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GENERIC DRUG ASSESSMENT COMMUNICATION MECHANISMS AND STRATEGIES TO FACILITATE TIMELY APPROVAL PART 2

AGENDA

The Agency recognizes Industry's need for Information

Transparency (Comms) pilot

Overview of the pilot, purpose and objective

Relevant Statistics

Current Success and evolution

Other communication vehicles/mechanisms

IR/DRLs/CRs

Information is key

Agency recognizes the need for timely information

- Our goals are aligned
- Transparency and gold standard science

Transparency pilot

- Developed to assist industry

Standard Communication Mechanisms

Transparency Pilot

Purpose/Objective: Initiative to convey more information when complicated Regulatory/Scientific issues arise

- Considerations/elements incorporated into information conveyed
  - Has the information been shared publicly
  - Potentially affected discipline/s
  - Specific to this ANDA or all ANDAs for a given RLD
  - Do we need more information from the applicant
  - Timing of Resolution

Please note not all situations are applicable or appropriate and in some situations the underlying issue cannot yet be disclosed

Transparency Pilot Continued

- At what point is it utilized (broadened from 60 day misses)
  - When goal dates will likely be missed due to a complicated issue
    - Not applicable for other types of situations where the goal date may be missed but imminent action may be possible: RLD updates, missing required documentation (example: receipt notices), Earliest Lawful Approval Date within 60 days of the goal date
  - Status inquires/updates provided by the Regulatory Project Manger
- Additional feature
  - Frequent touchpoints and escalation

Transparency Pilot Continued

Details

Started circa 10/2024 through present

Used across approximately 50 applications

Majority Categories:

Scientific (complex formulation issues), Data Integrity and Impurities

Successes

External: Positive feedback from Industry

Internal: Multiple stakeholder engagement to vet/clear communication

Cautionary

Agency initiated

Please keep communications channeled through RPM and limit multiple inquires to different points of contacts on same issue

Standard Communication Mechanisms

Complete Responses:

21 CFR 314.110

Amendments Guidance

GDUFA III commitment letter

IRs/DRLs

IR/DRL Guidance

GDUFA III commitment letter

Meetings

Post CRL, Post CRL Scientific, MCRM, EMCRM, RFRs, Pre ANDA, Control Correspondence

IR (Information Request)/DRL (Discipline Review Letter)/CR (Complete Response)

High level Definitions

- CR- reflects a complete assessment
- IR- Agency needs further information
- DRL-preliminary thoughts on possible deficiencies

Agency goal to limit use of CRs and utilize IRs/DRLs

- Disclaimer: the Agency will issue CRs when appropriate
- Deficiencies are commensurate and cannot be resolved via IRs
- Example: multiple disciplines still outstanding/ facility issues

Extensions From IRs/DRLs

The Agency aims to issue IRs/DRLs by the midpoint which will not extend the clock

- Unless there are major deficiencies in the ANDA and/or amendments contained unsolicited information which would extend

After midcycle late cycle IRs may be issued

- They may extend/not extend or be deferred

Above provisions outlined in GDUFA III Commitment Letter

Summary

FDA works hard to complete assessments by the original goal dates---OGD Primary Objective

FDA often utilizes extensions for Approval (AP)/ Tentative Approval (TA) during a cycle

Late cycle extensions often triggered by other events (multiple requests, Drug Master Files, labeling updates)

Conclusion

The Agency is committed to providing as much information as possible in a timely manner

GDUFA III provided multiple tools and mechanisms of enhanced communication, and we will continue to build upon this success with subsequent negotiations

First cycle approval is a common goal but also a TEAM EFFORT


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