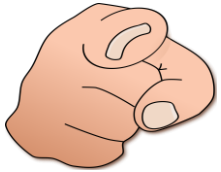
FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Regulatory Project Managers: What We Do and the Changes Coming for You



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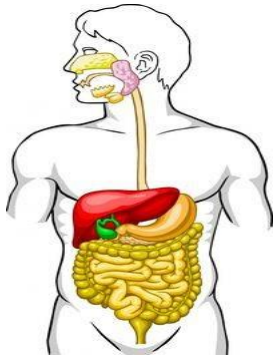
Division of Gastroenterology and Inborn Errors Products (DGIEP)

- Center for Drug Evaluations and Research (CDER)
  - Office of New Drugs (OND)
    - Office of Drug Evaluation III (ODE III)
      - Dr. Julie Beitz, Director
        - DGIEP
          - Dr. Donna Griebel, Division Director
          - Dr. Dragos Roman, Associate Director
          - Dr. Joyce Korvick, Deputy Director of Safety
          - Joette Meyer, Associate Director for Labeling



DGIEP Staff

- Clinical Reviewers
- Nonclinical Reviewers
- Regulatory Project Managers (RPM)
- Administrative Staff

Roles of a RPM

- Identify, coordinate, integrate, and schedule all activities required to complete the review of regulatory submissions
- Prepare essential documentation, coordinate all reviews and critical support activities, and monitor progress toward review performance goals
- Clarify regulatory issues and are present during communications between reviewers and the sponsor
- Prepare timelines and obtain team member commitment to milestones and target dates
- Ensure that all outgoing correspondence is consistent with laws and regulations

Prescription Drug User Fee Act (PDUFA)

- Origination (1992)
  - Reauthorization of the Prescription Drug User Fee Act (PDUFA) every 5 years

- July 9, 2012-Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144)

PDUFA V and PDUFA VI Goals Letter

- PDUFA V (2013-2017)
  - ✓ https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf
- PDUFA VI (2018-2022)
  - ✓ http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf
    - ✓ As of April 18, 2017, PDUFA VI has not passed legislation; therefore, the information in the PDUFA VI goals letter is only proposed at this time.

PDUFA V AND PDUFA VI Applications

- **Timelines-No changes** for NDA, Class 1 &2 resubmissions, Efficacy and Manufacturing Supplements submissions.
  - "The Program"-New Molecular Entity (NME) will remain
    - *Assessment of the Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs in PDUFA V-* *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM532647.pdf*

Meeting Sequence

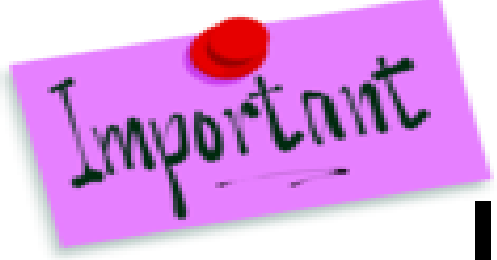
- Sponsor sends requests
  - Grant or Deny
  - FDA schedules, if granted
- Letter
  - Meeting date/finalized written responses date
  - Backgrounder due date
- Sponsor sends backgrounder
- Meeting held
- Meeting Minutes or Written Response issued

PDUFA V AND PDUFA VI Meetings

Meeting Type *Any type sponsor can request written responses (WR) 	Response Time (Calendar days)	Meeting Scheduling or Written Responses	Background Package (BP) Due to FDA
A	14	30	With request
B	21	60	30 days prior to meeting/WR
B(End of Phase)	14	70	50 days prior to meeting/WR
C	21	75	47 days prior to meeting/WR *new surrogate endpoint primary basis of approval, BP due at time of request

PDUFA V AND PDUFA VI Meetings (cont'd)

FDA Preliminary Responses	Sponsor Response	Meeting Minutes
 **No later than 5 days** prior to Type B(EOP) and C meetings.	**No later than 3 days** to respond	**30 days**



Important Notes

- **Meeting Times**
- **Submissions to FDA**
  - ✓ Electronic (Electronic Common Technical Document (eCTD)
    - 5/5/17:NDA, ANDA, BLA, Master Files
    - 5/5/18: Commercial IND
  - ✓ Paper
    - Investigator-sponsored IND

Refer to eCTD Guidance for more information: http://www.fda.gov/ectd

Important Notes (cont'd)

- **Protocol Review**
  - ✓Clean and Track-change version requested
- **Secure Email**
  - ✓SecureEmail@fda.hhs.gov.

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I am here for you!


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