Minutes from Stakeholder Meeting on MDUFA III Reauthorization, February 28, 2012

FDA (The Center for Devices and Radiological Health)

Minutes from Stakeholder Meeting on MDUFA III Reauthorization, February 28, 2012

Stakeholder Meeting on MDUFA III Reauthorization
February 28, 2012, 1:30 - 3:15 PM
HHS Humphrey Building, Washington, DC
Room 305A

Purpose

To provide a status update of the ongoing MDUFA III negotiations.

Participants

FDA

Malcolm Bertoni	Office of the Commissioner (OC)
Ashley Boam	Center for Devices and Radiological Health (CDRH)
Nathan Brown	Office of Chief Counsel (OCC)
Kate Cook	Center for Biologics Evaluation and Research (CBER)
Cynthia Garris	CDRH
Elizabeth Hillebrenner	CDRH
Toby Lowe	CDRH
Barbara Myklebust	CDRH
Barbara Zimmerman	CDRH

Stakeholders

Jason Barron	National Organization for Rare Disorders
Catherine A. Boudreaux	American Academy of Orthopaedic Surgeons
Paul Brown	National Research Center for Women & Families
Susan M. Campbell	WomenHeart: The National Coalition for Women with Heart Disease
Suzanne Henry	Consumers Union
Catherine Hill	American Association of Neurological

	Surgeons/ Congress of Neurological Surgeons
Jenny Liljeberg	American Society of Cataract and Refractive Surgery
Heidi Moline	Union of Concerned Scientists
Martha Nolan	Society for Women's Health Research
Kate Ryan	National Women's Health Network
Lisa Swirsky	Consumers Union
Melanie True-Hills	StopAfib.org
Cindy Tomlinson	American Society for Radiation Oncology
Mary Lee Watts	American Association for Cancer Research
Celia Wexler	Union of Concerned Scientists

Additional Registered Stakeholders

Cynthia Bens	Alliance for Aging Research
Michael Maroni	Alliance for Aging Research
Richard Martin	American Academy of Orthopaedic Surgeons

Meeting Start Time: 1:30 PM

Update on Negotiations

FDA reported that they have concluded negotiations with Industry. On February 17, 2012 they reached agreement with all four industry associations Industry on the final details of the fee structure and minor changes to the draft Commitment Letter and legislative language. The negotiated agreement is undergoing Administration review. Once cleared by the Administration, FDA will publish a summary of the agreement in a Federal Register (FR) Notice and post additional information on the FDA website. FDA will hold a public meeting very soon thereafter. Following a 30-day comment period beginning with publication of the FR Notice, FDA will consider all comments, make any changes if warranted, and then submit their formal recommendations to Congress through the Secretary. FDA will also brief Congressional committees.

FDA outlined several new or changed elements of the draft Commitment Letter since the update provided at the previous stakeholder meeting. FDA proposed and Industry agreed with a discretionary fee waiver provision that allows the Secretary, in the Secretary's discretion, to waive or reduce application and registration fees in the interest of public health. This is intended to be utilized if FDA changes its policy of enforcement discretion for laboratory developed tests (LDTs) during MDUFA III. Fee waivers are capped annually at 2% of the total fees, consistent with Dr. Shuren's recent statement at an Energy and Commerce subcommittee hearing that FDA's planned regulatory approach for LDTs would likely involve less than $3 million in annual costs. The provision will sunset at the end of MDUFA III.

As previously stated, both parties agreed on a program involving $595 million over 5 years before an inflation adjustor. The parties have now reached an agreement on

details of the fee structure. In general, application fees will increase by 2% over the fiscal year 2012 fees, before any inflation adjustment. Of note, 510(k) submission fees will increase slightly more as they will now be based on 2% of annual PMA fees rather than the current 1.84%. The bulk of the increase in revenue will come through establishment registration fees, which will rise from approximately $2400 to approximately $3900 before any inflation adjustment. The parties agreed that the annual inflation adjustor would be based on the rolling average of data from the previous three years, with 60% weighted towards payroll costs and benefits and 40% weighted towards the Consumer Price Index for the Washington, D.C. urban area.

Discussion

Stakeholders asked who FDA anticipates would attend the public meeting other than those represented in the monthly stakeholder meetings. FDA indicated they plan to actively reach out to all stakeholder groups in the same manner as was done for the September 2010 public meeting prior to negotiations. FDA also indicated they would invite stakeholders who participated in the monthly stakeholder meetings during negotiations to participate on panels. The meeting will also include initial statements from FDA leadership, an industry panel, and an open comment session for the general public. The meeting will be publicized via the FR Notice and anyone interested may register. Stakeholders asked if FDA plans to review comments from the public meeting and docket independently or with industry. FDA indicated they plan to conduct an initial review themselves. If FDA identifies comments that merit consideration of substantive changes to the package, FDA will meet with Industry to discuss such potential changes, with a goal of reaching agreement on a package both parties can support sending to Congress. FDA indicated that they believe the statute’s MDUFA reauthorization provisions governing negotiations would accommodate any additional discussions needed as a result of comments received.

Stakeholders asked approximately how many establishments exist. FDA replied that there are currently around 16,000 registered establishments who pay fees; however, some categories are currently exempted from fees. FDA noted that the MDUFA III agreement would eliminate exemptions. FDA estimates that this may increase the number of registered establishments paying fees by approximately 6,000. Due to uncertainty regarding the number of registered establishments and submission quantities, FDA and Industry agreed to an annual adjustment to the registration fees to avoid over- and under-collections; this might occur, for example, if the quantities of actual registrations varied significantly from the assumptions upon which the fee calculations were made.

Stakeholders asked for additional discussion of the performance goal structure. FDA explained that they have eliminated the two-tier structure in favor of single-tier goals. For example, currently 90% of 510(k)s must be reviewed in 90 days and 98% in 150 days. In the new goal structure, FDA will ramp up over the first half of MDUFA III to a single goal of completing review of 95% of 510(k)s within 90 days. Additionally, when goals are missed, FDA will communicate with the sponsor within 10 days for 510(k)s and 20 days for PMAs regarding issues precluding a decision,

and communicate with the sponsor regarding a plan for addressing them. The goal structure also includes interim substantive interaction goals which call for complete review and first interaction with a sponsor (if necessary) by 60 days for 510(k)s and by 90 days for PMAs. FDA noted that the Expedited PMA cohort was merged with the Original PMA cohort and that those PMAs requiring Advisory Panel review are now in a separate cohort. Both parties also agreed to a shared outcome goal for the average total time to decision, which involve a trimmed mean, eliminating the top and bottom 2% of 510(k)s and 5% of PMAs. Finally, this program institutes goals for review of CLIA waiver applications, which are consistent with PMA timeliness.

Stakeholders asked if the agreement articulates the conditions under which a device is reviewed by an Advisory Panel. FDA replied that such determinations are outside the scope of MDUFA negotiations. FDA will continue to follow the same regulations that outline when a device should be reviewed by Advisory Panel. In response to a follow-up question, FDA clarified the rationale behind the creation of a separate cohort for PMAs requiring Advisory Panel review. Specifically, in MDUFA II all original PMAs and panel track supplements were subject to the Tier 1 PMA goal of 60% and those that missed the Tier I goal would be subject to the Tier II goal. This was an implicit acknowledgment that approximately 30% of PMAs would be unable to meet the 180-day Tier 1 timeline because they would require Advisory Panel review (which also allowed an additional 10% of PMAs to slip to the Tier II timeline). While the intention was that most PMAs requiring Advisory Panel review would miss the Tier 1 goal but meet the Tier 2 goal, this proved a difficult process to manage. FDA believes that management of the review process will be more straightforward with separate cohorts, as expectations are clearly set with high-percentage goals for each cohort. In response to a stakeholder question, FDA clarified that there is no deadline for making a decision to bring a PMA to an Advisory Panel for review; however, they try to make this decision as soon as possible.

Stakeholders asked how many new FTEs will be hired under MDUFA III, noting an apparent disagreement between FDA and Industry over resource needs based on negotiation meeting minutes. FDA explained that inflation assumptions in MDUFA II were higher than experienced, resulting in slight under-spending and some additional available resources. FDA proposed to use these resources to hire 32 FTEs during fiscal year (FY) 2012 (i.e., the last year of MDUFA II) and proposed resources to maintain these FTE throughout MDUFA III. Industry agreed to this proposal, and also agreed to provide resources that would support hiring of 208 additional FTEs during the MDUFA III period. The total of 32 additional FTEs in the MDUFA II base moving into MDUFA III, plus the 208 new FTEs during MDUFA III, results in a total increase of 240 FTEs over current levels. Stakeholders asked where the new FTE would be allocated. FDA replied that they would be focussed on the premarket review offices, with the majority going to the CDRH Office of Device Evaluation (ODE) and Office of In-Vitro Diagnostics (OIVD). A small number of FTEs will be dedicated to the CDRH Office of the Center Director, CBER, and Office of the Commissioner. FDA noted that the definition of the process for device review in the Statute remains unchanged.

Stakeholders expressed concern that the resources Industry agreed to provide

under MDUFA III might not provide FDA a solid financial footing due to the small margin of error noted in the negotiation meeting minutes. FDA stated that they believe they can meet the performance goals with the resources that will be provided; however, first and foremost FDA is committed to its job to protect and promote public health. Stakeholders expressed concern that the agreement does not take into account legislative proposals currently under consideration in Congress that might increase FDA workload and burdens. FDA acknowledged that the Agency's ability to absorb the impact of any significant changes to workload is limited due to a smaller margin of error than initially proposed by FDA. Stakeholders requested additional information regarding the scaling back of program ambitions to meet the resource level Industry could agree to. FDA indicated this included removal of proposed performance goals for the pre-Submission process and additional funding for the 3 rd Party Review program.

Stakeholders asked how many types of fees exist under MDUFA II. FDA replied that MDUFA II includes application and establishment registration fees, just as MDUFA III will. Stakeholders also asked the percentage of the process covered by user fees. FDA replied that during MDUFA II user fees covered approximately 20% of the process, and during MDUFA III user fees are expected to cover approximately 35% of the process by FY 2017. In response to another stakeholder question, FDA confirmed that the definition of a small business remains the same.

Stakeholders questioned the status of Industry's proposal that FDA utilize a panel of outside experts. FDA stated that this proposal was not included in the agreement; however, the Center is piloting a different program to leverage input from outside experts as part of their strategic priorities. This program is called "Network of Experts". More information about this program can be found at: Network of Experts - Expert Utilization Standard Operating Procedure [1]. Stakeholders also asked for additional information regarding the commitments to engage patients in risk-benefit determinations. FDA explained that CDRH's strategic priorities included taking steps towards establishing a national forum for engaging with patients, consumers and health care professionals in a dialogue about issues of interest to them

Meeting End Time: 3:15 PM

SOURCE [2]

Links:
[1] http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm271521.htm
[2] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm295420.htm