# FDA Finalizes Guidance on Mandatory Electronic Submission of Promotional Materials

## Executive Summary

On Monday, June 24, 2019, the Food and Drug Administration (FDA or the Agency) finalized its guidance on electronic submissions of promotional materials.[1] The issuance of this guidance starts the two-year countdown clock for the mandatory submission of promotional materials via the Electronic Common Technical Document (eCTD). Beginning on June 24, 2021, all 2,253 filings of promotional materials, and all mandatory submissions of promotional materials for subpart H and E approvals must be submitted to the FDA via eCTD.

This POV provides an overview of the most significant aspects of the guidance, including the most important changes from the 2015 draft version. The Promotional Submissions Guidance affects the submission of all promotional materials (whether final samples, for advisory comments, or other) to the Agency. As explained further below, some of the provisions of the guidance will not come into full effect immediately, but many aspects of this guidance will have a direct impact on existing marketing and marketing services operations.

Companies that have not already adopted eCTD submissions should immediately begin planning for transition to eCTD for promotional materials, including:

1. Convene all relevant stakeholders (regulatory, marketing services, IT, and outside vendors) to begin preparation for converting all promotional submissions to the Electronic Common Technical Document (eCTD)[2]
2. Determine the timeframe for adopting FDA's electronic filing to meet the June 24, 2021, deadline.

All companies, including those that have already adopted eCTD submissions, should take these steps:

1. Review the changes in the final guidance from the draft version, and update procedures accordingly.
2. Review the guidance provisions for the contents of submissions of promotional materials against existing company standards.
3. Resolve any discrepancies between FDA's requested submission packages and the company's existing procedures.


## Background

Sponsors of prescription drugs and biologics are required to "submit specimens of … labeling or advertising devised for promotion of the drug product at the time of initial dissemination [or]… initial publication." (21 CFR 314.81(b)(3)(i)) In addition, companies that receive accelerated approval for certain products (so-called subpart H and subpart E products) are required to submit all of their initial launch promotional materials prior to product approval, and all subsequent promotional materials must be submitted to FDA 30 days prior to use. All of these post-marketing submissions are required for sponsors of prescription drugs, biologics, and vaccines.

In addition, companies submit other promotional materials to FDA. Such submissions are often voluntary requests for FDA to review and provide advisory comments on promotional materials prior to their use.[3] For example, this is an extremely common practice during a product's launch phase and for the initiation of new messaging, especially for DTC television advertising.

This guidance affects the submission of all promotional materials to either the Office of Prescription Drug

Promotion (OPDP) in the Center for Drug Evaluation and Research or the Advertising and Promotional Labeling Branch (APLB) within the Center for Biologics Evaluation and Research, regardless of whether those submissions are required post-marketing submissions or voluntary submissions.[4]

The distinction between post-marketing and other submissions is nonetheless crucial, as some of the guidance's provisions about required post-marketing submissions will become mandatory on June 24, 2021, as explained below. By contrast, for other submissions of promotional materials, it will still be permissible to provide materials via paper outside of the eCTD format.[5]

Normally, FDA guidances do not create binding requirements. There are exceptions to that general rule. When a law directs FDA to issue guidance to create mandatory requirements, then the contents of that guidance become binding. In this case, the law directed that certain submissions to the FDA be done electronically, and that FDA produce guidance providing the details of how to do so.

Consequently, unlike most guidances, some aspects of the Promotional Submissions Guidance will be mandatory.

## Guidance Overview

Section IV provides a breakdown of the various types of submissions covered by the Promotional Submissions Guidance and the content of those submissions, and Section VII includes a discussion of presentation issues for promotional materials submissions. Much of this information will be familiar to people already submitting promotional materials to the Agency. The guidance does provide much greater specificity for these submissions, and companies should compare both the content and format of their existing submissions packages against the recommendations provided in these sections.

## Changes From the Draft Version

There are dozens of small changes from the draft version of the guidance. The vast majority of these changes are minor wording or formatting issues that do not have a material impact on the content of submission of promotional materials. Overall, these changes do make the guidance easier to follow and make it more clear when the guidance is providing mandatory requirements or voluntary recommendations.

There are three material changes from the draft version of the guidance:

1. Deletion of all references to mandatory pre-dissemination review of television commercials
2. Clarification that electronic, non-paper submissions outside eCTD are still acceptable
3. An additional piece of information that is requested for all OPDP submissions, including correspondence

## DTC Television Commercials

The Food and Drug Administration Amendments Act of 2007 granted FDA authority to require that all DTC television spots be submitted to the Agency at least 45 days prior to use. The intention behind this provision is to enable the Agency to review and provide feedback to sponsors prior to the ads being aired. In 2012, FDA provided guidance about how it would implement such a pre-dissemination review requirement, if it were to implement that requirement.[6] That guidance and the corresponding pre-dissemination review have not been implemented. The draft version of the Promotional Submissions Guidance nonetheless included quite a few mentions of those submissions. All of that discussion has been removed from the finalized guidance. Although the 2012 guidance on pre-dissemination review has not been withdrawn, the complete omission of any mention of the requirement from the finalized guidance makes it clear that pre-dissemination review of television commercials is not part of FDA's current concerns.


## Non-Paper Electronic Submissions Outside eCTD

Not all submissions of promotional material will be required to be submitted via eCTD, even after June 24, 2021. For some

submissions, such as voluntary requests for advisory comments and responding to requests for information from the Agency, it will still be permissible to make use of non-eCTD submissions. The 2015 draft version of the guidance referred to non-eCTD submissions exclusively as "paper submissions." While FDA encourages sponsors to submit all promotional materials via eCTD, the finalized Promotional Submissions Guidance makes clear that when submissions of promotional materials to the Agency are made outside of eCTD, "sponsors are encouraged, but not required, to include one non-eCTD copy … on a CD."[7]

## Submissions Including Correspondence to OPDP

Few of the core requirements for submissions of promotional materials have changed from the draft to the finalized version of the guidance. One item was added to Section III. General Considerations. "For OPDP, address submissions that require correspondences to the attention of the OPDP Project Manager."

## Conclusion

FDA's issuance of a final version of the Promotional Submissions Guidance begins the countdown to June 24, 2021. On June 24, 2021, all required post-marketing submissions of promotional materials will be required to use the eCTD format. Companies that began making the transition when the draft guidance was issued in 2015 will find that very little has changed from the draft version of the guidance. That will lower the burden for coming into compliance with the finalized version. Companies that held off on making the transition now have a clearly defined deadline for making the transition and should begin preparations immediately.

*This POV was prepared exclusively for Intouch Group by PhillyCooke Consulting. PhillyCooke Consulting is not a law firm, and nothing in this advisory should be construed as offering legal advice or counsel.*


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**Supplemental Materials**

- Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs available from FDA website
- Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications available from FDA website
- Guidance for Industry: Direct-to-Consumer Television Advertisements — FDAAA DTC Television Ad Pre-Dissemination Review Program available from FDA website
- Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics available from FDA website
- Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act available from FDA website
- The 2015 draft version of the guidance has been removed from the FDA website. It is available for those who would like to do their own comparison to the final version

**Endnotes**

[1] This guidance is officially titled, "Providing Regulatory Submissions in Electronic and Non-Electronic Format — Promotional Labeling and Advertising Materials for Human Prescription Drugs." The guidance is herein referred to as the "Promotional Submissions Guidance" and is available from the FDA website

[2] For more on the eCTD format, see here

[3] Other submission types covered by the Promotional Submissions Guidance include general correspondence (page 12f), responses to FDA untitled or warning letters (page 16), and responses to information requests (page 16). For a comprehensive list of the submissions covered by this guidance, see Section IV (pages 5-16).

[4] Note that the Center for Veterinary Medicine (CVM) is not a signatory to this document, nor is the Center for Devices and Radiological Health (CDRH). There is no requirement to submit promotional materials to CDRH. It is unclear whether CVM or CDRH will accept electronic submissions of promotional materials. Marketers of veterinary medicines and medical devices should check with those divisions separately about submitting promotional materials.

[5] Note that the guidance also makes clear that complaints about promotional materials will not be accepted via eCTD. Such complaints should be submitted outside of the eCTD format, Promotional Submissions Guidance, page 16.

[6] See Guidance for Industry: Direct-to-Consumer Television Advertisements — FDAAA DTC Television Ad Pre-Dissemination Review Program available from FDA website

[7] Promotional Submissions Guidance, page 17.