U.S. FOOD & DRUG ADMINISTRATION

NEW DRUGS REGULATORY PROGRAM MODERNIZATION:

IMPLEMENTATION OF THE INTEGRATED ASSESSMENT OF MARKETING APPLICATIONS

A VIRTUAL PUBLIC WORKSHOP

OCTOBER 30, 2020 | 9:00 AM – 3:00 PM | VIA WEBCAST ONLY

LUNCH: 12:15 PM – 1:30 PM

Please remember to rejoin us at 1:30 for the FDA perspective panel

FDA Perspective: Integrated Assessment Panel – Experience with the Integrated Assessment

1:30 PM – 2:45 PM

Moderated by

Yoni Tyberg, MS, PMP

Acting Team Leader of Special Programs Staff, Office of New Drugs

FDA Perspective: Integrated Assessment Panel – Experience with the Integrated Assessment

Moderator:

Yoni Tyberg, MS, PMP

Panelists:

Sarah Connelly, MD

John Farley, MD, MPH

Kerry Jo Lee, MD

Stephanie Leuenroth-Quinn, PhD

Jinzhong Liu, PhD

Jennifer Mercier

Florence Moore, MS, PhD

Kellie Schoolar Reynolds, PharmD

Lisa Skarupa, MSN

Kimberly Struble, PharmD

Aliza Thompson, MD

Therri Usher, PhD

Concluding Remarks and What's Next

2:45 PM – 3:00 PM

Kevin Bugin, MS, PhDc, RAC
OND Director of Special Programs, US FDA

First of all, today was a huge success!

Success was in large part thanks to all of you!

- Thanks to those who joined the FDA today to provide feedback, be on panels, ask questions in the chat and share comments to the docket and previous dockets – we treasure the feedback, consider it, and as we learned today, really do use it!

- Thank you to all the workshop organizers and members from the workstream who have made this day possible

Recap: Welcome & Introduction to the Modernization

- NDRP Modernization's goal is to build on past successes and strengths by implementing problem-focused, interdisciplinary, team-based approaches.
- Six core Modernization strategic objectives include: scientific leadership, integrated assessment, benefit-risk monitoring, managing talent, operational excellence, and knowledge management.
- The Integrated Assessment initiative includes development of a new approach to the assessment of new drug product applications.

Recap: Rationale for Development & Core Design Features

- The new Integrated Assessment approach starts with early identification of key issues and focuses on 3 guiding principles: enhanced communication, interdisciplinary collaboration, and issue-based reviews.
- The Integrated Review Template is a three-part document consisting of the Executive Summary, Interdisciplinary Assessment, and Appendices.
- The Integrated Assessment retains scientific differences of opinion and Equal Voice through both the process (interdisciplinary meetings) and the template (documentation of scientific differences of opinion reside in the Executive Summary, the review issues section of the Interdisciplinary Assessment, and Appendices when necessary).
- The action package is distinct and separate from the Integrated Review document; however, the Integrated Review document is included within the streamlined action package.

Recap: Implementation

- 17 Divisions have been introduced to the Integrated Assessment for NMEs and BLAs with the goal of expanding the scope of marketing applications over time.
- Phased implementation has allowed an iterative approach through evaluation, feedback, and responsive refinement of the process and template.
- Internal assessment of completed Integrated Reviews is ongoing to ensure that the Integrated Review documents meet the needs of our stakeholders.

Recap: External Feedback: Synthesis & Emerging Themes

- FDA requested public comment on the Integrated Review Template in 2019 and 2020 to gather feedback on how the Integrated Review documentation can continue supporting our stakeholders' needs.
- Respondents included scientists, academics, industry, patient advocacy groups, and individuals.
- FDA has actively worked to address feedback and continues to monitor the synthesized concerns and benefits expressed by external stakeholder respondents.

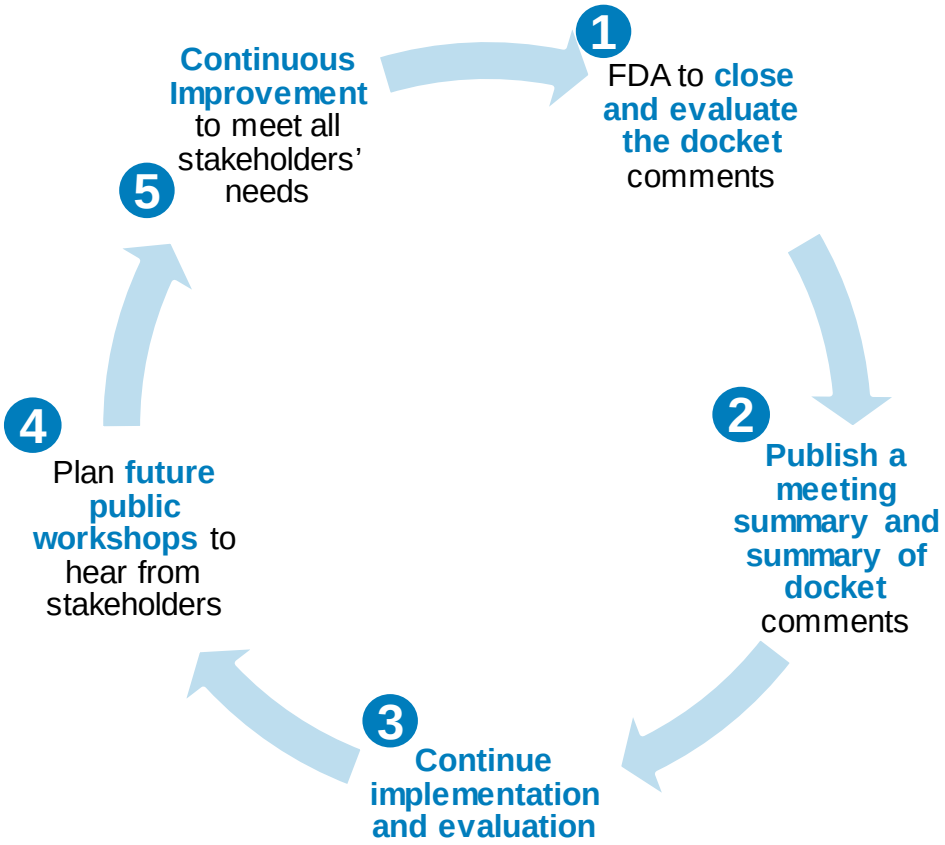
Recap: External Stakeholder Perspectives (Panel)

- FDA reviews used by diverse stakeholders encompassing industry, patient advocacy organizations, researchers, scientific journals, professional societies
- Provides clearer rationale for regulatory decisions and communication of key review issues identified during the application review
- Represents an opportunity to make information more available and accessible
- Some key recommendations:
  - *Inclusion of information regarding development program issues or to address expected redactions*
  - *Transparency on disagreements and independence for reviewers to document their assessments*
  - *Patient's perspective/experience data and how it was considered in the Benefit-Risk Assessment*
  - *Further incorporate information pertaining to exclusivity, review designation, and other details useful to inform clinical practice*
  - *Facilitate accessibility of information to researchers and patients (e.g., improved document navigation, methodological approach to analyses, and patient friendly / plain language enhancements)*

Recap: FDA Stakeholder Perspectives (Panel)

- Benefit of increased leadership engagement throughout the review process
- Increased collaboration in the process and documentation has been a positive outcome
- The increase in collaboration takes more time and effort, and there is a learning curve, especially with collaborative writing
- New review team roles i.e. CDS and ME have been very beneficial to the review team
- Less overall writing, but more intentional writing; less redundancy and more time for critical thinking in the writing
- Appreciated the very hands on support from the implementation team and the patience to take a phased approach
- Acknowledge good examples and build into training and resources
- Looking forward to expanding the IA across OND and to other application types

What's next?



- A recording of the workshop will be made available shortly after today
- A transcript will be made available 60-90 days
- Unanswered questions will be responded to in the meeting summary
- Docket is open until December 31, 2020 and we intend to respond via the meeting summary from today's workshop

Thanks again… and

Happy Halloween!

Halloween Food Safety Tips for Parents
Halloween Advice from CDC

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Thank you for joining us!

The Federal Register Notice will remain open for comment and question through December 31, 2020