Post-Approval Submission of Promotional Materials to the Office of Prescription Drug Promotion

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Learning Objectives

- Describe the post-approval submission process of promotional materials to OPDP

- Identify key considerations to facilitate submission of promotional materials to OPDP

Who Are We?

- OPDP protects the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated.

What Do We Do?

- OPDP reviewers have the responsibility for reviewing prescription drug advertising and promotional labeling to ensure that the information contained in these promotional materials is **not false or misleading**

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

What Do We Regulate?

- Prescription drug promotional materials made by or on behalf of the drug's manufacturer, packer, or distributor, including:
  - TV and radio commercials
  - Sales aids, journal ads, and patient brochures
  - Drug websites, e-details, webinars, and email alerts

Drug Approval and OPDP

Form 2253

- Post-Approval Reporting Regulations located in 21 CFR 314.81(b)(3)(i):
  - Require the submission of all promotional materials at the time of initial dissemination or publication
  - Must include Form FDA-2253 and current prescribing information (PI)

Drug Launch Phase

- Typically Day 1 to Day 120 after approval
- Launches are the initial promotional materials for a product and one of OPDP's top priorities because they form the first impressions of a drug or use
- Day 121 and onward would be considered non-launch

Challenge Question 1

Promotional materials must be submitted to the FDA at the time of initial dissemination or publication on the following form:

A. Form 3792

B. Form 356h

C. Form 2253

D. Form 3454

Advisory Comment Submissions

- Draft promotional materials can be voluntarily submitted for advisory comment at any time.
  - **21 CFR 202.1 (j)(4):**

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

- Launch materials for advisory comment are divided into core and non-core launch materials.

Advisory Submission Recommendations

- Ensure submissions are in accordance with guidance
  - *Providing Regulatory Submissions in Electronic and Non-Electronic Format — Promotional Labeling and Advertising Materials for Human Prescription Drugs*
- Annotate clearly and comprehensively
- Communicate with OPDP to coordinate submission for advisory

Press Release Considerations

- 2 working day turn-around for the review of draft press releases when requested by sponsors.
  - Typically only applies to press releases that only reference the PI.
- For press releases that include references outside the PI and/or require consultation, we will notify the sponsor and treat that press release as a regular launch or non-launch advisory submission.

Social Media Considerations

- Relevant Guidances:
  - Guidance for Industry Internet/Social Media Platforms with Character Space Limitations— Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices
  - Guidance for Industry Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices
  - Guidance for Industry Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics
  - Guidance for Industry Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices

Resubmissions, Amendments, and Withdrawals

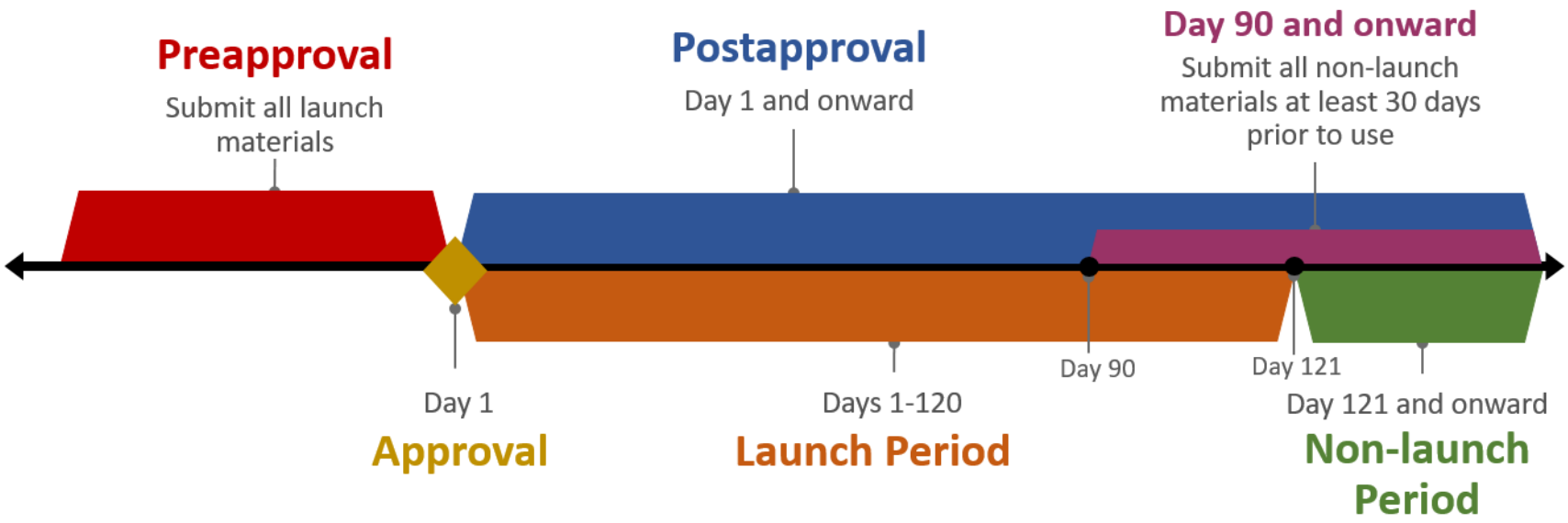
- The **Resubmission** Supporting Document is used when a Sponsor responds to a comment letter

- **Amendments** are used to submit materials that were missing from the original submission
  - Amendment (at least one clean material)
  - Reference Document (does not include clean material)

- **Withdrawals** are used to withdraw a previous submission to FDA

Accelerated Approval

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



Accelerated Approval Considerations

- Scenario - If a drug has multiple indications but only one received accelerated approval

- Scenario - Changes that affect previously finalized promotional materials

Challenge Question 2

Which of the following is not associated with accelerated approval products?

A. Applies to products as defined in 21 CFR part 314, subpart H, or 21 CFR part 601, subpart E.

B. Only core launch materials should be submitted prior to product approval

C. Non-launch materials should be submitted at least 30 days prior to use

D. Promotional materials should be submitted to the Agency in final form at the time of initial use in the public domain.

Bad Ad Program

To report potentially false or misleading prescription drug promotion:

- Email: BadAd@fda.gov
- Call toll-free 855-RX-BADAD or 855-792-2323
- Write:
  Bad Ad Program
  FDA/CDER/OPDP
  5901-B Ammendale Rd
  Beltsville, MD 20705-1266

Compliance Actions

Available at:

https://www.fda.gov/drugs/warning-letters-and-notice-violation-letters-pharmaceutical-companies/warning-letters-2020

Questions?

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