Industry Update

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AMDM 2023 IVD Focus Meeting

Agenda

- Key Developments in the last year
- Industry-wide trends
- Looking ahead to 2023 and beyond

Key Developments

- Rules
  - Proposed LDT Rule (Oct. 2023)
- Important IVD-specific draft and final guidance documents
  - Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program (June 2023)
- Also several Center-wide guidances
  - Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission (September 2023)
  - Content of Premarket Submissions for Device Software Functions (June 2023)
  - Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions (Draft April 2023)
  - Content of Human Factors Information in Medical Device Marketing Submissions (Draft December 2022)

Key Developments

- eSTAR
  - 510(k) electronic submission template became mandatory October 1, 2023
    - IVD specific template
  - De novo electronic submission template published
  - Pilot pre-sub template

- Customer Collaboration Portal
  - Track 510(k)s and Pre-submissions now
  - File any premarket submission via direct upload

Key Developments

- FTC Health Products Compliance Guidance (Dec. 2022)
  - Applies to *in vitro* diagnostics (including LDTs)
  - Provides guidance on how to ensure claims are truthful, not misleading, and adequately substantiated

- Notable FDA "enforcement actions"
  - Largely still focused on COVID (e.g., Empowered Diagnostics LLC in Oct. 2022)
  - Abbott Point of Care Canada Limited (Nov. 2022) – assay design changes
  - Abiomed Warning Letter (Sept. 2023) – MDDS insights

Trends

- MDUFA V – sees submissions running closer to “on time”
- Limitations on pre-submission questions
  - Requesting multiple pre-submissions
- Continue to see a more “routine” level of IHTOA letters
  - Many still focused on collection devices
- At home testing challenges
  - No longer granting clearances for general collection devices
  - Relying on older materials
  - Important to know regulatory status of collection materials

Looking Ahead

- End of the COVID-19 Public Health Emergency
  - Public Health Emergency ended (May 2023) but 564 Order is still in effect
  - 564 Orders will be individually terminated by the Secretary of HHS
  - Final guidance with transition plan issued in March 2023, but won't take effect until 564 Orders are terminated

- Proposed LDT Rule
  - Likelihood of litigation
  - Timing
  - Commenting
  - What can companies do now?

Questions & Discussion

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