

***Providing Regulatory Submissions in  
Electronic and Non-Electronic Format—  
Promotional Labeling and Advertising  
Materials for Human Prescription Drugs  
Final Guidance for Industry***

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# Timeline



- June 24, 2019 – FDA Published the Final Guidance titled “Providing Regulatory Submissions in Electronic and Non-Electronic Format – Promotional Labeling and Advertising Materials for Human Prescription Drugs”
- Guidance describes the structure and format for promotional submissions in eCTD format
  - Contains both Binding Requirements and Nonbinding Recommendations
- 24 months after the publication of the Final Guidance, required submissions described in the guidance must be submitted in eCTD format
  - Required submissions will be mandatory starting June 24, 2021
- Firms are not required—but are **STRONGLY** encouraged to—submit electronically other types of promotional material submissions
  - NOTE: Complaints should only be submitted as **paper copies** and cannot be accepted in eCTD

# Purpose

- Outlines requirements and recommendations for firms on how to make submissions pertaining to promotional materials for human prescription drugs to FDA
- Describes specific aspects of submitting promotional materials using module 1 (M1) of the electronic Common Technical Document (eCTD) using version 3.3 or higher of the *us-regional-backbone file*

# Binding Requirements vs. Nonbinding Recommendations



- Binding
  - the portion of this guidance that establishes the requirement for electronic submissions pursuant to section 745A(a) of the FD&C Act has binding effect
- Nonbinding
  - all other suggestions and recommendations for electronic submissions of promotional-related materials

# Promotional Materials under Section 745A(a)



- Two types of promotional material-related submissions are subject to the requirements of section 745A(a)
  - Promotional materials submitted in fulfillment of the postmarketing reporting requirements (i.e., Form FDA 2253 submissions or “2253 submissions”)
  - Presubmissions of promotional materials for accelerated approval products and other products where such submissions are required for approval (i.e., products approved when human efficacy studies are not ethical or feasible)

# Scope

## **Submissions pursuant to section 745A(a) of the FD&C Act**

- 2253 submissions
- Presubmissions of promotional materials for accelerated approval products and other products where such submissions are required for approval (i.e., products approved when human efficacy studies are not ethical or feasible)

## **Other promotional material-related submissions**

- Voluntary advisory submissions
- Resubmissions
- General correspondences
- Amendments
- Withdrawal requests
- Responses to notice of violation or warning letters
- Responses to information requests
- Reference documents
- Complaints

# Resources

- OPDP has developed multiple resources to assist submitters both during and after the 24-month transition period
  - OPDP eCTD Mailbox- [OPDPeCTD@fda.hhs.gov](mailto:OPDPeCTD@fda.hhs.gov)
  - OPDP eCTD Webpage – [www.fda.gov/OPDPeCTD](http://www.fda.gov/OPDPeCTD)
  - How-To Videos
  - Webinar Series
  - Test Submission Process

# Grouped Submissions

- FDA encourages Submitters to use the Grouped Function when submitting promotional materials that promote more than one Product
  - Discussed in Section VI-J of the Guidance
- How does it work and how do groups appear in the FDA Viewing Tool?
  - Demonstration



# Sample Submission

Brand	Sequence # Assigned	Application Containing Files
Brand Product A	0020	TRUE
Brand Product B	1003	FALSE
Brand Product C	1564	FALSE
Brand Product D	0271	FALSE
Brand Product E	0268	FALSE
Brand Product F	0987	FALSE
Brand Product G	0333	FALSE
Brand Product H	0851	FALSE

\*Submission should include PI for all Products

## m1-1-forms

Form FDA 2253: Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use  
[2253 NDA BrandProductA 2019 07 22 \(1\) \[new\]](#) +  
[Other Referenced Products Page test \[new\]](#) +

## m1-14-6-product-labeling-for-2253-submissions

[BrandProductA-PI \[new\]](#) +  
[BrandProductB-PI \[new\]](#) +  
[BrandProductC-PI \[new\]](#) +  
[BrandProductD-PI \[new\]](#) +  
[BrandProductE-PI \[new\]](#) +  
[BrandProductF-PI \[new\]](#) +  
[BrandProductG-PI \[new\]](#) +  
[BrandProductH-PI \[new\]](#) +

## m1-15-promotional-material (Professional)

m1-15-2-materials (Promotional 2253)

m1-15-2-1-material ([www-website](#)) material-id **12US19EXC0002** issue-date **20190830**

m1-15-2-1-1-clean-version

[12US19EXC0002 Products Page Corporate Website \[new\]](#) +

# Lifecycle Operators



- What does the guidance say about the use of Lifecycle Operators when submitting Promotional Materials?
- Lifecycle Operators inform the reviewer that the Promotional Material has been revised and represents an update from a previously submitted Material
- Discussed in the following locations of the Guidance
  - Section VI-L
  - Footnote 47
  - Lines 953, 967
- “Replace” Operator used when Promotional Materials have been revised
- “Delete” Operator used when Promotional Materials have been Withdrawn

# Social Media Updates

- How should firms submit a 2253 in eCTD format containing the list of all non-restricted sites that include real-time or interactive communications?
  - Discussed at Line 246 of the Draft Guidance titled “*Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics*”
  - Submission should include all required components of a Form 2253 Submission in eCTD format
    - Form 2253, Current PI, and Materials
  - Monthly social media update should be submitted with either a file or reference link under the materials section
    - When submitting a file, the document should include the site name, URL, date range, and date of the most recent social media update for that site
    - A reference link to a previous submission may also be used
      - The site name, URL, date range, and date of most recent social media update should be included in the 2253 comments

# Website Submissions

- How do Firms submit websites in eCTD?
  - Discussed in Section VII-E of the Guidance
  - Website submissions should clearly display and communicate how the promotional material will convey messages to the end user
  - Preferably will allow reviewers to interact with the piece in the same manner as the end user
  - Websites must be submitted in their entirety prior to first use
    - If a single page is added or revised, only the updated page needs to be submitted
    - Substantial updates and revisions to the website will require submission of the website in its entirety prior to dissemination
- When submitting updates to a Website, minor revisions should be submitted with the “New” Operator
  - Use the “Replace” Operator when the Website has been substantially revised or updated

# Accelerated Approval Annotations



- What annotations are required for Accelerated Approval Pre-Submission files?
  - Discussed in Section IV-B of the Guidance
  - Accelerated Approval Pre-Submission files must include annotated materials regardless of whether the the Submitter is seeking comments or not
  - All Accelerated Approval Pre-Submissions should include a clean copy of the draft materials and an annotated copy of the materials
  - The annotated copy of the draft material should include links to the annotated PI and/or annotated Reference Documents
    - Hyperlink should redirect to the source of support for the claim in either the PI or Reference
    - Hyperlinks should not redirect to a website or any content outside of either the current or any previous submissions
    - Hyperlink to the Reference Document only needs to link to the page where the source of support for the claim can be found
    - Firms should not send links to external websites

# Collaborative Marketing Agreements



- What are the recommendations when a different Firm markets and submits Promotional Materials on behalf of the Application Holder?
  - Discussed in Section III of the Guidance
  - Before submitting promotional materials, the Application Holder should submit a general correspondence to FDA which describes the agreement
  - All subsequent submissions should indicate the business relationship
    - Can be included in the comments section of the 2253
    - Should be included in the cover letter of any correspondence to OPDP
  - Application Holder is still responsible for promotion of the product



# Demonstration of a properly-structured 2253 in Viewing Tool



