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GENERIC DRUG STRATEGIES TO FACILITATE TIMELY APPROVAL (PART 1)

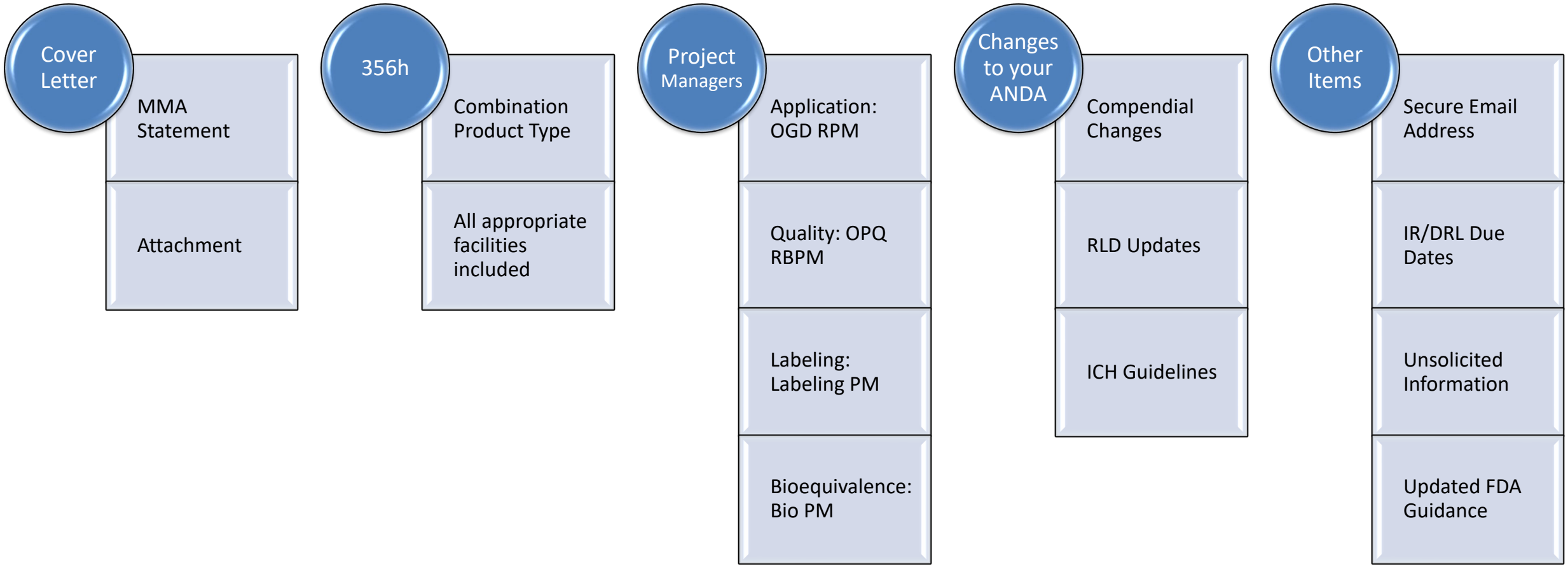
Everyone deserves confidence in their *next* dose of medicine.

Pharmaceutical quality assures the availability, safety, and efficacy of *every* dose.

Overview

- General Considerations
- Prioritization
- Pre-Submission Facility Correspondence
- Amendment Submissions
- Major to Minor Classification Changes
- Responding to Deficiencies
- Drug Master Files
- Patents and Exclusivities

General Considerations



Prioritization

- Evaluate if one of the prioritization criteria is appropriate for your application
  - MAPP 5240.3: Prioritization of the Review of Original ANDAs, Amendments, and Supplements
- Commonly submitted types of prioritization include first generic, public health emergency, drug shortage, and company hardship
- If eligible for a prioritization:
  - Request upon submission, with prioritization type and justification, of a new review cycle (new original, CRL response, request for full approval) to ensure the appropriate goal date is identified

Pre-Submission Facility Correspondence (PFC)

- Application must be prioritized to be eligible
- Facilities to be used for an application must be submitted at least 60 days prior to submission of full application or amendment
  - Substantial changes to facilities upon full application/amendment submission can result in invalidating PFC
- Valid PFC can result in a goal date 2 months shorter than usual for prioritized Original and Major amendment submissions
  - For Major amendments, the shorter goal date will take effect if the need for a pre-approval inspection is identified
- Guidance for Industry: ANDAs: Pre-Submission Facility Correspondence Related to Prioritized Generic Drug Submissions (June 2025)

Amendment Submissions

- Guidance for Industry: ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA (September 2024)
- Be knowledgeable of ANDA Amendments guidance
  - Appendix A can help identify the types of information that may result in a major extension
- Guidance for Industry: ANDA Submissions—Amendments and Requests for Final Approval to Tentatively Approved ANDAs (January 2024)
  - Be aware of full legally approvable date, and submit RFA accordingly
  - Major changes are made to the tentatively approved ANDA will result in a longer goal date

Major to Minor Classification Changes

- Requests for Reconsideration[1]
  - 30-day goal date (if requirements are met)
  - Submitted SEPARATELY from CRL Response submission
  - Can apply to any discipline's major deficiency
- Facility Major to Minor Reclassification Request[2]
  - Facility must be the only major deficiency in CRL
  - Submitted WITH CRL Response submission
  - Only for surveillance inspection deficiencies
  - Results in 4- or 5-month goal date (depending on prioritization)

1. Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-reconsideration-division-level-under-gdufa

2. MAPP: https://www.fda.gov/media/169330/download

Responding to Deficiencies

- Respond to deficiencies fully and completely to potentially avoid additional IRs
  - Promises to submit the information at a future date may be considered a partial response and may result in FDA not reviewing any information submitted with that amendment
- If the deficiency is not clear:
  - Reach out to the discipline PM who issued the deficiency in the IR or DRL
    - May be able to provide clarity on what the deficiency is asking
  - Submit a Post-CRL Clarification Teleconference request
    - Guidance for Industry: Post-Complete Response Letter Clarification Teleconferences Between FDA and ANDA Applicants Under GDUFA (October 2022)
- If additional time is needed to respond to a deficiency, request an extension on the response due date
  - Extensions may not always be granted

Drug Master Files (DMFs)

- Changes submitted to a DMF for an active pharmaceutical ingredient (API) may impact a referencing ANDA goal date
- Stay connected to DMF holders
  - Be aware of any planned submissions, solicited or unsolicited, particularly closer to an upcoming goal date
- Know of any facilities that may be used by DMF holder for your API
  - If the DMF has facilities that will not be used for the referencing ANDA, make sure the LOA clearly notes which DMF facilities are applicable to the ANDA

Patents and Exclusivities

- Address all patents, use codes, exclusivities listed in the Orange Book
- Documentation of litigation outcomes and/or submissions of all court decisions (late submission can impact timing of approval)
- Patent certification
  - Patent Certifications and Suitability Petitions

When to start planning for approval?

- From the first submission
- Build relationships with:
  - DMF holder
  - Facility points of contact
  - Application project managers, discipline project managers, and RBPMs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