LifeScience Alley®

August 12, 2015

On behalf of our nearly 700 member organizations and the more than 250,000 employees representing Minnesota's Medical Alley, LifeScience Alley is thankful for the opportunity to comment on the upcoming MDUFA IV negotiations.

The "Medical Alley" of Minnesota represents the most densely concentrated medical technology cluster in the world and has a rich history of producing some of the world's greatest health technology and health care innovations.

LifeScience Alley is looking forward to the upcoming MDUFA IV negotiations. MDUFA is an important foundation of the medical device industry's partnership with the FDA and we hope that the next stages of the negotiation process will encourage increased improvement in the consistency and predictability of medical device reviews.

MDUFA III was a substantial improvement over the previous medical device user fee agreement and it laid the groundwork for significantly improved performance through increased accountability, more meaningful goals, important process improvements, better metrics and additional resources. We appreciated being a part of the discussion then and hope we can offer strong suggestions and perspective in the upcoming negotiations.

We urge you to address several areas of concern for our members:

- Review Timetables: Although we have experienced improvement since the last user fees reauthorization, review times continue to lag the era of reviews preceding the user fee program. For U.S. device manufacturers to innovate, deliver new therapies to the patients who need them, and maintain a shrinking competitive advantage, improvement in review timetables is paramount. *We urge the FDA to make review timetables, consistency and predictability a highest priority and to implement the changes necessary for rapid improvement.*
- Reviewer Consistency: LifeScience Alley members continue to work with FDA reviewers who have a wide and varying range of training and expertise, adding significantly to inconsistent and unpredictable experiences. Because the FDA reviewer plays such a critical role in the outcome and accuracy of a review, this is a key area for improvement. *We urge the FDA to improve the consistency of reviews by implementing strategies that will ensure the highest level of competency among all reviewers.*
- Staff Turnover: While employee retention is an issue that affects many organizations, it is particularly important for FDA to improve staff retention to ensure consistency and build increased experience within the agency. *We encourage the FDA to continue to identify best practices to enhance employee retention and minimize staff turnover, with a focus on the retention of experienced reviewers.*

LifeScience Alley’s comments and suggestions are the product of the collective experiences of our members and includes the inconsistencies outlined here. This variation and the harmful impact it can have on predictability and consistency was highlighted in the 2014 Booz Allen Hamilton "Independent Assessment of FDA Device Review Process Management" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM400676.pdf) ***We urge FDA to act on the recommendations contained in this report.***

We sincerely hope that you recognize the value and impact these provisions can have on improving and saving lives, while moving our economy forward.

Thank you for the opportunity to comment on the upcoming MDUFA negotiation process. We look forward to working with you now and in the future.

Sincerely,

Shaye Mandle
President & CEO
LifeScience Alley