The worksheets for standard costs for FY 2011, the latest year for which standard cost data are available, show a standard cost (rounded to the nearest thousand dollars) of $5,092,000 for a new molecular entity NDA and $11,203,000 for a BLA. Based on these standard costs, the total cost to review the 46 applications in these two categories in FY 2011 (10 BLAs and 36 NDAs with clinical data) was $295,342,000. (**Note:** no investigational new drug (IND) review costs are included in this amount.) Records acquired from CDER and CBER by the Office of Policy and Planning (OPP), Economics Staff, indicate that a total of 16 of these applications (12 NDAs [excluding the President's Emergency Plan for AIDS Relief NDAs] and 4 BLAs) received priority review, which would mean that the remaining 30 received standard reviews. Because a priority review compresses a review that ordinarily takes 10 months into 6 months, OPP estimates that a multiplier of 1.67 (10 months divided by 6 months) should be applied to non-priority review costs in estimating the effort and cost of a priority review as compared to a standard review. This multiplier is consistent with published research on this subject. In the article ''Developing Drugs for Developing Countries,'' published in *Health Affairs,* Volume 25, Number 2, in 2006, the comparison of historical average review times by David B. Ridley, Henry G. Grabowski, and Jeffrey L. Moe supports a priority review multiplier in the range of 1.48 to 2.35. The multiplier derived by FDA falls well below the mid-point of this range. Using FY 2011 figures, the costs of a priority and standard review are estimated using the following formula: $(16\ \alpha * 1.67) + (30\ \alpha) = \$295{,}342{,}000$ where ''α'' is the cost of a standard review and ''α times 1.67'' is the cost of a priority review. Using this formula, the cost of a standard review for NMEs is calculated to be $5,207,000 (rounded to the nearest thousand dollars) and the cost of a priority review for NMEs is 1.67 times that amount, or $8,696,000 (rounded to the nearest thousand dollars). The difference between these two cost estimates, or $3,489,000, represents the incremental cost of conducting a priority review rather than a standard review.

Section 524 of the FD&C Act specifies that the fee amount should be based on the average cost incurred by the Agency for a priority review in the previous FY. FDA is setting fees for FY 2013, and the previous fiscal year is FY 2012. However, the FY 2012 submission cohort has not been closed out yet, and the cost data for FY 2012 are not complete. The latest year for which FDA has complete cost data is FY 2011. Accordingly, FDA will adjust the FY 2011 incremental cost figure above by the average amount by which FDA's average salary and benefit costs increased in the 3 years prior to FY 2012, to adjust the FY 2011 amount for cost increases in FY 2012. That figure, published in the **Federal Register** notice on August 1, 2012 setting PDUFA fees for FY 2013, is 2.01 percent. Increasing the FY 2011 incremental priority review cost figure of $3,489,000 by 2.01 percent results in an estimated cost of $3,559,000 (rounded to the nearest thousand dollars). This is the priority review user fee amount for FY 2013 that must be submitted with a priority review voucher in FY 2013, in addition to any PDUFA fee that is required for such an application.

III. Priority Review Fee Schedule for FY 2013

The fee rate for FY 2013 is set out in Table 1 of this document:

TABLE 1—PRIORITY REVIEW SCHEDULE FOR FY 2013

Fee category	Fee rate for FY 2013
Applications Submitted With a Priority Review Voucher in Addition to the Normal PDUFA Fee	$3,559,000

IV. Implementation of Priority Review Fee

Under section 524(c)(4)(A) of the FD&C Act, the priority review user fee is due upon submission of the application for which the priority review voucher is used. Section 524(c)(4)(B) of the FD&C Act specifies that the application will be considered incomplete if the priority review user fee and all other applicable user fees are not paid in accordance with FDA payment procedures. FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section of the FD&C Act, and FDA may not collect priority review voucher fees prior to a relevant appropriation for fees for that FY. Beginning with FDA's appropriation for FY 2009, the annual appropriation language states specifically that ''priority review user fees authorized by 21 U.S.C. 360n (section 524 of the FD&C Act) may be credited to this account, to remain available until expended.'' (Pub. L. 111–8, Section 5, Division A, Title VI).

The priority review fee established in the new fee schedule must be paid for any application that is received after September 30, 2012, and submitted with a priority review voucher. This fee must be paid in addition to any other fee due under PDUFA. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. The user fee identification (ID) number should be included on the check, followed by the words ''Priority Review.'' Payments can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000.

If checks are sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (**Note:** This U.S. Bank address is for courier delivery only.) The FDA post office box number (P.O. Box 979107) must be written on the check. The tax identification number of the Food and Drug Administration is 53–0196965.

Wire transfer payments may also be used. Please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: 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 Dr., Rockville, MD 20850.

Dated: August 30, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–22587 Filed 9–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Food and Drug Administration/ American Glaucoma Society Workshop on the Validity, Reliability, and Usability of Glaucoma Imaging Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

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

public workshop entitled ''FDA/American Glaucoma Society (AGS) Workshop on the Validity, Reliability, and Usability of Glaucoma Imaging Devices.'' FDA is co-sponsoring the workshop together with the AGS, a nonprofit organization that supports glaucoma specialists and scientists through the advancement of education and research. The purpose of this public workshop is to provide a forum for discussing the validity, reliability, and usability of glaucoma imaging devices. The primary topic to be discussed relates to imaging of the posterior segment of the eye (e.g., retinal nerve fiber layer, optic nerve head, ganglion cell layer) using Optical Coherence Tomography (OCT, time domain and spectral domain), with particular emphasis on normative databases and the diagnostic performance of OCT for therapeutic glaucoma products (regulatory considerations) and clinical decision making (clinical practice considerations).

DATES: *Date and Time:* The public workshop will be held on October 5, 2012, from 8 a.m. until 5 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

Contact Person: Brad Cunningham, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993. Phone: 301–796–6620, FAX: 301–847–8126, email: *bradley.cunningham@fda.hhs.gov*.

Registration: AGS will charge a registration fee to cover its share of the expenses associated with the workshop. The registration fee is $200 for AGS members and $300 for non-AGS members. Registration is available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by September 17, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. the morning of the workshop (October 5, 2012). AGS will charge an on-site registration fee of $400.

If you need special accommodations due to a disability, please contact Ms. Cindy Garris at *Cynthia.Garris@fda.hhs.gov* or 301–796–5861, no later than September 17, 2012.

To register for the public workshop, please visit the AGS Web site at: *https://www.formstack.com/forms/?1237628-fpPvbj6eU2*. For more information on the workshop, please see the FDA's Medical Devices News & Events—Workshops & Conferences calendar at: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this meeting/public workshop from the posted events list.) Those interested in attending but unable to access the electronic registration should fax the PDF form on the AGS Web site (*http://www.americanglaucomasociety.net/client_data/files/2012/259_fdaagsworkshopregistrationform.pdf*) to 415–561–8531 to register. Please complete either the online registration form or the PDF form with the contact information for each attendee, including name, title, affiliation, address, email, and telephone number. If there are any questions with registration, please contact the AGS administrative offices at 415–561–8587. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Persons interested in viewing the webcast must register online by September 17, 2012. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after October 1, 2012. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm*. To get a quick overview of the Connect Pro program, visit *http://www.adobe.com/go/connectpro_overview*. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcript will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this public workshop from the posted events list.)

SUPPLEMENTARY INFORMATION:

I. Background

Advances in glaucoma diagnostic devices have been rapid, and these devices are of increasing importance in the diagnosis and clinical management of glaucoma. Device hardware is often upgraded and innovative software, such as measurement algorithms, image registration, and normative databases, is being added to existing hardware configurations. The optimal endpoints and strategies for assessing the safety and effectiveness of these new diagnostic tools in the management of glaucoma are unclear.

While there are several ophthalmic assessments (e.g., imaging, perimetry, tonometry, etc.) and ocular spaces (e.g., posterior segment, anterior chamber angle, etc.) relevant to the diagnosis and management of glaucoma, the primary topic of this workshop is the imaging of the posterior segment (e.g., retinal nerve fiber layer, optic nerve head, ganglion cell layer, etc.) with Optical Coherence Tomography (OCT, time domain and spectral domain).

II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to:

- Issues related to the use of OCT technology (time domain and spectral domain) in the diagnosis and treatment of glaucoma.
- Approaches to verify/validate new diagnostic technologies and their associated claims as well as factors that affect the quality of their images and measurements.
- Normative/reference databases and their impact on the diagnostic use of OCT devices.

Dated: September 5, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–22518 Filed 9–12–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Service Delivery Area Designation for the Mashpee Wampanoag Indian Tribe

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: This Notice advises the public that the Indian Health Service (IHS) established the geographic boundaries of the Service Delivery Area (SDA) for the newly recognized Mashpee Wampanoag Indian Tribe. The SDA was established on December 22, 2008 and services were provided to eligible beneficiaries beginning on January 19, 2009. The Mashpee SDA is comprised of Barnstable, Bristol, Norfolk, Plymouth and Suffolk counties in the State of Massachusetts. The counties listed are designated administratively as the SDA, to function as a Contract Health Service Delivery Area (CHSDA), for the purposes of operating a Contract Health Service (CHS) program pursuant to the Indian Self-Determination and Education Assistant Act (ISDEAA), Public Law 93–638.

DATES: This notice is effective 30 days after date of publication in the **Federal Register** (FR).

ADDRESSES: Comments may be mailed to Betty Gould, Regulations Officer, Indian Health Service, 801 Thompson Avenue, Suite 450, Rockville, Maryland 20852. Comments will be made available for public inspection at this address from 8:30 a.m. to 5 p.m. Monday–Friday beginning approximately two weeks after publication of this notice.

FOR FURTHER INFORMATION CONTACT: Carl Harper, Director, Office of Resource Access and Partnerships, Indian Health Service, 801 Thompson Avenue, Suite 360, Rockville, Maryland 20852. Telephone 301/443–2694 (This is not a toll free number).

SUPPLEMENTARY INFORMATION: The IHS currently provides services under regulations in effect on September 15, 1987 and IHS republished at 42 CFR part 136, Subparts A–C. Many of the newly recognized Tribes do not have reservations and either Congress has legislatively designated counties to serve as SDAs or the Director, IHS, exercised reasonable administrative discretion to designate SDAs to effectuate the intent of Congress for these Tribes. The Director, IHS, published notice of the establishment of SDAs in the June 21, 2007 FR Notice (72 FR 34262–01). The SDAs function as CHSDAs for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93–638. Thus, the CHSDA list incorporates the SDAs that operate as CHSDAs for newly recognized Tribes. At 42 CFR part 136 subpart C, a CHSDA is defined as the geographic area within which CHS will be made available by the IHS to members of an identified Indian community who reside in the area. Residence within a CHSDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12 creates no legal entitlement to contract health services but only potential eligibility for services. Services needed but not available at an IHS/Tribal facility are provided under the CHS program depending on the availability of funds, the person's relative medical priority, and the actual availability and accessibility of alternate resources in accordance with the regulations.

As applicable to the Tribes, these regulations provide that, unless otherwise designated, a CHSDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation (42 CFR 136.22(a)(6) (2007). In the **Federal Register** on February 22, 2007 (72 FR 8007), the Mashpee Wampanoag Indian Tribe was officially recognized as an Indian Tribe within the meaning of Federal law. After consultation with the Tribal governing body, the SDA for the Tribe was agreed upon. The purpose of this FR notice is to notify the public of the Mashpee Wampanoag Indian Tribe SDA to incorporate Barnstable, Bristol, Norfolk, Plymouth and Suffolk counties in the State of Massachusetts. The SDA was established on December 22, 2008 and services were provided to eligible beneficiaries beginning on January 19, 2009.

Under 42 CFR 136.23 those otherwise eligible Indians who do not reside on a reservation but reside within a CHSDA must be either members of the Tribe or maintain close economic and social ties with the Tribe. In this case, the Tribe estimated the eligible user population to be 1,422 enrolled Mashpee Wampanoag members who are actively involved with the Tribe.

The Mashpee Wampanoag Indian Tribe is located in the town of Mashpee, Barnstable County, Massachusetts, on the southeastern portion of Cape Cod along Nantucket Sound. A significant number of the Mashpee Wampanoag SDA eligible user population also reside in the counties of Bristol, Norfolk, Plymouth and Suffolk counties in the state of Massachusetts. These five counties are adjacent to each other. Barnstable, Bristol, Norfolk, Plymouth and Suffolk counties are not part of any other Tribe's CHSDA or SDA. It is important for the Mashpee Wampanoag Indian Tribe to be able to deliver health care services to enrolled members residing in these five counties. The Tribe believes eligible Tribal members living in the counties of the proposed SDA should also be eligible for CHS. The financial resources required to meet the immediate needs of the Tribal members residing in the five counties were determined by the IHS and were placed in the Nashville Area CHS budget. Since

This notice does not contain reporting or recordkeeping requirements subject to prior approval by the Office of Management and Budget under the Paperwork Reduction Act of 1980.

CONTRACT HEALTH SERVICE DELIVERY AREAS AND SERVICE DELIVERY AREAS

Tribe/reservation	County/state
Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona.	Pinal, AZ.
Alabama-Coushatta Tribes of Texas	Polk, TX.[1]
Alaska	Entire State.[2]
Arapahoe Tribe of the Wind River Reservation, Wyoming	Hot Springs, WY, Fremont, WY, Sublette, WY.
Aroostook Band of Micmac Indians of Maine	Aroostook, ME.[3]
Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana.	Daniels, MT, McCone, MT, Richland, MT, Roosevelt, MT, Sheridan, MT, Valley, MT.