U.S. FOOD & DRUG ADMINISTRATION

Components of New Drug Application and Biologics License Application

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OND | CDER

Learning Objectives

- Review application approval pathways
- Discuss content and format of an application
- Review forms and documentation with examples on best practices related to Module I

Brief Regulatory Background

- First federal consumer protection law: 1906 Pure Food and Drugs Act
- 1938 Foods, Drugs and Cosmetic Act:
  - tightened the control for food and drugs
  - included new consumer protection against unlawful cosmetics and medical devices
  - enhanced the government's ability to enforce the law
- In 1962, Amendment to FD&C act (Kefauver-Harris amendment) required drug manufacturers to prove that a medication was not only safe, but effective

Regulatory Background (cont.)

- The Drug Price Competition and Patent Term Restoration Act of 1984, (Hatch-Waxman Amendments,) established the approval pathway for generic drug products, abbreviated new drug application (ANDA) under section 505(j) of FD&C Act.
- The Prescription Drug User Fee Act (PDUFA) was created by Congress in 1992 and authorized Food and Drug Administration to collect user fees for certain human drug and biological products
- PDUFA must be reauthorized every five years
- PDUFA VI reauthorized from 2018 through 2022

Application Regulatory Pathways

- New Drug Applications (NDA):
  - Section 505(b)(1)
  - Section 505(b)(2)
  - Section 505(j) Abbreviated New Drug Application (*ANDA)*
- Biological License Applications (BLA):
  - Licensed under Public Health Service Act, Sections 351(a) , also regulated under FD&C act
  - Public Health Service Act, Sections 351(k) *Biosimilars*

NDA Regulatory Pathways (cont.)

FDA

505(b)(1) Applications

- An application that contains full reports of investigations of safety and effectiveness (FD&C Act, Section 505(b)(1))
- The applicant either owns or has a right of reference to all the information needed to support approval

NDA Regulatory Pathways (cont.)

505 (b)(2) Applications:

- Contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the Applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted
- Typically rely upon:
  - the Agency's findings of safety and effectiveness for listed drug(s)
  - literature

NDA Regulatory Pathways (cont.)

505(j) Applications (Abbreviated New Drug Application (ANDA))

- Contains information to show that the proposed product is equivalent to a previously approved product (FD&C Act, Section 505(j))
- Rely upon a previously approved drug that is Reference Listed Drug (RLD) in the Orange Book
- Should be bioequivalent to the (RLD)

Draft guidance for Industry, Determining Whether to Submit an ANDA or a 505 (b)(2) Application :https://www.fda.gov/media/122522/download

Biologics Approval Pathways

- BLA approval: the product, the manufacturing process, and the manufacturing facilities meet applicable requirements to ensure the continued safety, purity and potency of the product.
  - Approval= Issuance of license
  - Therapeutic biological products that CDER regulates, include:
    - Monoclonal antibodies for *in vivo* use
    - Proteins intended for therapeutic use, extracted from plants/animals/microorganisms, including recombinant versions (except clotting factors)
      - » Cytokines, growth factors, enzymes, immunomodulators; and thrombolytics
    - Other non-vaccine therapeutic immunotherapies

- Abbreviated Licensure Pathway (Biosimilars) should be
  - highly similar to the reference product and interchangeable (can be expected to produce the same clinical result as the reference product)

Approval Pathways (cont.)

- Over the counter (OTC) drugs can use NDA pathways or can be approved under final OTC Monograph
- Medical Gas Application (Section 575 and 576, FD&C Act)
  - For medicinal use of human & animals
  - Not considered PDUFA applications
  - Managed by Office of Process and Regulatory Operations (OPRO) under Office of Pharmaceutical Quality

Draft guidance for industry – Certification Process for Designated Medical Gases
https://www.fda.gov/media/70973/download

NDA vs. BLA

NDA	BLA
• Product should be safe and effective • 505(b)(1) approval pathway • 505(b)(2) approval pathway • 505(j) approval pathway • Detailed 314 regulations (as compared to 601 regulations) • Orange Book: lists approved drug Products under NDA and ANDA • Withdrawal effective the date published in Federal Register notice	• Product should be safe, pure, and potent and the facility(ies) meet standards to be safe, pure, and potent • §351(a) BLA licensure pathway • §351(k) BLA licensure pathway • Specific U.S. License number • Purple Book: Lists biological products (including biosimilar and interchangeable products) licensed by FDA • BLA is withdrawn, once the revocation letter is issued

Content and Format

- 21 CFR 314.50 for NDA
- 21 CFR 601.2 for BLA
- Associated Guidance Documents

FDA Guidance:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents#guidancesearch

Common Technical Document (CTD) Triangle

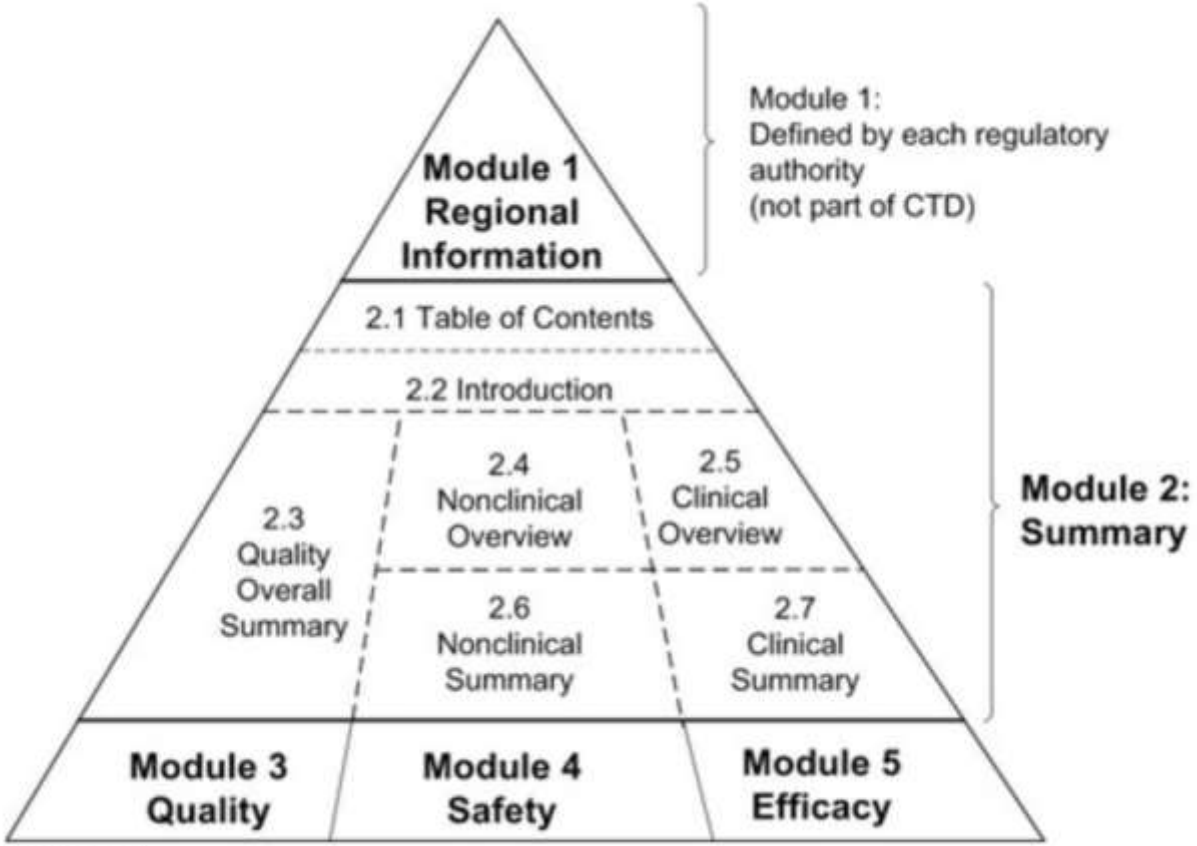

Figure 1

eCTD Modules

Module I	Module II	Module III - V
Regional & Administrative Information	**Summaries**	**Quality, Non-Clinical and Clinical Reports**
▪ Form 356h ▪ Form 3397 ▪ Form 3674 ▪ Field Copy Certification ▪ Debarment Certification ▪ Financial Certification & Disclosure (Form 3455) ▪ Patent and Exclusivity ▪ References ▪ Pediatric Administrative ▪ Labeling	▪ Quality Overall Summary ▪ Nonclinical Overview ▪ Clinical Overview ▪ Nonclinical Written and Tabulated Summaries ▪ Clinical Summaries	▪ Clinical includes -Integrated Summary of Safety + Integrated Summary of Efficacy ▪ Clinical Pharmacology ▪ Clinical Microbiology ▪ Statistical ▪ Information on Manufacturing, Clinical and Analytical sites ▪ Orphaned Files

- 1. Regional
  - 1.1. Forms
    - 1.1.2. Form FDA 356h: Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use
    - 1.1.3. Form FDA 3397: User Fee Cover Sheet
    - 1.1.7. Form FDA 3674: Certification of Compliance
  - 1.2. Cover Letters
  - 1.3. Administrative Information
    - 1.3.1. Contact/Sponsor/Applicant Information
    - 1.3.2. Field Copy Certification
    - 1.3.3. Debarment Certification
    - 1.3.4. Financial Certification and Disclosure
    - 1.3.5. Patent and Exclusivity
  - 1.4. References
    - 1.4.1. Letter of Authorization
  - 1.6. Meetings
  - 1.9. Pediatric Administrative Information
    - 1.9.1. Request for Waiver of Pediatric Studies
  - 1.12. Other Correspondence
    - 1.12.14. Environmental Analysis
  - 1.14. Labeling
    - 1.14.1. Draft Labeling

Content

Application form (form 356h)

- name and address of the applicant
- the date of the NDA
- the NDA number
- the name of the drug product, including its established, proprietary, code, and chemical names, dosage form and strength, and route of administration
- the identification numbers of IND, drug master files, and other applications under this part that are referenced in the NDA
- drug product's proposed indications for use
- statement whether the submission is an original submission, a 505(b)(2) application, a resubmission
- if RX or OTC
- Applicant’s signature. If NDA Applicant is a non-US company, then US agent

Form 356h (cont.)

6. Authorized U.S. Agent *(Required for non-U.S. applicants)*		
Authorized U.S. Agent Name		Telephone Number *(Include area code)*
Address 1 *(Street address, P.O. box, company name c/o)*		FAX Number *(Include area code)*
Address 2 *(Apartment, suite, unit, building, floor, etc.)*		Email Address
City	State	U.S. Agent DUNS
ZIP Code		

Form 356h (cont.)

APPLICATION INFORMATION	16. Application Type *(Select one)*	☐ New Drug Application (NDA) ☐ Biologics License Application (BLA) ☐ Abbreviated New Drug Application (ANDA)
17. If an NDA, identify the type	☐ 505(b)(1) ☐ 505(b)(2)	18. If a BLA, identify the type ☐ 351(a) ☐ 351(k)
19. If a 351(k), identify the biological reference product that is the basis for the submission.		
Name of Biologic:		Holder of Licensed Application:
20. If an ANDA, or 505(b)(2), identify the listed drug product that is/are the basis for the submission.		
Name of Drug:		Application Number of Relied Upon Product:

What is the basis for the submission:

- Listed drug in the supporting published literature necessary for approval.
- Referenced in the labeling

Form 356h
What is New

15A. Proposed Indication for Use

Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☐ No

Does this product have an FDA Orphan Designation for this indication? ☐ Yes ☐ No

If yes, provide the Orphan Designation number for this indication:

Continuation Page for #15

15B. SNOMED CT Indication Disease Term *(Use continuation page for each additional indication and respective coded disease term)*

- **Field 15B**: Snomed CT Indication Disease Term(s)
- **SNOMED CT** stands for **S**ystematized **No**menclature of **Med**icine **C**linical **T**erms.
- For coding study data indications and for additional tracking and metrics analysis

https://browser.ihtsdotools.org/

Form 356h
What is New

22. Submission Sub-Type ☐ Presubmission ☐ Amendment ☐ Initial Submission ☐ Resubmission		23. If a supplement, identify the appropriate category. ☐ CBE ☐ Prior Approval (PA) ☐ CBE-30	
24. For Originals and all Supplements, is the product a combination product (21 CFR 3.2(e))? ☐ Yes ☐ No	Combination Product Type *(See instructions)*	Request for Designation (RFD) Number	
25. Does the submission contain: *Only* Pediatric data? ☐ Yes ☐ No	Human factors information? ☐ Yes ☐ No	26. Proposed Marketing Status *(Select one)* ☐ Prescription Product (Rx) ☐ Over-The-Counter Product (OTC)	

- **Field 24**: Combination Products
- If initial submission for a product for which a Request for Designation (RFD) was submitted, include the six-digit RFD number

Form 3397 (User fee Form)

User Fee Table (Oct. 1, 2018- Sept. 30, 2019)

Application	Fees
NDA/BLA Fee - Clinical Data Required	$ 2,588,478
NDA/BLA Fee - No Clinical Data Required	$ 1,294,239
Program Fee	$ 309,915
ANDA Fee	$178,799
Type II DMF Fee	$55, 013
Biosimilars Fee- Clinical Data Required	$1,746,745
Biosimilars Fee- No Clinical Data Required	$873,373
Program	$304,162

For questions, please contact the User Fee Helpdesk at (301) 796-7200 or userfees@fda.gov.

Form 3674
Clinical Trial Certification

- Clinical trials registered at www.ClinicalTrials.gov are identified by The NCT (National Clinical Trial) number(s)
- The NCT number(s) required in the form (only if box c checked)
- Helps easily correlate various reports, medical reviews, advisories, health alerts with specific applicable clinical trials identified by the NCT number
- Should be included in the labeling (package insert (PI)), if applicable

https://www.fda.gov/downloads/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/UCM106692.pdf

Debarment Certification

- Requires that applicants certify that they did not and will not use in any capacity the services of any debarred persons in connection with a drug product application
- Acceptable
  "[Name of the applicant] hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug, and Cosmetic Act in connection with this application"
- Use of conditional language, such as to the best of my knowledge, is unsatisfactory.
- If foreign applicant: should be signed by US agent and foreign applicant both

Draft guidance for industry, Submitting Debarment Certification Statements
https://www.fda.gov/media/72557/download

Financial Certification & Disclosure Form 3454/3455

- Applies to any covered clinical study of a drug or device to establish that the product is effective
- To help ensure that financial interests and arrangements of clinical investigators that could affect reliability of data submitted to FDA in support of product marketing are identified and disclosed by the Sponsor
- If no financial arrangement submit Form 3454
- If a disclosure of financial arrangement submit Form 3455
- Required for bioequivalence studies that are the basis for approval
- Should be signed by Applicant. Authorized Representative can sign if authorized to sign on the applicant's behalf.

https://www.fda.gov/media/69872/download

Patent and Exclusivity

- FDA does not regulate patent laws but grants exclusivity
- If an NDA Applicant is submitting information on a patent that claims a proposed drug or a proposed method of using the drug that is the subject of the pending NDA
- Requires patent certification with the application with respect to each patent issued by US Patent and Trademark Office for the listed drug (drug substance/products or method of use)

Patent Certification (cont.)

- For each such patent, the applicant must provide the patent number and provide appropriate certification
- Required even if the patent(s) is expired or there are no relevant patent

Draft guidance for industry,: Applications covered by Section 505 (b)(2)
https://www.fda.gov/media/72419/download

Form 3542a

- Form 3542a - to be submitted with an original unapproved NDA application, on a FDA form 3542a to your intent to list patents for your product that is the subject of the pending NDA

- Form 3542 –to be submitted for patent information on a patent that claims an approved drug or an approved method of using the drug

- Must be submitted to the NDA, not to Orange Book ✓

https://www.fda.gov/media/69894/download

Exclusivity

- Exclusivity Request:
  - 351(k) application 12 years after the date of first licensure of the reference product
  - Orphan Drug - 7 years
  - New Chemical Entity-5 years
  - Generating Antibiotics Incentives Now (GAIN)-5 years
  - New Clinical Investigation – 3 years
  - Pediatric Exclusivity- 6 months (attached to existing exclusivity)

References

- Cross Reference:
  - Owns the data in previously submitted applications
- Right of Reference:
  - Right of Reference: right to reference data in other applications
    - Need Letter of Authorization
    - e.g., Drug Master File (DMF) holder authorizes FDA reviewers to review the information submitted in the DMF in support of the application

Pediatric Administrative

- Under Pediatric Research Equity Act (PREA), application for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration requires Pediatric assessment
  - Pediatric Study Plan (PSP) should be submitted and agreed upon by FDA before NDA submission
  - If pediatric studies not submitted with the application, request for Deferral/Waiver (based on Agreed PSP)

draft guidance: Pediatric Study Plans: https://www.fda.gov/media/86340/download

Labeling

- SPL formatted content of labeling (.XML file) and a Microsoft (MS) Word formatted version (.docx file) should be submitted with original BLA/NDA/ANDA submissions
- Annotated labeling which refers to specific sections of the application supported by certain data
- Should conform to
  - Specific Requirement for Prescribing Information (SRPI)
  - Pregnancy and Lactation Labeling Rule (PLLR format) along with review of available pregnancy, lactation and female-male reproductive potential

SRPI checklist: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/UCM373025.doc
PLLR draft guidance: https://www.fda.gov/media/90160/download

General Considerations

- All forms and certifications must be signed by appropriate signatories. Electronic forms must be electronically signed
- Submission must be in English and legible
- Ensure the hyperlinks are navigable

Challenge Question

Company A submits an application for an immediate-release oral tablet to the Division of Magic Drugs, referencing published literature necessary for approval and cross referencing safety data from their previously approved Wonder Drug, which is an extended-release tablet. As company owns these data, they should submit their application as

A. 505 (b)(1) Application

B. 505(b) (2) Application

C. 505 (j) Application

D. None of the above

References

- 21 CFR 314.50 available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.50
- 21 CFR 601.2 available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=601&showFR=1
- Center for Drug Evaluation and Research List of Guidance Documents https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs
- Guidance for Industry: How to Comply with the Pediatric Research Equity Act https://www.fda.gov/media/72274/download
- Guidance for Industry: User Fee Waivers, Reductions, and Refunds for Drug and Biological Products https://www.fda.gov/media/72340/download

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NDA and BLA Application Review Process

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Division of Transplant and

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Office of Antimicrobial Products (OAP)

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Learning Objectives

- Develop an understanding of the review process and the timeline for an application.
- Discuss the end of review actions and their implications
- Best Practices to make application as complete as possible

Initiating the Process

- Receipt of an application
- Review by Chief Project Management Staff and team assignments
- Cursory review to identify “glaring” omissions before acknowledgement
  - User fee
    - Guidance for Industry – User Fee Waivers, Reductions, and Refunds for Drug and Biological Products https://www.fda.gov/media/72340/download
  - Structured Product Labeling
  - Form 3674

Initial Review
RPM Responsibilities

Regulatory Project Manager (RPM) receives initial NDA submission

- Prescription Drug User Fee Act (PDUFA) time clock begins when application is received
  - Use the received date when calculating dates, NOT the letter date.
  - Acknowledge application receipt in writing by Day 14
- Ensure conformance to regulatory requirements
  - Ensure correct across internal tracking systems
  - Administratively complete and compliant
  - Confirm proposed proprietary name was submitted separately where applicable
- Conduct Physician Labeling Rule (PLR) format review of the prescribing information
- Begin RPM filing review

Initial Review (cont.)

Determine Review Team

- Confirm Signatory Authority
- Confirm Cross-Discipline Team Leader (CDTL)
- Request reviewers from appropriate team leader(s) and other Centers where applicable

Three major tasks to accomplish (by Day 60)

- Determine fileability and document (review needs to be archived in DARRTS or PANORAMA)
- Plan the review activities
- Communicate decision to the Applicant as applicable

Initial Review (cont.)

Priority/Standard review designation

- Filing meeting is scheduled based on tentative decision on review timeline (Day 30 for a priority application/Day 45 for a standard application).
  - Priority Review: 6 months from received date for non-program applications
  - Standard review: 10 months from received date for non-program applications

Schedule initial milestone meetings

- The RPM schedules the filing, planning, mid-cycle, labeling planning, and wrap-up meetings once the review team members have been identified.

Program Timelines

What's Different for NME Program review?	What's the Same for NME Program reviews?
6/10 mo clocks begin at 60 day filing date	User fees, other than usual yearly increases
Agreement on complete application at pre-submission meeting	60-day filing decision
Late submissions w/in 30 days of application receipt, if agreed upon at the pre-sub meeting	Refuse To File and Standard/Priority review criteria
Mid-cycle communication	74-day letters
Late-cycle meeting, including *FDA* meeting package	PMRs/PMCs + labeling discussions

By Day 45

Hold filing meeting to make filing decision

- Hold by Day 45 for standard reviews (Day 30 for priority reviews)
- The filing meeting has three main purposes
  - Confirm final review classification (standard vs. priority)
  - Identify significant review issues to communicate to applicant
  - Determine fileability of application
- Filing Decision (based on filing reviews)
  - File the application
  - Refuse to file the application

MAPP 6025.4 – Good Review Practice Refusal to File
https://www.fda.gov/media/87035/download

Milestone Meetings for non-NME

Meeting type	Standard Review	Priority Review
Filing	Day 45	Day 30
Planning	Day 45	Day 30
Mid-cycle	Month 5.0	Month 3.0
Wrap-up	5 – 8 weeks prior to the PDUFA goal date	2 – 4 weeks prior to the PDUFA goal date

- The review team may decide to hold additional meetings as needed, depending on the complexity of the review

Program Milestone Meetings

Meeting type	Standard Review	Priority Review
Filing	Day 45	Day 30
Planning	Day 45	Day 30
Mid-cycle	Month 5.0	Month 3.0
Mid-cycle Communication w/ Applicant (Program only)	Within 14 days of Internal Mid-Cycle Meeting	
Wrap-up	5 – 8 weeks prior to the PDUFA goal date	2 – 4 weeks prior to the PDUFA goal date
Late-Cycle (Program only)	12 Days before AC or by month 9 if no AC	12 Days before AC or by month 6 if no AC

Conduct Review- Mid-Cycle (Program Applications Only)

FDA

Internal Mid-Cycle Communication Planning:

- Determine what to convey to applicant with regard to identified key issues/deficiencies and the need for additional information
- Date or proposed date for the Late Cycle Meeting (LCM) and other projected milestone dates for the remainder of the review cycle
- Advisory Committee update (if applicable)
- Postmarketing Requirements (PMR)/Commitments (PMC) and Risk Evaluation and Mitigation Strategies (REMS) issues
- Timeline for review activities associated with a scheduling recommendation under the Controlled Substances Act (if applicable).
- Determine who will convey the deficiencies/information, and the order in which the deficiencies/information will be conveyed
- Determine who will participate in the Mid-Cycle Communication Meeting

During the Mid-Cycle Communication Teleconference

- Mid-Cycle Communication teleconference is led by the Cross Discipline Team Leader (CDTL)
- RPM coordinates the call and takes minutes.
- Ensure items below are addressed at the Mid-Cycle Communication teleconference if applicable.
  - Significant Review Issues
  - Information Requests (IRs)
  - Major Safety Concerns
  - Risk Management: Preliminary review team thinking regarding risk management/REMS.
  - AC Meeting: Updates regarding the proposed date and plans for the AC meeting (if an AC meeting is anticipated).
  - Drugs with Abuse Potential: updates regarding the timeline for review activities associated with a scheduling recommendation under the Controlled Substances Act.

Mid-Cycle Communication (Meeting Minutes)

- This communication fulfills the "Mid-Cycle Communication" milestone for 'Program' applications (NME NDAs, Original 351(a) BLAs, and Original 351(k) BLAs (biosimilars))
- Issued to the Applicant within 30-days of the Mid-Cycle Communication teleconference

Conduct Review – Late-Cycle (Program Application Only)

Hold internal meeting for Late-Cycle Meeting which is scheduled when application is first received per timeline.

Prepare the Late Cycle Pre-Meeting Background Package

The Late-Cycle Meeting Background Package - issued no later than 10 calendar days (or 2 calendar days for expedited review) prior to the Late-Cycle Meeting.

Send Late-Cycle Meeting Background Package to Applicant.

Hold Late-Cycle Meeting with Applicant:

- **Late-Cycle Meeting Minutes - Completed and issued within 30-days of the meeting**

Conduct Review – Wrap - Up

- RPMs schedules and facilitate the wrap-up meeting where reviewers discuss the approvability of the application and address any outstanding critical issues that have not been resolved.

- The agenda includes discussions regarding risk management, major labeling issues, post-marketing commitments, and the need for Center-level input.

- At the meeting, a plan for resolution of issues is discussed and a preliminary decision on the regulatory action should be made.

Conduct Review
Wrap – Up (cont.)

- If indicated, send REMS notification letter [this step may be handled by the Safety RPM]

- Begin REMS discussion with Applicant [this step may be handled by the Safety RPM per the Division practices]

- Send labeling/PMR/PMC to Applicant [per timeline; this date is specified in the 74-day letter]

Conduct Review – Wrap - Up (cont.)

- Labeling PMR/PMC discussions with applicant begin: RPM schedules discussions with applicant after substantially complete labeling has been conveyed; as applicable

- Communicating Labeling/PMC/PMR to Applicant: This letter is used to convey labeling and PMC/PMR comments by the date communicated to the sponsor in the 74-day letter

Taking an Action

- The team works to resolve remaining issues such as labeling, PMRs/PMCs, and REMS. The letter is finalized based on the regulatory action to be taken

- Exclusivity determination made by the exclusivity board

Taking an Action - (Approval)

- If the decision is to approve the application, the RPM drafts an Approval Letter and circulates it for editing by the review team (including the signatory authority)

- All reviews must be finalized and signed (in the electronic archive) before the action letter is signed and issued

- Once the applicant confirms receipt, the RPM immediately notifies the FDA Press Office and Office of Communication if an FDA communication was prepared

Taking an Action - (Complete Response)

- If the decision is to not approve the application, the RPM drafts a Complete Response (CR) letter, which includes the deficiencies found by the review team and recommendations for corrective action.

- The need for a REMS, or any REMS deficiencies are included in the CR letter and labeling may or may not be included in a CR letter.

- Applicant can resubmit a Class 1 or Class 2 resubmission w/ 2 or 6 month user fee goal date respectively

Taking an Action - (Tentative Approval)

- If the action is to tentatively approve the application, the RPM drafts a Tentative Approval Letter and circulates it for editing by the review team (including the signatory authority)
  - Due to Patent and/or Exclusivity
  - Due to Orphan Exclusivity
  - Due to a 30-month Stay/Patent Infringement Complaint
- A drug product that is granted tentative approval is not an approved drug and cannot be marketed until an approval letter is issued by the FDA.
- To obtain final approval of this application, submit an amendment two or six months prior to the: (1) expiration of the patent(s) and/or exclusivity protection or (2) date you believe that your NDA will be eligible for final approval, as appropriate.
- 21 CFR 314.105

Taking an Action
(Applicable to All Outcomes)

- After the action letter is signed, the RPM sends a courtesy copy by FAX or secure e-mail to the applicant and promptly contacts the applicant to confirm that the applicant has received the official written regulatory action.

- The official letter is also sent to the applicant via U.S. Postal mail.

- The review clock stops when the action letter is signed.

Challenge Question

What are the differences between applications in the Program or non-Program applications? Choose all that apply

a. Review timelines

b. Refuse to File criteria

c. Mid-cycle communication

d. Labeling Discussions

e. Late-cycle meeting, including FDA meeting package

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