

## FDA releases warning letter on video marketing

David BenBassett and Sara Weiner, **Interactive Strategy**

June 23, 2010

**Summary:** On May 27, 2010, the Food and Drug Administration (FDA) issued a warning letter to Eisai Corporation regarding a consumer-targeted method-of-action video posted on the website for Gliadel<sup>®</sup> Wafer (polifeprosan 20 with carmustine implant), a drug used as an alternative to surgery or radiation in patients with malignant gliomas. The letter criticizes the minimization of risk information in the video, citing lack of integration of risk information to main video content and concern for audio and visual cues that imply the ad is over prior to presenting the risk information. The letter also takes issue with the misuse of efficacy claims and research data. Marketers should ensure that risk information is given the same focus as benefit information and integrated into the overall creative experience, and continue to make sure content is consistent with the clinical data.

### Key Information

The video and website were submitted to the FDA using Form FDA-2253. The letter to Eisai, which only cites the video, was released on May 27, 2010, and posted to the FDA website on June 17, 2010.

The method-of-action video is targeted toward people considering treatment for gliomas and informs viewers about an alternative to radiation. The video appeared on the Gliadel<sup>®</sup> consumer website, and no registration was required.

In its warning letter, the FDA took issue with: 1) the placement and creative presentation of the risk information; and 2) the inaccurate efficacy claims. According to the letter, the video failed to **“convey any of the serious risks of Gliadel<sup>®</sup> during the audiovisual portion of the video.”** When the risk information was presented, it was after numerous audio and visual cues that implied that the ad had ended, such as presentation of the **“MGI Pharma logo and a significant period of silence.”**<sup>1</sup>

Additionally, the FDA stated that the ad includes misleading statements about the product’s method of action and its efficacy.

### Implications and Action Items

The letter focuses on proper presentation and integration of risk information in an online consumer video. In the May 2009 FDA guidance on risk presentation, the FDA clearly indicated that the risk information must be presented in a manner consistent with the treatment of benefits information, including the same type of creative emphasis, language, and font.

Here are some important guidelines for marketers to follow when developing consumer-targeted videos:

- **Apply** FDA guidelines to all audiovisual materials with the same vigilance that one would apply to all other media, and review at each step to ensure there are no potential issues
- **Reevaluate** placement of risk information—risk information should not be isolated in the last frame or come after any creative or audio signals that may indicate the ad has ended
- **Ensure** all efficacy statements and benefit claims are supported by substantial evidence and consistent with the Prescribing Information

To review the Eisai warning letter, please visit <http://tiny.cc/gliadel> (PDF). For more reviews of FDA guidelines, please visit <http://www.rtcrm.com/whitepapers> and <http://www.rtcrm.com/blogs>. FDA warning letters and FDA guidelines can be found at <http://www.fda.gov>.



<sup>1</sup> FDA Warning Letter to Eisai Medical Research Inc., May 27, 2010