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**POV:** FDA Updates Guidance on Submitting Promotional Materials Electronically

APRIL 2015



## EXECUTIVE SUMMARY

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On Tuesday, April 21, 2015, the Food and Drug Administration (FDA) issued a new **draft guidance** entitled, “Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs Guidance for Industry.”<sup>1</sup> This guidance affects the submission of all promotional materials (whether final sample, for advisory comments or other) to the FDA.

Though some guidance provisions will not come into full effect immediately, many aspects will have a direct impact on existing marketing and marketing services operations. Failure to comply with the final guidance may result in rejection of marketing material submissions and potentially a negative impact on business.

In light of this draft guidance, Intouch Solutions recommends companies take the following steps:

- + Review the guidance provisions for the contents of submissions of promotional materials against existing company standards
- + Resolve any discrepancies between the FDA's requested submission packages and the company's existing procedures
- + 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)<sup>2</sup>
- + Determine the feasibility of adopting the FDA's electronic filing requirements (once mandatory)
- + File comments with the FDA about suggested changes to the electronic filing requirements to make it easier for companies to comply



1  
Review the guidance provisions



2  
Resolve any discrepancies



3  
Convene all relevant stakeholders



4  
Adopt electronic filing requirements



5  
File comments with the FDA



## BACKGROUND

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According to the Code of Federal Regulations, 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 the FDA 30 days prior to use. All of these postmarketing submissions are required for companies.



In addition, companies submit other promotional materials to the FDA. Such submissions are most often requests that the FDA review and provide advisory comments prior to their use.<sup>3</sup> This is extremely common 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 (CDER) or the Advertising and Promotional Labeling Branch (APLB) within the Center for Biologics Evaluation and Research (CBER), regardless of whether those submissions are postmarketing or other promotional material submissions.<sup>4</sup>

The distinction between postmarketing and other submissions is nonetheless crucial, as some of the guidance's provisions about required postmarketing submissions will become mandatory 24 months after the finalization of the guidance, as explained further below. By contrast, for other submissions of promotional materials, it will still be permissible to provide materials via paper outside of the eCTD format.<sup>5</sup>



## GUIDANCE OVERVIEW

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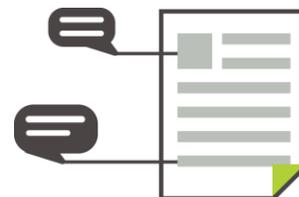
Section IV provides a breakdown of the various types of submissions that are covered by this guidance and the content of those submissions, and Section VII includes a discussion of presentation issues for promotional material submissions. Much of this information will be familiar to people already submitting promotional materials to the FDA.

The guidance does provide much greater specificity for these submissions, and companies should compare both the content and format of their existing submission packages against the recommendations provided in these sections.

In the midst of the discussion of the content of submission packages, the guidance makes one startling suggestion for the submission of final promotional materials at the time of first use or initial dissemination:

*Firms are also encouraged to submit annotated versions of the promotional material(s) cross-referenced to the product labeling and references, if applicable. (Promotional Submissions Guidance, page 6)*

Those familiar with companies' promotional review process will appreciate that typically materials go through several stages of review prior to the final sample submission to the FDA. Commonly, an annotated version of the material with accompanying references is only supplied at the very early stages of this review process, with this information omitted from subsequent stages of review. Later stages in the review process might feature some light



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referencing, such as a list of references on materials directed to healthcare professionals; however, even in those cases, the later stages of the process do not include fully annotated references.

It is important to note that this encouragement is provided in a portion of the guidance that will become mandatory once finalized because this discussion is regarding the contents of the required postmarketing submission of materials at the time of initial dissemination or first use. However, the language in this passage (“encouraged to” vs. “should” or “required”) and the fact that this passage is separated from the formal bulleted list of requirements makes it clear that this particular piece will not be mandatory, even after the final guidance is issued.

#### DTC TELEVISION COMMERCIALS

The Food and Drug Administration Amendments Act of 2007 granted the FDA authority to require that all DTC television spots be submitted to them at least 45 days prior to use. The intention behind this provision is to enable them to review and provide feedback to sponsors prior to the ads being aired. In 2012, the FDA provided guidance about how it would implement such a pre-dissemination review requirement if it were to do so.<sup>6</sup> That guidance and the corresponding pre-dissemination review have not yet been implemented, and this new guidance on the submission of all promotional materials makes it clear that the FDA is not yet implementing that guidance or the pre-dissemination review requirement.<sup>7</sup> Also, this guidance is not intended to replace or supersede that 2012 guidance.<sup>8</sup>





## FDA'S NEXT STEPS

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This guidance is in draft status. There will be a 90-day comment period, which will expire on July 21, 2015.<sup>9</sup> Following that, the FDA will determine whether the draft guidance requires changes in light of the feedback it has received. At that point, the FDA will either issue a final guidance or a revised draft guidance. Given the nature of this topic, it is extremely likely that they will finalize this guidance promptly. Twenty-four months following the issuance, the guidance recommendations provided on required submissions of promotional material will become mandatory. Hence, it is essential that companies determine the impact of adhering to these recommendations now. The outcome of that determination might be filing comments with the FDA requesting changes or making changes within the company to begin preparing for these new guidelines.

## RECOMMENDATIONS

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In light of this draft guidance, Intouch Solutions recommends companies take the following steps:

- + Review the guidance provisions for the contents of submissions of promotional materials against existing company standards
- + Resolve any discrepancies between the FDA's requested submission packages and the company's existing procedures
- + 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)<sup>2</sup>
- + Determine the feasibility of adopting the FDA's electronic filing requirements (once mandatory)
- + File comments with the FDA about suggested changes to the electronic filing requirements to make it easier for companies to comply



## SUPPLEMENTAL MATERIALS

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- + Guidance for Industry: Direct-to-Consumer Television Advertisements — FDAAA DTC Television Ad Pre-Dissemination Review Program available from FDA website at <http://www.fda.gov/downloads/Drugs/Guidances/UCM295554.pdf>
  - + 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 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM381352.pdf>
  - + Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications available from FDA website at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM333969.pdf>
- Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act available from FDA website at <http://www.fda.gov/downloads/Drugs/Guidances/UCM384686>

## ENDNOTES

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<sup>1</sup> This guidance is herein referred to as the “Promotional Submissions Guidance” and is available from the FDA website at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>

<sup>2</sup> For more on the eCTD format, see

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm>

<sup>3</sup> Other submission types covered by the Promotional Submissions Guidance include general correspondence (page 11f), responses to FDA unfilled or warning letters (page 14f), and responses to information requests (page 15). For a comprehensive list of the submissions covered by this guidance, see section IV (pages 5-16).

<sup>4</sup> 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.

<sup>5</sup> 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 15f.

<sup>6</sup> See Guidance for Industry: Direct-to-Consumer Television Advertisements — FDAAA DTC Television Ad Pre-Dissemination Review Program available from FDA website at

<http://www.fda.gov/downloads/Drugs/Guidances/UCM295554.pdf>



<sup>7</sup> In two separate places, the guidance uses identical language regarding the pre-dissemination review. "The draft guidance [on pre-dissemination review] is not for implementation," Promotional Submissions Guidance, page 8 note 11 and again page 17 note 18.

<sup>8</sup> For additional information on how the pre-dissemination review requirement would work and some problematic aspects of FDA's recommendation, see Cooke, Dale, Appendix C of Effective Review and Approval of Digital Promotional Tactics, Food and Drug Law Institute, Washington, DC, 2013.

<sup>9</sup> Note that although the formal comment period will expire on July 21, 2015, the FDA will always accept comments on a guidance, regardless of whether it is a draft or final guidance. The importance of the close of the comment period is that it sets an earliest possible date for the FDA to issue a revised draft or final guidance. The earliest possible date for the mandatory recommendations in this guidance to take effect is July 21, 2017. A more realistic timeline would be for a revised or final guidance to be issued by the end of this year or early next year, with the new requirements taking effect 24 months after that date.

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