U.S. FOOD & DRUG ADMINISTRATION

Ready to Launch:
Essentials of Submitting Initial Promotional Materials to the Office of Prescription Drug Promotion

Rachael E. O. Conklin, MS, RN, RAC
Regulatory Review Officer
DAPR 1, Office of Prescription Drug Promotion
CDER | US FDA

A Brief Introduction….

- OPDP is responsible for reviewing promotional material for prescription drug products.

- For more detailed information regarding OPDP's mission and organization please visit: https://www.fda.gov/about-fda/center-drug-evaluation-and-research/office-prescription-drug-promotion-opdp

Learning Objectives

- To improve understanding of the submission of launch promotional materials to OPDP.
- To address challenges or questions that may occur during the launch phase.

A (Very) Short Introduction to Prescription Drug Promotion

Prescription Drug Promotion

- **Form FDA-2253**: Required submission for all promotional labeling and advertising materials at the time of initial dissemination or publication.
  - **21 CFR 314.81(b)(3)**

Prescription Drug Promotion

- **Advisory Submission**: Sponsors are able to *voluntarily* submit proposed promotional materials to OPDP for review and comment.
  - **21 CFR 202.1 (j)(4):**

    "Any advertisement may be submitted to the Food and Drug Administration prior to publication for comment."

Prescription Drug Promotion: Categories of Promotional Materials

Promotional Labeling

- Labeling is written, printed or graphic material on or "accompanying" a product
- Promotional labeling generally includes labeling other than FDA-required labeling
  - e.g., brochure, mailing pieces
- Must be accompanied by approved product labeling
- Supplied or disseminated by the manufacturer, distributor, packer, or any party acting on behalf of the sponsor

Advertising

- Not defined in the FD&C Act
- Must be accompanied by a "Brief Summary" of information about side effects, contraindications, and effectiveness
- Issued or caused to be issued by the manufacturer, packer, or distributor
- Examples include:
  - Print (e.g., journal or magazine)
  - Broadcast (e.g., TV, radio)

The Launch Phase

The Launch Phase

- Launches are the initial promotional materials for a product.
- They may be voluntarily submitted for advisory comments.

➢ Launches are one of OPDP's top priorities because consumers and healthcare providers are forming first impressions of a drug or use.

The Launch Phase

- Typically 120 calendar days from the approval of a new:
  - Drug
  - Indication
  - Delivery System
  - Formulation
  - Dosage form, dosing regimen, or strength
  - Route of Administration

The Launch Phase: Exceptions

- In cases where a drug is not marketed upon approval, the launch phase is 120 days from initial marketing of the drug.
- Audience specific marketing: healthcare provider [HCP] vs consumer [DTC]
  - Drug A is initially only marketed to a HCP audience
  - Two years later Drug A's Sponsor decides to begin marketing to a consumer audience
  - DTC materials may be submitted as a launch for advisory comments

The Launch Phase: Tips for a Smooth Submission Process

- Revise to reflect current label/final label.
- Ensure that *all parts* of each submission are legible.
- Annotate clearly and comprehensively.

A Note on Press Releases

- Press releases (PR) may be submitted for advisory comments as part of the launch.
- Generally there is a 2 working day turn-around for the review of draft PRs when requested by sponsors.
- **HOWEVER** this 2 working day turn-around typically applies to PRs that only reference the PI.

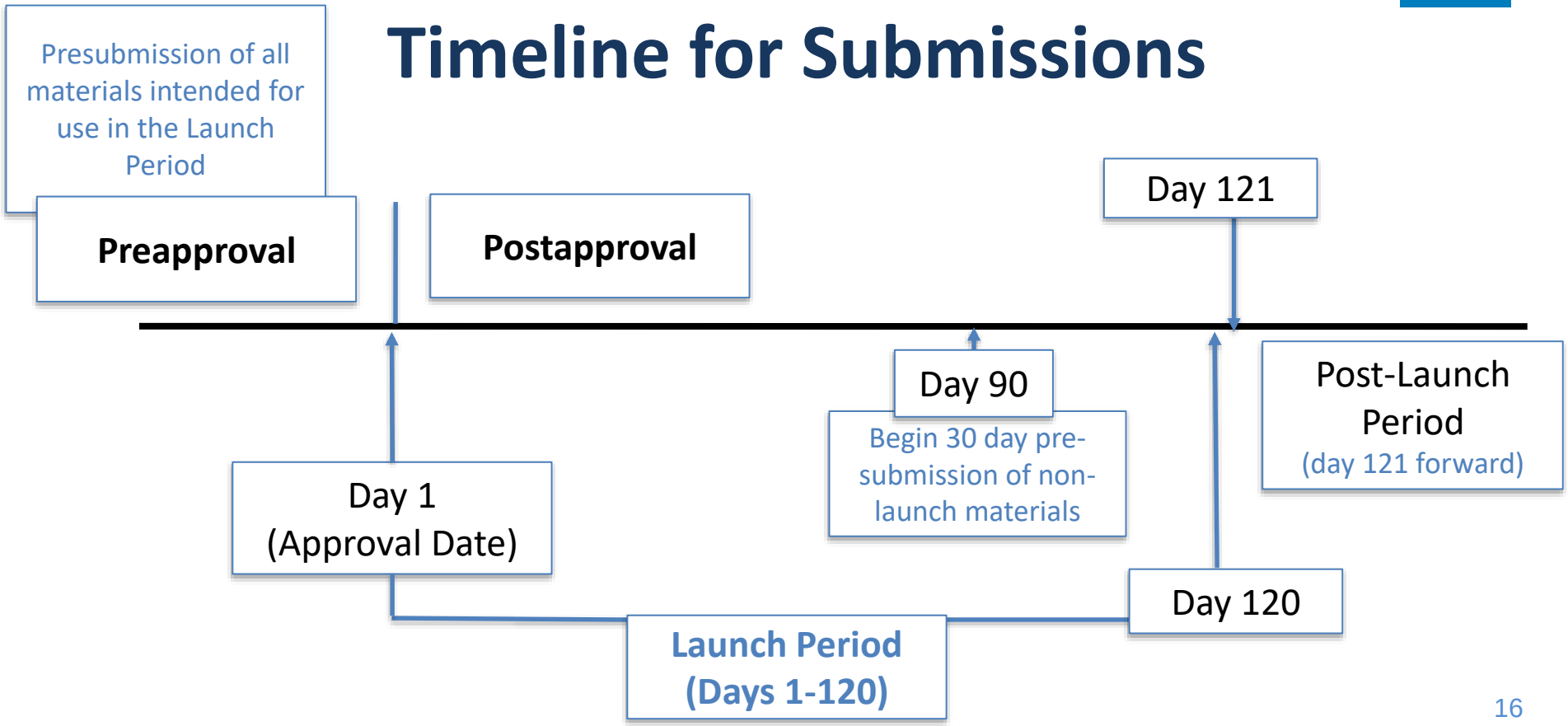
Products approved under **Subpart E** (21 CFR 601.45) or **Subpart H** (21 CFR 314.550)

Accelerated Approval Launches

Accelerated Approval Launches: A Little Different

- The launch phase is still 120 days from approval.
- HOWEVER *all materials* that are intended for use in the 120 days following marketing approval must be **submitted prior to approval of the drug**.

Accelerated Approval: Timeline for Submissions



Submission Process

Resources

- OPDP Regulatory Information: https://www.fda.gov/about-fda/center-drug-evaluation-and-research/opdp-regulatory-information

- Electronic Common Technical Document (eCTD):https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd

- For questions regarding eCTD submissions to OPDP: OPDPeCTD@fda.hhs.gov

- FAQs: https://www.fda.gov/about-fda/center-drug-evaluation-and-research/opdp-frequently-asked-questions-faqs

Resubmissions & Amendments

- **Resubmission Supporting Document**: Used when a Sponsor is responding to an Advisory letter
  - Acknowledgement of Advisory Letter
  - Revision of Materials to address Advisory Comments
  - Rebuttal of Advisory comments

Resubmissions & Amendments

- **Amendments**: Used to submit materials that were missing from the original submission
- Two types of Supporting Documents:
  - Amendments
  - Reference Document

Resubmissions & Amendments:

Amendments

Amendment

- Should include at least one clean material
- May also include missing Annotated Material, Annotated PI, and/or References

Reference Document

- Does not include clean material
- Should include annotated Materials, Annotated PI, and/or References

Questions?

FDA U.S. FOOD & DRUG ADMINISTRATION