OMUFA Progress Meeting (via Zoom)

June 6, 2023

3:00-4:00 pm

Agenda:

- **Introductions**
- **FDA Updates**
- **Industry Updates**
- **Questions for Industry**
- **Industry Questions**

Participants:

FDA		Industry	
Theresa Michele	CDER (OND)	Barbara Kochanowski	CHPA
Celia Peacock	CDER (OND)	Lisa Parks	CHPA
Dan Brum	CDER (OND)	David Spangler	CHPA
Phong Pham	CDER (OND)	Lauren Quinn	CHPA (Haleon)
Carol Bennett	CDER (ORP)	James Kim	CHPA (ACI)
Michael Bernstein	CDER (ORP)		
Anuj Shah	CDER (ORP)		
Andrea Frydl	CDER (OCOMM)		
Matthew Brancazio	CDER (DUFM)		
Grace Carmouze	CDER (OEP)		

- **Introductions**
    - Welcome, Lisa Parks (CHPA)
    - Welcome, Andrea Frydl (FDA)

- **FDA Updates**
    - Scheduling of monograph meetings
        - Meeting management performance goals compliance at 100% for monograph meetings received after October 1, 2022.
    - Guidances
        - Draft Meetings guidance
            - Posted February 1, 2022.
            - Comment period is closed.
            - FDA working toward final guidance.
        - Electronic submission draft guidance

        - Posted September 27, 2022.
        - Comment period is closed.
        - Working toward final guidance.

    - Content and format draft guidance
        - Posted April 13, 2023.
        - Comment period open until June 12, 2023.

    - Consolidated proceedings/dispute resolution draft guidance
        - Guidance is in clearance.

    - Solid oral dosage forms
        - Progress is ongoing.
        - Candy-like dosage forms workshop to be announced soon.

- User fees:
    - FRN posted on March 24, 2023.

- Deemed Final Orders
    - Complete.
    - FDA issuing FRN to withdraw corresponding federal regulations.
        - FDA will keep links to Federal Register notices with historical information for reference.
        - FDA will plan to add an FAQ about Category 3 ingredients to the website.

- IT Update
    - CDER NexGen Portal went live on October 3, 2022, for monograph meeting requests; sponsors/requestors are successfully using the portal to request meetings and MGF numbers.
    - OTC Monographs @ FDA permanent system also went live on October 3, 2022.

- Hiring Update
    - Recruitment ongoing.

- Cataloguing Paper Documents
    - FDA awarded contract on Feb 2, 2023.
    - FDA working with contractor to sort and catalogue documents.

- **FDA Questions for CHPA**

    - Any feedback on use of the new IT system for monograph meeting submission?
        - CHPA reports overall feedback has been positive with some issues that were quickly addressed with FDA support team.

- **CHPA Questions for FDA**

    - What is the timeline for OMUFA II?
        - FDA and CHPA discussed the upcoming meetings planned for OMUFA II negotiations.

    - Would FDA please add a Q&A about Category 3 ingredients in general to the website, explaining why they no longer appear in final orders and clarifying marketing status?
        - FDA will plan to add a Q&A to the website about Category 3 ingredients.

    - How do we submit a report that is not being submitted as part of a meeting request (should it be sent directly to the RPM or through the NextGen Portal)?
        - FDA investigating options. Industry may contact the RPM and ask what to do in specific situations.

    - Progress on annual forecast/What is FDA's plan to make progress against nonGRASE (formerly Cat 3) ingredients?
        - DFOs are now complete setting the stage for ongoing work.
        - FDA plans to provide progress updates in its annual forecast.

    - How can stakeholders find "formerly Cat 3" ingredients now that they have been omitted from the final AOs?
        - FDA clarified that even pre-OTC Reform Category 3 ingredients were not part of the final monographs, and they were never included in the DFOs; therefore, it is not accurate to describe them as now being omitted. DFOs are now available and relevant historical rulemaking discussing the former Category 3 ingredients (now addressed under 505G(a)(3)) will remain available in the Federal Register. FDA is also retaining its website representing the status of OTC rulemakings prior to the enactment of the CARES Act (e.g., before March 27, 2020) for historical reference only.