Minutes from Stakeholder Meeting on MDUFA III Reauthorization, October 13, 2011

U.S. Food & Drug Administration

Stakeholder Meeting on MDUFA III Reauthorization
October 13, 2011, 1:30 - 3:10 PM
HHS Humphrey Building, Washington, DC
Room 425A

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)
Sharon Davis	Center for Devices and Radiological Health (CDRH)
Cindy Garris	CDRH
Toby Lowe	CDRH
Barbara Myklebust	CDRH
Thinh Nguyen	OC
Arleen Pinkos	CDRH
Ruth Watson	Office of Legislation (OL)
Nicole Wolanski	CDRH
Barbara Zimmerman	CDRH

Stakeholders

Cynthia Bens	Alliance for Aging Research
Paul Brown	National Research Center for Women & Families
Susan M. Campbell	WomenHeart: The National Coalition for Women with Heart Disease
Suzanne Henry	Consumers Union
Jeanie Kennedy	American Academy of Orthopedic Surgeons

Jenny Liljeberg	American Society of Cataract and Refractive Surgery
Heidi Moline	Union of Concerned Scientists
Rebecca O'Connor	Parkinson's Action Network
Kate Ryan	National Women's Health Network
Roslyne D. W. Schulman	American Hospital Association
Andrew Sperling	National Alliance on Mental Illness
Leslie Stevens	Society for Women's Health Research
Lisa Swirsky	Consumers Union
Cindy Tomlinson	American Society for Radiation Oncology
Additional Registered Stakeholders	
Pamela Bradley	American Association for Cancer Research
Campbell Hutton	Juvenile Diabetes Research Foundation
Beth Swickard	Alliance for BioTherapeutics

Meeting Start Time: 1:45 PM

Update on Negotiations

FDA reviewed the status of negotiations with Industry. At this time, the Agency is still working with Industry to reach agreement on a technical program. Both parties have traded several counter-proposals and are converging in some areas; however key topics such as quantitative goals for FDA review times and Industry's desire for total time goals remain unresolved as of early October. FDA believes a reduction in total time to decision would benefit public health, and the Agency is working with Industry to find a formulation that appropriately accounts for Industry's share of responsibility for improvements in a total time metric. FDA believes that reducing the number of review cycles would contribute to reduced total time to decision and that this could be accomplished by clarifying submission requirements up front and reviewing only submissions that pass a more rigorous and objective screening for adequate quality.

Industry's Counter-Proposal

On August 31, 2011 Industry offered a counter-proposal on scientific and regulatory review capacity, training, performance reports, and guidance document development. Specifically, Industry suggested that the Agency should reduce the ratio of staff to front-line supervisors prior to MDUFA III. FDA stated that a reorganization to achieve this could not be fully implemented without additional resources. Industry agreed to apply user fees to supplement managerial training as well as to provide all staff with training on changes under MDUFA III. Industry requested additional granularity in quarterly reporting throughout MDUFA III. Discussions are ongoing regarding what level of granularity is appropriate to balance the need to maintain the integrity of FDA's management responsibilities with their accountability to the public. In response to stakeholders' questions, FDA

explained that quarterly reports under MDUFA II are publicly available online and address FDA's performance against metrics outlined in the Commitment Letter. With respect to guidance document development, Industry suggested reallocated current resources to achieve improvements. FDA explained that the user fee reauthorization process is not the forum for redirecting budget authority appropriations.

There was a discussion of how lab developed tests (LDTs) will be handled under MDUFA III. The American Clinical Laboratory Association (ACLA) was invited to join negotiations because FDA had publicly announced its reconsideration of the current policy of enforcement discretion for LDTs, and ACLA represents the lab community that produces many LDTs. FDA has not yet published any draft guidance announcing a new policy. ACLA has proposed that LDTs be exempted from the requirements of MDUFA III regardless of whether FDA determines that they will regulate LDTs during this five-year period. This remains unresolved and must be addressed prior to conclusion of negotiations.

Subsequent Discussions

FDA explained that the parties have continued to try to work through the Commitment Letter language. Progress has been made in developing a structured Pre-Submission program which would be a means for companies to obtain clarification of submission requirements, interpretation of guidance documents, and answers to specific questions. The program would involve scheduling meetings in a specific timeframe, clear documentation of agreements, and compliance with agreements by both parties except when new information may materially affect safety and effectiveness. One important goal of this program is to reduce occasions in which companies must redo testing.

Another area under discussion is submission acceptance criteria. This would involve an initial review within a reasonable timeframe against objective criteria to determine if the submission is complete. If the submission is not complete, FDA would refuse to accept or file it without penalty on the review clock. This would incentivize applicants to submit complete submissions and assist FDA in meeting performance goals.

Substantive interaction goals are being discussed to ensure the FDA performs a complete review and identifies all major deficiencies by a specific time point in the middle of the review process such that sufficient time remains to work out remaining issues within the review goal timeline.

In place of the current two-tier goal structure, single tier goals are being considered that would apply to a higher percentage of submissions. If this single goal is missed, alternative mechanisms are being considered to incentivize its completion in a timely manner. FDA believes this will produce a more efficient use of resources and reduce times to decision.

There has been discussion of implementing new total time goals which include both FDA and applicant times. Based on current data, submissions with longer total times

tend to include a greater portion of industry time, often due to extensions that allow applicants to conduct additional testing or collect additional clinical data. To reduce total time to decision, it is important to reduce the number of review cycles and industry response time. FDA is concerned with committing to goals they cannot control; however, the Agency expects that commitments to procedures it can control, such as Pre-Submissions and substantive interactions, should result in a reduction in total time.

Discussion

Stakeholders asked if there is any intention to make binding agreements during 510(k) or PMA reviews indicating that FDA has everything they need and can proceed forward. FDA replied that there is currently a process to obtain binding agreements through formal Agreement Meetings. FDA intends to leave this process in place. Negotiation discussions have focussed on Pre-Submissions, which are not intended to be as formal as agreement meetings, but are intended to provide guidance and advice, on which the applicant can rely, relating to the type of information needed in a submission. FDA also explained that the substantive interaction goals under discussion are intended to ensure FDA provides a complete list of outstanding issues to the sponsor mid-review. Stakeholders commented that information may be revealed later that can materially affect safety and effectiveness. FDA indicated that neither party intends this new process to preclude consideration of such information. FDA also commented that better reviewer-to-supervisor ratios should minimize instances where information is missed in the first review cycle.

Stakeholders inquired as to application of user fees to postmarket work. FDA replied that it is difficult to obtain support for this given concerns among industry that issues with the premarket program have not been addressed adequately, but indicated that these issues are still under discussion in the negotiations. FDA noted that the 510(k) program, being based on substantial equivalence to predicate devices, creates a strong tie between substantial equivalence determinations and postmarket performance.

Stakeholders noted previous Industry concerns about uncertainty regarding the IOM report on 510(k)s and asked what impact its release has had on negotiations. FDA stated that they plan to publicize their complete response to the report in a matter of weeks, and that the Agency has already indicated that they do not plan to eliminate the 510(k) program. Stakeholders indicated their disappointment that the August 9, 2011 negotiation meeting minutes did not reflect any indication that FDA planned to implement the seven recommendations that were referred to IOM. Stakeholders believe these recommendations reflect important safety issues. FDA acknowledged stakeholders’ views and indicated that these topics will be addressed in FDA’s formal response, which is forthcoming.

Stakeholders inquired about FDA’s financial discussions with Industry. FDA explained that they can not accomplish process improvements without increases in technical review staff, managers, and operating dollars to support training and other provisions in the draft Commitment Letter. In response to inquiries, FDA

stated their commitment to maintaining review standards. Stakeholders predicted that budget authority appropriations could be tight for the Agency. FDA has conducted studies to evaluate how they can improve efficiency and productivity and commented that new practices, such as better reviewer-to-supervisor ratios, require investment. Stakeholders asked about the resources needed to support the Commitment Letter under discussion, and the likelihood that Industry and FDA would be able to reach agreement on user fee revenues. FDA explained that the current program under discussion would likely require more resources than the program initially proposed by FDA in April.

Stakeholders expressed their dissatisfaction with Industry's proposal to pay user fees for FDA to leverage external experts rather than hire additional staff. FDA explained that internal work such as the Network of Experts is outside the scope of user fee negotiations, but that the Third Party review program has been discussed with Industry. FDA has found such discussions to be constructive as Industry has put forward ideas for improving the Third Party review program, but the required resources have not yet been discussed. FDA confirmed for stakeholders that they will maintain sign-off authority on all Third Party reviews.

Stakeholders asked when FDA believes final agreement will be reached. FDA noted pressure from their leadership and the Department to accelerate the process with the hope of soon reaching a draft agreement that will be beneficial for FDA, Industry, and patients. Stakeholders also asked if FDA was under pressure from Congressional committees regarding their timeline. FDA replied that Congress established a process and a target deadline in the Statute; FDA continues to work toward that deadline, although each passing day without an agreement makes that goal more challenging.

Meeting End Time: 3:10 PM

SOURCE [1]

Links:
[1] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm280351.htm