

any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Information in an application on the product and process development and justification for the final formulation and system design is approved by OMB under control numbers 0910–0001 and 0910–0014.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: July 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19041 Filed 8–2–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0181]

Guidance for Industry on Label Comprehension Studies for Nonprescription Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

availability of a guidance for industry entitled “Label Comprehension Studies for Nonprescription Drug Products.” The guidance provides recommendations on the design of label comprehension studies that can be used to assess the extent to which consumers understand the information conveyed by proposed nonprescription drug product labeling. This guidance finalizes the draft guidance published on May 1, 2009.

DATES: Submit either electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Murewa Oguntimein, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5475, Silver Spring, MD 20993–0002, 301–796–4869.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Label Comprehension Studies for Nonprescription Drug Products.” This guidance is intended for individuals or organizations involved in the development of label comprehension studies for nonprescription drug products. This guidance discusses general concepts that should be considered in the design and conduct of a label comprehension study. This guidance also incorporates advice obtained from the September 25, 2006, meeting of the Nonprescription Drug Advisory Committee that considered issues related to the analysis and interpretation of consumer studies conducted to support marketing of nonprescription drug products, and comments submitted to the draft guidance published in the **Federal Register** of May 1, 2009 (74 FR 20322).

This guidance is being issued consistent with FDA’s good guidance

practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on label comprehension studies for nonprescription drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: July 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19043 Filed 8–2–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0363]

Medical Device User Fee Rates for Fiscal Year 2011

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) 2011. The Federal Food, Drug, and Cosmetic Act (the act), as amended by 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 2011 fee rates are provided in this document. These fees apply from October 1, 2010, through September 30, 2011. 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 2011 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/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm>.

For questions relating to this notice: David Miller, Office of Financial Management (HFA-100), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-796-7103.

SUPPLEMENTARY INFORMATION:

I. Background

Section 738 of the act (21 U.S.C. 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 license 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 2011 is \$236,298. From this starting point, this document establishes FY 2011 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 2011 is \$2,179. 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 2011 go into effect on October 1, 2010, and will remain in effect through September 30, 2011.

II. Fees for FY 2011

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 \$236,298 for FY 2011 (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) (21 U.S.C. 360c(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 \$2,179 in FY 2011, 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 2011 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).) The number of establishments submitting fees in FY 2009 was 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 2011 rates for all medical device fees.

TABLE 1.—MEDICAL DEVICE FEES FOR FY 2011

Application Fee Type	Standard Fee, as a Percent of the Standard Fee for a Premarket Application	FY 2011 Standard Fee	FY 2011 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	\$236,298	\$59,075
Premarket report (submitted under section 515(c)(2) of the act)	100%	\$236,298	\$59,075
Efficacy supplement (to an approved BLA under section 351 of the PHS Act)	100%	\$236,298	\$59,075
Panel-track supplement	75%	\$177,224	\$44,306
180-day supplement	15%	\$35,445	\$8,861
Real-time supplement	7%	\$16,541	\$4,135
510(k) premarket notification submission	1.84%	\$4,348	\$2,174
30-day notice	1.6%	\$3,781	\$1,890
513(g) request for classification information	1.35%	\$3,190	\$1,595
Annual Fee Type			
Annual fee for periodic reporting on a class III device	3.5%	\$8,270	\$2,068
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	\$2,179	\$2,179

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 2010, your status as a small business will expire at the close of business on September 30, 2010. You must re-qualify for FY 2011 in order to pay small business fees during FY 2011.

If you are a domestic (U.S.) business, and wish to qualify as a small business for FY 2011, you must submit the following to FDA:

1. A completed FY 2011 MDUFMA Small Business Qualification Certification (Form FDA 3602). This form is provided in FDA's guidance document, "FY 2011 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 2010, except—

- If you submit your FY 2011 MDUFMA Small Business Qualification before April 15, 2011, and you have not yet filed your return for 2010, you may use tax year 2009.

- If you submit your FY 2011 MDUFMA Small Business Qualification on or after April 15, 2011, and have not yet filed your 2010 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 2011, you must submit the following:

1. A completed FY 2011 MDUFMA Foreign Small Business Qualification Certification (Form FDA 3602A). This form is provided in FDA's guidance document, "FY 2011 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 (2009 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, 2010, through September 30, 2011, you must pay the fee in effect for FY 2011. 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 2010 or FY 2011 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 2010 and FY 2011 fee rates will be available on the Cover Sheet Web Site beginning on the date of publication of this document, and only the FY 2011 rates will appear after September 30, 2010)

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 "Create a 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, 2010. One choice is for applications that will be received on or before September 30, 2010, which will be subject to FY 2010 fee rates. A second choice is for applications that will be received on or after October 1, 2010, which will be subject to FY 2011 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 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 \$5,000.00.

(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 your 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, 1350 Piccard Dr., Rockville, MD 20850.

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

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 User Fee (DFUF) order through the User Fee Web site at https://fdasfinapp8.fda.gov/OA_HTML/fdaCacLogin.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 2011 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 DFUF 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 2011 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: Wells Fargo, Attn: Food and Drug Administration—Lockbox 70961, rm. NC0810, 1525 West WT Harris Blvd., Charlotte, NC 28262. (Note: This Wells Fargo 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, U.S. 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 2011, or to Register a New Establishment for FY 2011

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 or FY 2010. Biologics 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 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-19038 Filed 8-2-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; SBIR Phase II Topic 60.

Date: August 18, 2010.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Marina Broitman, PhD, Scientific Review Officer, Division of

Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892-9608, 301-402-8152, mbroitma@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; SBIR Phase II Topic 59.

Date: August 20, 2010.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Marina Broitman, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892-9608, 301-402-8152, mbroitma@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: July 28, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Design of Clinical Trials of Aerosolized Antimicrobials for the Treatment of Cystic Fibrosis; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop regarding scientific issues in clinical development of aerosolized antimicrobials for the management and/or treatment of patients with cystic fibrosis. Aerosolized antimicrobials are used to treat chronic bacterial infection in the lungs and thus improve the respiratory symptoms in patients with cystic fibrosis. This public workshop is intended to provide information for and gain perspective from health care providers, patients and patient advocacy organizations, academia, and industry on various aspects of the design of clinical trials of aerosolized

antimicrobials in patients with cystic fibrosis. The input from this public workshop will help in developing topics for further discussion.

Dates and Times: The public workshop will be held on September 23, 2010, from 8:30 a.m. to 5:30 p.m. and on September 24, 2010, from 8 a.m. to 4 p.m.

Location: The public workshop will be held at the Crowne Plaza Hotel, 8777 Georgia Ave., Silver Spring, MD 20910. Seating is limited and available only on a first-come, first-served basis.

Contact Persons: Chris Moser or Lori Benner, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Antimicrobial Products, 10903 New Hampshire Ave., Bldg. 22, rm. 6209, Silver Spring, MD 20993-0002, 301-796-1300.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited. Seating will be available on a first-come, first-served basis. To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and fax number) to CFWORKSHOP@fda.hhs.gov Persons without access to the Internet can call 301-796-1300 to register. Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Lori Benner (see Contact Persons) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop regarding scientific considerations in the design of clinical trials of aerosolized antimicrobials to treat chronic bacterial infection in the lungs and thus improve the respiratory symptoms in patients with cystic fibrosis. The development of clinical trial endpoints to establish efficacy is a major challenge in the design of informative clinical trials of aerosolized antimicrobials for the management and/or treatment of patients with cystic fibrosis. The workshop will include discussion of clinical trial endpoints to establish efficacy, such as timing and definitions of pulmonary exacerbations, changes in the results of pulmonary function testing, and changes on patient reported outcome measures. An important consideration will be the evaluation of new aerosolized antimicrobials in the context of approved aerosolized antimicrobials on the basis of these or other efficacy endpoints. Other issues in the design of clinical trials of aerosolized antimicrobials include: The development of drug resistance and