GDUFA III Negotiations - Update

Industry priorities – four core areas of focus

1. Advancing Approvals
   a. Imminent Action
   b. Use of Mid-cycle Division Review Letters (DRLs)
   c. Use of Information Requests (IRs) & DRLs
   d. Pre-Submission Facility Correspondence (PFC)
2. Establishing a Sound Foundation
   a. Resource Capacity Planning Adjustor
   b. Operating Reserve Adjustment
   c. Revision of Inflation Adjustor
   d. Revise Section 905 of FDARA
3. Inspections
   a. Meeting Following Issuance of Warning Letter (WL)
   b. Reinspection of a Facility Following a WL or Official Action Indicated (OAI)
   c. Partial Release of WL
   d. Reclassification of Major due to Facility
   e. Predictability in Inspection Schedule
4. Complex Generics
   a. Product Development Meeting and Pre-Submission Meeting
   b. Mid-Review Cycle Meeting
   c. Improvements to the Post-Complete Response Letter (CRL) meetings/T-cons
   d. Process Improvements for the Product-Specific Guidances

aam
Association for Accessible Medicines

GDUFA III Negotiations - Timeline

- September 17, 2020 through May/June 2021 – Active negotiations
- May/June 2021 through July 2021 – Finalize Commitment Letter
- July 2021 through November 2021 – FDA ratifies the UFA Packet
- November 2021 FDA Public Meeting – UFA Packet
- January 2, 2022 – FDA submits the UFA Packet to Congress
- January 2022 through August 2022 Congress legislates User Fees
- September 2022 – User Fee Legislation submitted to the President
- October 1, 2022 – User Fees are implemented

FDA Inspections During COVID – An Update

- Foreign inspections are on hold except for;
  - India and China where FDA has in-country inspectors – these inspectors have returned to their respective country but there are limited inspectors compared to the inspectional need,
  - Mission Critical inspections – see Page 4 of the January 29, 2021 updated Guidance → ***Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers,***
  - Mutual Recognition Authority (MRA),
  - Section 704(a)(4) → Allows FDA to request, in advance of or in lieu of an inspection – also referred to as 'paper inspections.'
- Virtual Inspections;
  - AAM raised this point with the FDA at the January 26, 2021 and their response continues to be – 'we don't do virtual inspection',
  - FDA's primary response as to why they don't presently conduct virtual inspections is that industry doesn't have, nor has the FDA developed Guidance that sets specific criteria and specifications for → acceptable types of equipment – camera optics, pixel rating, etc. Thus, a virtual inspection in one company's facility will likely not be equivalent to others.

BsUFA III Timeline

- November 19, 2020 → Public Meeting to kick-off BsUFA III
- December 10, 2020 → Initial Planning Meeting with FDA
  - The purpose of this meeting was to discuss the timeline and logistics regarding an initial meeting between FDA and industry for BsUFA III negotiations.
- January 26, 2021 → BC provided a statement during the BsUFA II Public Meeting – on the ***Interim Assessment of the BsUFA II Program***
- January 29, 2021 → Initial Meeting between FDA & Industry associations (AAM/BC, BIO, Forum, PhRMA) to begin collaborative strategy sessions
- March 2021 (tentatively set for March 9th) → Commencement of the BsUFA III negotiations

Additional Updates

- Nitrosamines
  - AAM White Paper Submitted to FDA
  - AAM Working with PhRMA & CHPA – Cross Industry Influence
  - IGBA Science Committee Working Group – AAM, CGPA, IPA, Medicines for Europe
- Quality Metrics
  - Quality Metrics Principles
    - FDA Must Operate Within the Bounds of New and Clear Statutory Authority
    - Quality Metrics Data Must be Collectible and Participation Must be Feasible
    - Quality Metrics Must be Validated and Correlated to FDA's Goals
    - Quality Metrics Must be Normalized by Product Type and Product Risk
    - Quality Metrics Must Not Create Perverse Incentives
  - Possible Quality Metrics
    - Lot Acceptance Rate
    - Product Quality Complaint Rate
    - Invalidated Out-of-Specification OOS Rate (IOOSR)