



Regulatory review of advertising on streaming media

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This article discusses advertising on streaming media and what regulatory reviewers should take into consideration when reviewing online videos.

Introduction

Television. One word, many meanings – it could be the wide-screen home TV, the latest Hulu-exclusive series we binge-watch on an iPad, or the 5-minute Snapchat original series that releases a new episode every week. There is no shortage of places for consumers to view video content outside of a traditional “linear” television viewing experience.¹

With the advent of connected TV, pharma can now advertise to consumers through multiple social and digital channels. As a result, pharma has numerous possibilities for allocation of marketing dollars. Connected TV (CTV) ad spend alone rose by 48% from 2020 to 2021, with advertisers spending \$13.41 billion dollars for digital advertising to appear on home screens and in-stream video ads on platforms such as Hulu, Roku, and Youtube.¹ This article discusses some

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key regulatory considerations when it comes to pharmaceutical advertisements on streaming media and how that affects the regulatory review of online videos.

Television has undergone significant changes in recent decades, but regulatory guidance has not evolved at the same pace. Part 202 of the Code of Federal Regulations (21 CFR 202.1)² and guidance from the US Food and Drug Administration³ provide guidance for broadcast advertisements, including “media such as television, radio, or telephone communications systems.”³ This definition notably leaves out streaming and internet services. One possible approach to addressing the omission of streaming and internet services from the definition is to apply the learnings in the regulations and guidance to short-form video ads that look and feel like a television ad, even if they are not placed on traditional linear TV platforms. An example of that would be a 1-minute video of a “major statement” that is placed on a brand’s YouTube page.

A major statement is the disclosure of the product’s major risks in either the audio or audio and visual parts of the presentation.⁴ This statement surveys the purpose of conveying all of the product’s most important risk information in consumer-friendly language. Given the variety of risk profiles among products, the amount of information needed to satisfy the major statement requirement will vary among products. FDA guidance on direct-to-consumer (DTC) television ads⁵ notes the categories of TV ads which sponsors have to submit for pre-dissemination review. Two categories – the initial TV ad following an approval or new expanded approval, and the first ad following a safety update – allows FDA to provide feedback on the major statement. This requirement for pre-dissemination review is also emphasized in PhRMA’s 2018 Guiding Principles⁶ in which one of the principles requires companies to submit all new DTC television advertisements to the FDA before releasing them for broadcast.

Not all video is created equal

With CTV ad spend being so significant, brands may try to maximize their returns by repurposing across other platforms. For example, a DTC television ad that runs through a traditional, linear TV buy could then be posted on a brand’s YouTube page. In some cases, however, the conversion is more complicated. Taking that same DTC ad and modifying it to an online video for use across a social media channel may require a heavier lift. It will be important for regulatory reviewers to understand the differences across channels and how these differences may affect the final product. **Table 1** (p. 3) shows a selection of platforms available and the associated capabilities that can be used to play videos.

Timing limitations

Timing limitations could affect the advertiser’s ability to adequately cover safety information, depending on where the video content “lives.” In certain online video platforms, such as Instagram and Snapchat, video limitations may be as short as 15 seconds. Given the FDA’s guidance on covering benefit and risk with equal prominence, it may be difficult to voice over both efficacy and safety messages in the same way that longer-form, linear TV videos do.⁸

Table 1. Overview of platforms⁷

Platform ^a	Capabilities
Facebook	Watch tab, in-feed ads, stories
Instagram	Stories, reels, IGTV, in-feed ads
Twitter	In-feed ads
YouTube	Channel, paid ads, skippable ads
Snapchat	Video ads, story ads, collection ads, commercials
TikTok	Brand takeovers, top-view ads, paid ads
Streaming services (connected TV)	Hulu, Sling, HBO Max

^aSee Figure 2 for examples.

The FDA is vigilant in its monitoring of equal prominence in print and/or video and this is borne out by its multiple enforcement actions.^{9,10} These considerations could hinder repurposing across those platforms. Reviewers should engage with their marketing teams to consider developing videos that would best fit each platform. For example, in a short, 15-second ad, a sponsor may want to consider a reminder ad if there is a need to mention a specific brand or an unbranded ad directing viewers to another website for more information. For a longer-form ad, that is still shorter than a traditional broadcast ad, the sponsor might consider equalizing the time between efficacy and safety, even if that means that risk information is being condensed, knowing that the viewer can be directed elsewhere to find a more complete presentation of risk information.

Interactivity

Reviewers should consider the high variability in functionality across platforms. For example, if viewers are watching on a digital platform, such as YouTube, the advertisement may have a link to an outside website or to download a resource (**Figure 1**, p. 4).

When discussing how to meet adequate provision requirements, it is important to understand whether the brand team will use these functions. The FDA has provided guidance on the use of adequate provision for broadcast advertisements only.³ However, in a 2019 enforcement regarding a TV ad for Paragard, the FDA did not mention the failure to reference a concurrent print advertisement (sometimes referred to as “book of record”), which raises the question as to whether a concurrent print advertisement is necessary when it speaks to safety and directs users to a healthcare provider for further information.¹¹ Therefore, in considering placement of these ads on a digital platform, use of adequate provision may not be necessary because users can link out. Instead, it may be prudent to use that function and direct viewers on how to access the prescribing information (via use of superimposed text on screen). Reviewers should consider educating marketing on how the video may need to be revised if used on a platform where these capabilities vary.

Figure 1. Example of link out and skippable ad functionality



Note The functionality accompanying streaming and online videos differs across platforms. In this YouTube ad example, the sponsor is able to link out to a website and provide a call to action to download a resource. In addition, the viewer can skip the ad and go straight to the desired content [red text added for emphasis].

Source: YouTube

Another functionality consideration is the potential to skip ads (Figure 1). This ability, which typically appears 5 seconds into the video, allows viewers to bypass the rest of the ad and go straight to the desired content. Although it presents a higher level of interactivity than typical linear TV or platforms without skippable abilities, one approach is to consider the skippable ad as the equivalent of having a viewer pick up a remote to change the channel. In that lens, a TV ad could be repurposed across skippable ad platforms without any major revisions to the location of the major statement.

Player size

With the various mechanisms available to showcase an advertisement, there are also variously sized players housing the ad. Reviewers should take the size of the player into consideration when reviewing video assets. Other points to consider include:

- How the size of the video affects the viewer’s ability to comprehend both the visual and audio portions of the ad;
- Whether there are Supers on screen, and if so, whether they are fully visible and readable; and
- Whether there are competing background visuals or audio messages while the Supers are on screen.

Common terms^{1,3,12}

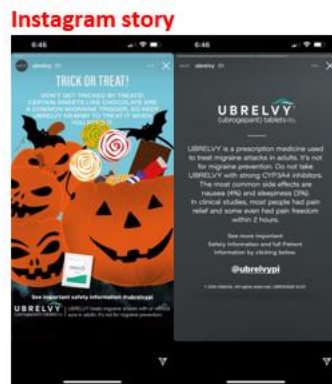
The following are some terms that may be useful during the promotional review team discussions:

- **Broadcast advertisements** – Advertisements placed on media, such as television, radio, or telephone communications.
- **Connected TV (CTV) or streaming services.** CTV is TV that connects to the internet to provide options beyond what is offered from a cable provider, including digital TV apps such as Hulu and YouTube.
- **Linear TV.** Also known as live TV, linear TV is the traditional way of watching TV where multiple viewers watch the same program at a scheduled time.
- **Online videos.** An umbrella term for using videos to promote a product or service across digital and social channels.

Conclusion

It is crucial for reviewers to stay abreast of the changes as each platform evolves. Reviewers need to engage with and educate their marketers about the regulatory environment. Guidances often may not tie in directly with the platform; but one can take learnings from the guidances, as well as previous enforcement actions (or lack thereof), to inform one on how to proceed.

Figure 2. Examples of pharma ads/posts on digital platforms



These posts illustrate the many ways videos can be used across platforms, sometimes with the same platform having different functionality depending on the type of asset. For example, users are able to like and comment on Instagram posts, but not Instagram stories.

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