

## FDA Issues “Facebook Share” Warning Letter

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**Summary:** In a warning letter publicly posted on August 4, 2010, the FDA cited the “Facebook Share” functionality on Novartis’ Tasigna website for failing to deliver appropriate risk and efficacy information, and for failure to pre-clear the communications. This suggests that DDMAC considers “Facebook Share” and other content sharing technology – generated messages to be promotional material, and all stakeholders must fully understand and evaluate this functionality before including it on any branded or unbranded website

### Key Information

The FDA warning letter cites the “Facebook Share” functionality of Novartis’ Tasigna website for disseminating misleading content about the drug on Facebook. Tasigna is a second-line treatment for chronic myelogenous leukemia (CML) and carries a black box warning for severe risks. Tasigna’s HCP and consumer websites include a “Facebook Share” tool that, upon a visitor’s action, pulls information from the page to share on Facebook. This information makes representations about the efficacy of Tasigna but fails to communicate any risk information. The content also indicates that Tasigna is approved to treat all individuals with CML, although it is only approved as a second-line treatment for patients with chronic or accelerated CML. Furthermore, the unique messages created for the shared content were not submitted for required pre-clearance by the Division of Drug Marketing, Advertising and Communications (DDMAC).

*This warning indicates that the FDA considers “Facebook Share” content to be promotional material and requires it to be submitted to the same review process as all other promotional copy.*

### Violations:

1. **Omission of Risk Information:** “Facebook Share” text does not mention the black box warning or any risks associated with Tasigna. The HCP-directed shared content reads: “Tasigna (nilotinib) is used to treat a type of leukemia called Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML),” and the consumer-directed content states: “In addition to taking Tasigna (nilotinib) 200-mg capsules, talking to your doctor and receiving health tips can help you treat your CML.”
2. **Broadening of Indication:** Shared content implies that Tasigna is used to treat all individuals with CML; however, it is only approved as a second-line treatment for chronic or accelerated CML.
3. **Overstatement of Efficacy:** One instance of the “Facebook Share” text on the consumer-directed site refers to Tasigna as a “next generation” treatment and implies an unproven superiority over other tyrosine kinase inhibitors that treat PH+ CML.
4. **Failure to Submit:** Novartis failed to submit these materials to DDMAC for approval before or at the time of publication.

### Implications and Action Items

Because information sent through “Facebook Share” and other content sharing technology is now considered promotional material, it is imperative to understand how the technology generates messages and to assess the return-on-investment (ROI) before including this sharing technology on a website.

- **Consider** the appropriateness of content sharing technology: If a drug’s target market is not an active user of social media or the content does not lend itself to word-of-mouth advocacy, the risks associated with implementing and managing “content sharing technology may outweigh the benefits.
- **Understand** how each type of content sharing technology works: It is important to understand how each unique sharing technology being considered generates content and to vet all content as unique messages.
- **Take note** that the FDA is paying closer attention to sharing technology: Because the FDA considers this content promotional material, it is subject to the same review and management requirements as other copy.
- **Leverage** precedent: Google’s “adquate provision” format for pharma paid search ads can serve as a guide on how to balance risk and benefit information. Google search ads now are able to display the following: “Click to see full safety and prescribing information, including black boxed warnings, at [www.drug.com](http://www.drug.com).”