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.

Dated: July 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18603 Filed 7–30–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0785]

Medical Device User Fee Rates for Fiscal Year 2013

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) 2013. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device User Fee Amendments of 2012 (Title 2 of the Food and Drug Administration Safety and Innovation Act, Public Law 112–144, which was signed by the President on July 9, 2012) (MDUFA III), authorizes FDA to collect user fees for certain medical device submissions, and annual fees both for certain periodic reports and for establishments subject to registration. The FY 2013 fee rates are provided in this document. These fees apply from October 1, 2012, through September 30, 2013. 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 recognized by the U.S. Treasury. 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 2013 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 Medical Device User Fees:* Visit FDA's Web site, *http://www.fda.gov/mdufa.*

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 FD&C 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'' or ''applications''); 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).) Additionally, the Secretary may, at the Secretary's sole discretion, grant a fee waiver or reduction if the Secretary finds that such waiver or reduction is in the interest of public health. (See 21 U.S.C. 379j(f).)

Under the FD&C 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 FD&C Act specifies the base fee for a premarket application for each year from FY 2013 through FY 2017; the base fee for a premarket application received by FDA during FY 2013 is $248,000. From this starting point, this document establishes FY 2013 fee rates for other types of submissions, and for periodic reporting, by applying criteria specified in the FD&C Act.

The FD&C Act specifies the base fee for establishment registration for each year from FY 2013 through FY 2017; the registration fee for FY 2013 is $2,575. There is no reduction in the registration fee for small businesses. Each establishment that is registered (or is required to register) with the Secretary under section 510 of the FD&C Act (21 U.S.C. 360) because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device is required to pay the annual fee for establishment registration.

II. Fees for FY 2013

Under the FD&C 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).) For FY 2013, the standard fee is the base fee; for FY 2014 through FY 2017, the base fee will be adjusted as specified in the FD&C Act so for these fiscal years, the standard fee will be the adjusted base fee. (See 21 U.S.C. 379j(b) and (c).) The standard fee for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $248,000 for FY 2013. (See 21 U.S.C. 379j(b).) The fees set by reference to the standard fee for a premarket application are:

- For a panel-track supplement, 75 percent of the standard fee;
- For a 180-day supplement, 15 percent of the standard fee;
- For a real-time supplement, 7 percent of the standard fee;
- For a 30-day notice, 1.6 percent of the standard fee;
- For a 510(k) premarket notification, 2 percent of the standard fee;
- For a 513(g) request for classification information, 1.35 percent of the standard fee; and
- For an annual fee for periodic reporting concerning a class III device, 3.5 percent of the standard 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 for the submission. (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 for the submission. (See 21 U.S.C. 379j(d)(2)(C) and (e)(2)(C).)

The statute sets the annual fee for establishment registration at $2,575 in FY 2013. There is no small business rate for the annual establishment registration fee; all establishments pay the same fee.

Table 1 of this document set out the FY2013 rates for all medical device fees.

TABLE 1—MEDICAL DEVICE FEES FOR FY 2013

Application fee type	Standard fee, as a percent of the standard fee for a premarket application	FY 2013 standard fee	FY 2013 small business fee
Premarket application (a PMA submitted under section 515(c)(1) of the FD&C Act (21 U.S.C. 360e(c)(1)), a PDP submitted under section 515(f) of the FD&C Act (21 U.S.C. 360e(f)), or a BLA submitted under section 351 of the Public Health Service (PHS) Act (42 U.S.C. 262)).	Base Fee Adjusted as Specified in the Statute.	$248,000	$62,000
Premarket report (submitted under section 515(c)(2) of the FD&C Act) ..	100%	248,000	62,000
Efficacy supplement (to an approved BLA under section 351 of the PHS Act).	100%	248,000	62,000
Panel-track supplement	75%	186,000	46,500
180-day supplement	15%	37,200	9,300
Real-time supplement	7%	17,360	4,340
510(k) premarket notification submission	2%	4,960	2,480
30-day notice	1.6%	3,968	1,984
513(g) (21 U.S.C. 360c(g)) request for classification information	1.35%	3,348	1,674
Annual Fee Type			
Annual fee for periodic reporting on a class III device	3.5%	8,680	2,170
Annual establishment registration fee (to be paid by the establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, as defined by 21 U.S.C. 379i(13)).	Base Fee Adjusted as Specified in the Statute.	2,575	2,575

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 (full) fee for that submission.

If your business qualified as a small business for FY 2012, your status as a small business will expire at the close of business on September 30, 2012. You must re-qualify for FY 2013 in order to pay small business fees during FY 2013.

If you are a domestic (U.S.) business, and wish to qualify as a small business for FY 2013, you must submit the following to FDA:

1. A completed FY 2013 MDUFA Small Business Qualification Certification (Form FDA 3602). This form is provided in FDA's guidance document, ''FY 2013 Medical Device User Fee Small Business Qualification and Certification,'' available on FDA's Web site at *http://www.fda.gov/mdufa.* 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 2012, except:

- If you submit your FY 2013 MDUFA Small Business Qualification before April 15, 2013, and you have not yet filed your return for 2012, you may use tax year 2011.
- If you submit your FY 2013 MDUFA Small Business Qualification on or after April 15, 2013, and have not yet filed your 2012 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 must 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 2013, you must submit the following:

1. A completed FY 2013 MDUFA Foreign Small Business Qualification Certification (Form FDA 3602A). This form is provided in FDA's guidance document, ''FY 2013 Medical Device User Fee Small Business Qualification and Certification,'' available on FDA's Internet site at *http://www.fda.gov/mdufa.* 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 (2011 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 must 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 Fees

If your application or submission is subject to a fee and your payment is received by FDA from October 1, 2012, through September 30, 2013, you must pay the fee in effect for FY 2013. The later of the date that the application is received in the reviewing center's document room or the date the U.S. Treasury recognizes the payment determines whether the fee rates for FY 2012 or FY 2013 apply. FDA must receive the correct fee at the time that an application is submitted, or the application will not be accepted for filing or review.

FDA requests that you follow the steps below before submitting a medical device application subject to a fee 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

Log on to the MDUFA Web site at: *http://www.fda.gov/mdufa,* click on ''MDUFA FORMS'' at the left side of the page, and then under the MDUFA Forms heading, click on the link ''Create MDUFA 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, 2012. One choice is for applications that will be received on or before September 30, 2012, which will be subject to FY 2012 fee rates. A second choice is for applications that will be received on or after October 1, 2012, which will be subject to FY 2013 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 314–418–4013 if you have any questions concerning courier delivery.)

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 the U.S. Treasury recognizes the payment. It is helpful if the fee payment arrives at the bank at least 1 day before the application arrives at FDA.

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 *www.Pay.gov,* a Web-based payment system, for online electronic payment. You may make a payment via electronic check or credit card after submitting your cover sheet. 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 may charge a wire transfer fee between $15 and $35. 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 the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 1350 Piccard Drive, 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, Bldg. 66, 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 the Annual Fee for Periodic Reporting

As of FY 2011, you are no longer able to create a cover sheet and obtain a PIN to pay the MDUFA Annual Fee for Periodic Reporting. Instead, you will be invoiced at the end of the quarter in which your PMA Periodic Report is due. Invoices will be sent based on the details included on your PMA file; you are responsible to ensure your billing information are kept up-to-date (you can

update your contact for the PMA by submitting an amendment).

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 invoice number.
- Mail the paper check and a copy of invoice 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 FedEx, DHL, 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 314–418–4013 if you have any questions concerning courier delivery.)

2. If paying with a wire transfer:

- Please include your invoice number in your wire transfer. Without the invoice number, your payment may not be applied and you may be referred to collections.
- The originating financial institution may charge a wire transfer fee between $15 and $35. Please ask your financial institution about the fee and include it with your payment to ensure that your invoice is fully paid.

Use the following account information when sending a wire transfer: New York Federal Reserve Bank, U.S. Department of the 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.

VI. Procedures for Paying Annual Establishment Fees

In order to pay the annual establishment fee, firms must access the Device Facility User Fee (DFUF) 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 create a DFUF order and 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 2013 until it has completed the steps below to register and pay any applicable fee. (See 21 U.S.C. 379j(g)(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 Evaluation 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 FY 2013 store. Complete the DFUF order by entering the number of establishments you are registering that require payment. 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 DFUF Order

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

1. If paying by 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 check. 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 979108, St. Louis, MO 63197–9000. (**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: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (**Note:** This U.S. 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 979108) 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 Device Facility 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 may charge a wire transfer fee between $15 and $35. 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, 1350 Piccard Drive, Rockville, MD 20850.

C. Step Three—Complete the Information Online To Update Your Establishment's Annual Registration for FY 2013, or To Register a New Establishment for FY 2013

Go to the Center for Devices and Radiological Health'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 2012. Manufacturers of licensed biologics 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, click on the Device Registration and Listing Module (DRLM) of FURLS button. 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, email: *reglist@cdrh.fda.gov* or call 301–796–7400 for assistance. (Note: this email 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 BERS 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 establishments engaged only in the manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

Dated: July 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–18647 Filed 7–30–12; 8:45 a.m.]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Maternal and Child Health Bureau Performance Measures for Discretionary Grants (OMB No. 0915–0298)—[Revision]

The Health Resources and Services Administration's (HRSA) Maternal and Child Health Bureau (MCHB) intends to continue to collect performance data for Special Projects of Regional and National Significance (SPRANS), Community Integrated Service Systems (CISS), and other grant programs administered by MCHB.

HRSA's MCHB proposes to continue using reporting requirements for SPRANS projects, CISS projects, and other grant programs administered by MCHB, including national performance measures, previously approved by OMB, and in accordance with the ''Government Performance and Results Act (GPRA) of 1993'' (Pub. L. 103–62). This Act requires the establishment of measurable goals for Federal Programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for MCHB discretionary grants were initially approved in January 2003. Approval from OMB is being sought to continue the use of these measures. Some of these measures are specific to certain types of programs and will not apply to all grantees. Through the experience of utilizing these measures, we are enhancing them to better reflect program goals. Specifically, additional outcome measures that can be utilized by grantees that predominantly provide infrastructure services are being developed for submission to OMB.

The estimated response burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Burden hours per response	Total burden hours
Grant Report	900	1	900	41	36,900
Total	900		900		36,900

Email comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 24, 2012.

Jennifer Riggle,

Deputy Director, Office of Management.

[FR Doc. 2012–18637 Filed 7–30–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office