *inversely* with the prognosis of various disorders, such as ischemia/reperfusion injuries, atherosclerosis, organ transplantation, and several autoimmune diseases. Indeed, in animal-model studies, inducing a mild case of jaundice actually improved outcome. Unfortunately, bilirubin is relatively insoluble, and so is not a practical pharmaceutical itself.

Biliverdin has lower direct toxicity and substantially greater solubility than bilirubin, and also appears to have some direct therapeutic effects similar to bilirubin. Accordingly, biliverdin has been widely studied lately. Generating high yields of pure biliverdin is difficult, however, because any system with the enzymes to break down hemoglobin also has enzymes converting biliverdin to bilirubin. The inventors have created a system of generating microorganisms (yeast) lacking the enzymes that break biliverdin down to bilirubin.

Applications: Production of biliverdin for immunomodulatory and cytoprotective therapy (or adjuvant) in any condition involving an overactive immune response.

Advantages:

• High yield of biliverdin with low contamination of bilirubin.

• Produces only active isomers of biliverdin.

• Unlike prior methods, new method uses starting material that is inexpensive and plentiful.

Development Status: Successful generation of *Candida albicans* with biliverdin-generating system.

Inventors: Michael L. Pendrak and David D. Roberts (NCI).

Patent Status: HHS Reference No. E–040–2004/0—Issued U.S. Patent 7,504,243; Pending U.S. Application 12/364,054 (divisional, filed 02 Feb 2009).

Relevant Publication: ML Pendrak *et al.* Heme oxygenase in Candida albicans is regulated by hemoglobin and is necessary for metabolism of exogenous heme and hemoglobin to alpha-biliverdin. J Biol Chem. 20 Jan 2004;279(5):3426–3433.

Licensing Status: Available for licensing.

Licensing Contact: Bruce Goldstein, JD, MS; (301) 435–5470; *goldsteb@mail.nih.gov.*

Collaborative Research Opportunity: The Laboratory of Pathology in the Center for Cancer Research of the National Cancer Institute is seeking parties interested in collaborative research directed toward clinical applications of biliverdin. For more information about the research, please contact either Dr. Michael Pendrak (NCI/CCR Laboratory of Pathology) at (301) 496–6264, or Dr. April Franks (NCI Technology Transfer Center) at (301) 496–0477.

Dated: July 28, 2009.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. E9–18496 Filed 7–31–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0338]

Medical Device User Fee Rates for Fiscal Year 2010

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

fee rates and payment procedures for medical device user fees for fiscal year (FY) 2010. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the Medical Device User Fee Stabilization Act of 2005 (MDUFSA), and the Medical Device User Fee Amendments of 2007 (title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA)), authorizes FDA to collect user fees for certain medical device submissions, and annual fees both for certain periodic reports and for certain establishments subject to registration. The FY 2010 fee rates are provided in this document. These fees apply from October 1, 2009, through September 30, 2010. To avoid delay in the review of your application, you should pay the fee before or at the time you submit your application to FDA. The fee you must pay is the fee that is in effect on the later of the date that your application is received by FDA or the date your fee payment is received. If you want to pay a reduced small business fee, you must qualify as a small business before you make your submission to FDA; if you do not qualify as a small business before you make your submission to FDA, you will have to pay the higher standard fee. This document provides information on how the fees for FY 2010 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT:

For information on MDUFMA: Visit FDA's Web site, *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeand/ModernizationActMDUFMA/default.htm*.

For questions relating to this notice: David Miller, Office of Financial Management (HFA–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3917.

SUPPLEMENTARY INFORMATION:

I. Background

Section 738 of the act (21 USC 379j) establishes fees for certain medical device applications, submissions, supplements, and notices (for simplicity, this document refers to these collectively as ''submissions''); for periodic reporting on class III devices; and for the registration of certain establishments. Under statutorily-defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee. (See 21 U.S.C. 379j(d) and (e).)

Under the act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol (PDP), or a biologics licensing application (BLA)). The act specifies the standard fee for a premarket application for each year from FY 2008 through FY 2012; the standard fee for a premarket application received by FDA during FY 2010 is $217,787. From this starting point, this document establishes FY 2010 fee rates for other types of submissions, and for periodic reporting, by applying criteria specified in the act.

The act specifies the annual fee for establishment registration for each year from FY 2008 through FY 2012; the registration fee for FY 2010 is $2,008. There is no reduction in the registration fee for small businesses. An establishment must pay the registration fee if it is any of the following types of establishments:

- *Manufacturer.* An establishment that makes by any means any article that is a device, including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.
- *Single-Use Device Reprocessor.* An establishment that performs additional processing and manufacturing operations on a single-use device that has previously been used on a patient.
- *Specification Developer.* An establishment that develops specifications for a device that is distributed under the establishment's name but which performs no manufacturing, including an establishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment's name by a contract manufacturer.

The fees for FY 2010 go into effect on October 1, 2009, and will remain in effect through September 30, 2010.

II. Fees for FY 2010

Under the act, all submission fees and the periodic reporting fee are set as a percent of the standard (full) fee for a premarket application (see 21 U.S.C. 379j(a)(2)(A)), and the act sets the standard fee for a premarket application, including a BLA, a premarket report, and an efficacy supplement, at $217,787 for FY 2010 (see 21 U.S.C. 379j(b)); this is referred to as the ''base fee''). The fees set by reference to the base fee are—

- For a panel-track supplement, 75 percent of the base fee;
- For a 180-day supplement, 15 percent of the base fee;
- For a real-time supplement, 7 percent of the base fee;
- For a 30-day notice, 1.6 percent of the base fee;
- For a 510(k) premarket notification, 1.84 percent of the base fee;
- For a 513(g) request for classification information, 1.35 percent of the base fee; and
- For an annual fee for periodic reporting concerning a class III device, 3.5 percent of the base fee.

For all submissions other than a 510(k) premarket notification, a 30-day notice, and a 513(g) request for classification information, the small business fee is 25 percent of the standard (full) fee. (See 21 U.S.C. 379j(d)(2)(C).) For a 510(k) premarket notification submission, a 30-day notice, and a 513(g) request for classification information, the small business fee is 50 percent of the standard (full) fee. (See 21 U.S.C. 379j(e)(2)(C).)

The statute sets the annual fee for establishment registration at $2,008 on FY 2010, and there is no small business rate for the annual establishment registration fee; all establishments pay the same fee. The statute authorizes increases in the annual establishment fee for FY 2010 and subsequent years if the estimated number of establishments submitting fees for FY 2009 is fewer than 12,250. (See 21 U.S.C. 379j(c)(2)(A).) FDA estimates that the number of establishments submitting fees in FY 2009 will be in excess of 12,250, so no establishment fee increase is warranted under this provision of the statute.

Table 1 of this document sets out the FY 2010 rates for all medical device fees.

TABLE 1.—MEDICAL DEVICE FEES FOR FY 2010

Application Fee Type	Standard Fee, as a Percent of the Standard Fee for a Premarket Application	FY 2010 Standard Fee	FY 2010 Small Business Fee
Premarket application (a PMA submitted under section 515(c)(1) of the act (21 U.S.C. 360e(c)(1)), a PDP submitted under section 515(f) of the Act, or a BLA submitted under section 351 of the Public Health Service (PHS) Act (42 U.S.C. 262))	Set in statute	$217,787	$54,447
Premarket report (submitted under section 515(c)(2) of the act)	100%	$217,787	$54,447
Efficacy supplement (to an approved BLA under section 351 of the PHS Act)	100%	$217,787	$54,447
Panel-track supplement	75%	$163,340	$40,835
180-day supplement	15%	$32,668	$8,167
Real-time supplement	7%	$15,245	$3,811
510(k) premarket notification submission	1.84%	$4,007	$2,004
30-day notice	1.6%	$3,485	$1,742
513(g) (21 U.S.C. 360c(g)) request for classification information	1.35%	$2,940	$1,470
Annual Fee Type			
Annual fee for periodic reporting on a class III device	3.5%	$7,623	$1,906
Annual establishment registration fee (to be paid by each establishment that is a manufacturer, a single-use device reprocessor, or a specification developer, as defined by 21 U.S.C. 379i(13))	Set in statute	$2,008	$2,008

III. How to Qualify as a Small Business for Purposes of Medical Device Fees

If your business has gross receipts or sales of no more than $100 million for the most-recent tax year, you may qualify for reduced small business fees. If your business has gross sales or receipts of no more than $30 million, you may also qualify for a waiver of the fee for your first premarket application (PMA, PDP, or BLA) or premarket report. You must include the gross receipts or sales of all of your affiliates along with your own gross receipts or sales when determining whether you meet the $100 million or $30 million threshold. If you want to pay the small business fee rate for a submission, or you want to receive a waiver of the fee for your first premarket application or premarket report, you should submit the materials showing you qualify as a small business 60 days before you send your submission to FDA. If you make a submission before FDA finds that you qualify as a small business, you must pay the standard fee for that submission.

If your business qualified as a small business for FY 2009, your status as a small business will expire at the close of business on September 30, 2009. You must re-qualify for FY 2010 in order to pay small business fees during FY 2010.

If you are a domestic (U.S.) business, and wish to qualify as a small business for FY 2010, you must submit the following to FDA:

(1) A completed FY 2010 MDUFMA Small Business Qualification Certification (Form FDA 3602). This form is provided in FDA's guidance document, ''FY 2010 Medical Device User Fee Small Business Qualification and Certification,'' available on FDA's Web site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm.* This form is not available separate from the guidance document.

(2) A certified copy of your Federal (U.S.) Income Tax Return for the most recent tax year. The most recent tax year will be 2009, except—

- If you submit your FY 2010 MDUFMA Small Business Qualification before April 15, 2010, and you have not yet filed your return for 2009, you may use tax year 2008.
- If you submit your FY 2010 MDUFMA Small Business Qualification on or after April 15, 2010, and have not yet filed your 2009 return because you obtained an extension, you may submit your most-recent return filed prior to the extension.

(3) For each of your affiliates, either—

- If the affiliate is a domestic (U.S.) business, a certified copy of the affiliate's Federal (U.S.) income tax return for the most recent tax year, or
- If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected. The applicant should also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its

affiliates, identifying the name of each affiliate, or that the applicant has no affiliates.

If you are a foreign business, and wish to qualify as a small business for FY 2010, you must submit the following:

(1) A completed FY 2010 MDUFMA Foreign Small Business Qualification Certification (Form FDA 3602A). This form is provided in FDA's guidance document, ''FY 2010 Medical Device User Fee Small Business Qualification and Certification,'' available on FDA's Internet site at *http://www.fda.gov/cdrh/mdufma*. This form is not available separate from the guidance document.

(2) A National Taxing Authority Certification, completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is headquartered. This Certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected.

(3) For each of your affiliates, either—

• If the affiliate is a domestic (U.S.) business, a certified copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year (2008 or later), or

• If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates for the gross receipts or sales collected. The applicant should also submit a statement signed by the head of the applicant's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the applicant has no affiliates.

IV. Procedures for Paying Application and Annual Report Fees

If your application or submission is subject to a fee and your payment is received by FDA from October 1, 2009, through September 30, 2010, you must pay the fee in effect for FY 2010. The later of the date that the application or annual report is received in the reviewing center's document room or the date that the check is received by U.S. Bank determines whether the fee rates for FY 2009 or FY 2010 apply. FDA must receive the correct fee at the time that an application or annual report is submitted, or the application or annual report will not be accepted for filing or review.

FDA requests that you follow the steps below before submitting a medical device application or annual report subject to a fee. Please pay close attention to these procedures to ensure that FDA links the fee with the correct application. (Note: In no case should the check for the fee be submitted to FDA with the application.)

A. Step One—Secure a Payment Identification Number (PIN) and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment (Note: Both the FY 2009 and FY 2010 fee rates will be available on the Cover Sheet Web Site beginning on the date of publication of this document, and only the FY 2010 rates will appear after September 30, 2009)

Log on to the MDUFMA Web site at: *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm* and, under the MDUFMA Forms heading, click on the link ''User Fee Cover Sheet.'' Complete the Medical Device User Fee cover sheet. Be sure you choose the correct application submission date range. (Two choices will be offered until October 1, 2009. One choice is for applications that will be received on or before September 30, 2009, which will be subject to FY 2009 fee rates. A second choice is for applications that will be received on or after October 1, 2009, which will be subject to FY 2010 fee rates.) After completing data entry, print a copy of the Medical Device User Fee cover sheet and note the unique PIN located in the upper right-hand corner of the printed cover sheet.

B. Step Two—Electronically Transmit a Copy of the Printed Cover Sheet with the PIN to FDA's Office of Financial Management

Once you are satisfied that the data on the cover sheet is accurate, electronically transmit that data to FDA according to instructions on the screen. Because electronic transmission is possible, applicants are required to set up a user account and use passwords to assure data security in the creation and electronic submission of cover sheets.

C. Step Three—Submit Payment for the Completed Medical Device User Fee Cover Sheet as Described in this Section, Depending on the Method You Will Use to Make Payment

(1) If paying with a paper check:

• All paper checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. (FDA's tax identification number is 53–0196965, should your accounting department need this information.)

• Please write your application's unique PIN, from the upper right-hand corner of your completed Medical Device User Fee cover sheet, on your check.

• Mail the paper check and a copy of the completed cover sheet to: Food and Drug Administration, P.O. Box 956733, St. Louis, MO, 63195–6733. (Please note that this address is for payments of application and annual report fees only and is not to be used for payment of annual establishment registration fees.)If you prefer to send a check by a courier (such as Federal Express (FEDEX), DHL, United Parcel Service (UPS), etc.), the courier may deliver the check to: U.S. Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the U.S. Bank at 314–418–4821 if you have any questions concerning courier delivery.)

It is helpful if the fee arrives at the bank at least 1 day before the application arrives at FDA. FDA records the official application receipt date as the later of the following: (1) The date the application was received by FDA or (2) the date U.S. Bank receives the payment. U.S. Bank is required to notify FDA within 1 working day, using the PIN described previously in this document.

(2) If Paying With Credit Card or Electronic Check (Automated Clearing House (ACH)):

FDA has partnered with the U.S. Department of the Treasury to utilize Pay.gov, a web based payment application, for online electronic payment. Pay.gov can now be used to submit online payments for cover sheets to the FDA. You now have the option to make a payment via electronic check or credit card after submitting your coversheet. To pay online, select the ''Pay Now'' button. Credit card transactions for cover sheets are limited to $4,000.00.

(3) If paying with a wire transfer:

• Please include your application's unique PIN, from the upper right-hand corner of your completed Medical

Device User Fee cover sheet, in your wire transfer. Without the PIN your payment may not be applied to your cover sheet and review of you application will be delayed.

• The originating financial institution usually charges a wire transfer fee between $15.00 and $35.00. Please ask your financial institution about the fee and include it with your payment to ensure that your cover sheet is fully paid.Use the following account information when sending a wire transfer: New York Federal Reserve Bank, U.S. Department of Treasury, TREAS NYC, 33 Liberty St, New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 5600 Fishers Lane, Rockville, MD 20857.

D. Step Four—Submit Your Application to FDA With a Copy of the Completed Medical Device User Fee Cover Sheet

For all applications sent after August 1, 2009, please submit your application and a copy of the completed Medical Device User Fee cover sheet to one of the following addresses:

(1) Medical device applications should be submitted to: Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center— WO66, rm. 0609, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002.

(2) Biologic applications should be sent to: Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center (HFM–99), suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448.

V. Procedures for Paying Annual Establishment Fees

If you are required to pay an annual establishment registration fee, you must pay for each establishment prior to registration. Payment must be submitted by first creating a Device Facility Use Fee (DFUF) order through the User Fee Web site at *https://fdasfinapp8.fda.gov/OA_HTML/fdaCAcdLogin.jsp*. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) You will be issued a PIN once you place your order. After payment has been processed, you will be issued a payment confirmation number (PCN). You will not be able to register your establishment if you do not have a PIN and a PCN. An establishment required to pay an annual establishment registration fee is not legally registered in FY 2010 until it has completed the steps below to register and pay any applicable fee. (See 21 U.S.C. 379j(f)(2).)

Companies that do not manufacture any product other than a licensed biologic are required to register in the Blood Establishment Registration (BER) system. FDA's Center for Biologics and Research (CBER) will send establishment registration fee invoices annually to these companies.

A. Step One—Submit a Device Facility User Fee Order With a PIN From FDA Before Registering or Submitting Payment

To submit a DFUF Order, you must create or have previously created a user account and password for the User Fee Web site listed previously in this section. After creating a user name and password, log into the Establishment Registration User Fee 2010 store. Complete the DFUF order by entering the number of establishments you are registering. Once you are satisfied that the data on the order is accurate, electronically transmit that data to FDA according to instructions on the screen. Print a copy of the final DFUF order and note the unique PIN located in the upper right-hand corner of the printed order.

B. Step Two—Pay For Your Device Facility User Fee Order

Unless paying by credit card, all payments must be in U. S. currency and drawn on a U.S. bank.

(1) If paying with credit card or electronic check (ACH):

The DFUF order will include payment information, including details on how you can pay online using a credit card or electronic checks. Follow the instructions provided to make an electronic payment.

(2) If paying with a paper check:

If you prefer not to pay online, you may pay by a check, in U.S. dollars and drawn on a U.S. bank, mailed to: Food and Drug Administration, P.O. Box 70961, Charlotte, NC 28272–0961. (Note: This address is different from the address for payments of application and annual report fees and is to be used only for payment of annual establishment registration fees.)

If a check is sent by a courier that requests a street address, the courier can deliver the check to: Wachovia Bank, Attn: Food and Drug Administration—Lockbox 70961, rm. NC0810, 1525 West WT Harris Blvd., Charlotte, NC 28262. (Note: This Wachovia Bank address is for courier delivery only; do not send mail to this address.)

Please make sure that both of the following are written on your check: (1) The FDA post office box number (P.O. Box 70961) and (2) the PIN that is printed on your order. A copy of your printed order should also be mailed along with your check. FDA's tax identification number is 53–0196965.

(3) If paying with a wire transfer:

Wire transfers may also be used to pay annual establishment fees. To send a wire transfer, please read and comply with the following information:

• Include your order's unique PIN, from the upper right-hand corner of your completed Medical Device User Fee order, in your wire transfer. Without the PIN your payment may not be applied to your facility and your registration will be delayed.

• The originating financial institution usually charges a wire transfer fee between $15.00 and $35.00. Please ask your financial institution about the fee and include it with your payment to ensure that your order is fully paid. Use the following account information when sending a wire transfer: New York Federal Reserve Bank, US.. Dept of Treasury, TREAS NYC, 33 Liberty St, New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 5600 Fishers Lane, Rockville, MD 20857.

C. Step Three—Complete the Information Online to Update Your Establishment's Annual Registration for FY 2010, or to Register a New Establishment for FY 2010

Go to CDRH's Web site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm* and click the ''Access Electronic Registration'' link on the left of the page. This opens up a new page with important information about the FDA Unified Registration and Listing System (FURLS). After reading this information, click on the link (Access Electronic Registration) at the bottom of the page. This link takes you to an FDA Industry Systems page with tutorials that demonstrate how to create a new FURLS user account if your establishment did not create an account in FY 2009. Biologics license manufacturers should register in the BER system at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/default.htm.*

Enter your existing account ID and password to log into FURLS. From the FURLS/FDA Industry Systems menu, there will be a button that you will click to go to the Device Registration and Listing Module (DRLM) of FURLS. New establishments will need to register and existing establishments will update

their annual registration using choices on the DRLM menu. Once you choose to register or update your annual registration the system will prompt you through the entry of information about your establishment and your devices. If you have any problems with this process, e-mail: *reglist@cdrh.fda.gov* or call 301–796–7400 for assistance. (Note: this e-mail address and this telephone number are for assistance with establishment registration only, and not for any other aspects of medical device user fees.) Problems with BER should be directed to *bloodregis@fda.hhs.gov* or call 301–827–3546.

D. Step Four—Enter Your DFUF Order PIN and PCN

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. This process does not apply to licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to companies who only manufacture licensed biologics devices. Fees are only required for those establishments defined in section I of this document.

Dated: July 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–18456 Filed 7–31–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting; Moving Into the Future—New Dimensions and Strategies for Women's Health Research for the National Institutes of Health

Notice is hereby given that the Office of Research on Women's Health (ORWH), Office of the Director, National Institutes of Health, Department of Health and Human Services, in collaboration with the Warren Alpert Medical School of Brown University and the Women & Infants Hospital of Rhode Island, will convene a public hearing and scientific workshop on September 21–23, 2009, at the Women & Infants Hospital of Rhode Island Conference Center, Providence, Rhode Island.

Purpose of the Meeting

With rapid advances in science and wider global understanding of women's health and sex/gender contributions to well-being and disease, the purpose of the meeting is to ensure that NIH continues to support cutting-edge women's health research that is based upon the most advanced techniques and methodologies. The meeting format is designed to promote an interactive discussion involving leading scientists, advocacy groups, public policy experts, health care providers, and the general public. The Providence meeting is the third in a series that will be convened throughout the Nation to help the ORWH and NIH move into the next decade of women's health research.

As science and technology advance and fields such as computational biology demonstrate the power of interdisciplinary research, it remain critical for sex and gender factors to be integrated into broad experimental methodologies and scientific approaches across the lifespan. Biomedical and behavioral research are also necessary to understand how cultural, ethnic, and racial differences influence the causes, diagnosis, progression, treatment, and outcome of disease among different populations, including women of diverse geographic locations and socioeconomic backgrounds. Furthermore, health differences among diverse populations of women remain a critical area in need of continued focus and attention.

The ORWH challenges all meeting attendees to assist the NIH in defining the women's health research agenda of the future by thinking beyond traditional women's health issues. The ORWH and NIH ask meeting participants to consider creative strategies to identify areas of research that are best poised for advancement, identify innovative ways in which persistent issues of health and disease can be addressed, and explore new horizons of scientific concepts and investigative approaches. Attention also needs to be paid to new areas of science application, new technologies, and continuing basic science investigations. Clinical questions that are not currently the focus of research priorities need to be considered to ensure that women's health research is optimally served and that the ORWH can continue to provide leadership for the benefit of women's health, nationally and internationally.

Meeting Format

The meeting will consist of public testimony, scientific panels, and eight concurrent scientific working groups. Specifically, on September 21, individuals representing a full spectrum of organizations interested in biomedical and behavioral research on women's health issues will have an opportunity to provide public testimony from 1:30 to 5:30 p.m. On September 22 and 23, plenary sessions will focus on the intersection of health care, public policy, and biomedical research; on emerging issues and trends in health care; and on research paradigms of the future. The eight concurrent afternoon sessions on September 22 will focus on a range of research areas, including Prenatal, Infancy, and Childhood Years; Adolescent Years; Reproductive and Middle Years; Pregnancy; Menopausal Transition; Elderly, Frail Elderly, and Healthy Aging; Oral Health and Systemic Conditions; and Careers in Dentistry, Bioengineering, and other Non-Medical Disciplines.

On September 23 the morning session will be devoted to reports by the working group co-chairs regarding the recommendations emerging from working group deliberations on the previous day. The meeting will adjourn at 1:15 p.m. on September 23.

Public Testimony

The ORWH invites individuals with an interest in research related to women's health to provide written and/or oral testimony on these topics and/or on issues related to the sustained advancement of women in various biomedical careers. Due to time constraints, only one representative from an organization or professional specialty group may give oral testimony. Individuals not representing an organized entity but a personal point of view are similarly invited to present written and/or oral testimony. A letter of intent to present oral testimony is necessary and should be sent electronically to *http://www.orwhmeetings.com/movingintothefuture/* or by mail to Ms. Jory Barone, Educational Services, Inc., 4350 East-West Highway, Suite 1100, Bethesda, MD 20814, no later than September 13, 2009. The date of receipt of the communication will establish the order of those selected to give oral testimony at the September meeting.

Those wishing to present oral testimony are also asked to submit a written form of their testimony that is limited to a maximum of 10 pages, double spaced, 12-point font, and should include a brief description of their organization. Electronic submission to the above Web site is preferred; however, for those who do not have access to electronic means, written testimony, bound by the restrictions previously noted and postmarked no later than September 13, 2009, can be mailed to Ms. Jory Barone at the above address. All written presentations must meet the established