

Novartis Unbranded Website Warning Letter

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Summary: The FDA restates its commitment to the “Net Impression” standard set in July 2009, in an April 24th 2010 letter regarding multiple Novartis unbranded websites. These are the first Web executions to be cited for Net Impression violations based on a complete experience, not just one page or one section of an interactive element. DDMAC not only cites issues with design elements, but also criticizes empirical data and sourced research. Additionally, the lack of direct competition in the category creates an unusual core marketing issue — unbranded content becomes inherently branded whenever a treatment is mentioned. As a result, unbranded websites are clearly being held to a stricter standard, and the FDA is wasting no time scrutinizing every page, word, and link.

Key Information

An FDA warning letter dated April 21, 2010, cites cmlalliance.com and gistalliance.com for noncompliance, focusing criticism primarily on the HCP sections of the sites. The basis for the letter is that Gleevec has a unique indication not offered by any other medication. Usually, unbranded websites are in the clear when discussing treatment options (without brand name) and linking to branded sites. However, when no competition exists, unbranded content becomes inherently branded. Thus, DDMAC states that by coupling the indication with references to Novartis, these two unbranded websites actually become branded. Additionally, the unbranded websites use brand colors and the generic name of the Rx, they source several clinical studies that mention the product by name, and mention an off-label use of the treatment. Through its critique of all of these elements, one begins to see how the FDA is implementing the “Net Impression” standard: No single element creates a substantial issue; it’s the effect that all elements together create. It is also important to recognize how thorough DDMAC is being in investigating digital content, from clicking through individual links to checking domain registration data.



Violations

1. **No competition:** Gleevec is the only first-line Rx for Ph+ CML.
2. **Generic mentions:** The generic name for Gleevec, imatinib mesylate, is used on the unbranded website and downloadable PDFs.
3. **Linking:** Copy reads “learn about a 1st line prescription treatment for Ph+ CML” and links to gleevec.com.
4. **Visual elements:** gistalliance.com (unbranded) uses same orange as gleevec.com (branded). Link color is a different orange, but creates similar effect to untrained eyes.
5. **Logo and Registration:** Novartis logos are present on unbranded website and sites are registered to Novartis.

Implications and Action Items

These citations reinforce long-standing rules. Brands should continue to ensure unbranded and branded campaigns do not have similar aspects when running concurrently. If an Rx has no competition, brands will need to be careful not to cross the line and create a “default” branded situation.

The most important implication is the enforcement of the “Net Impression” standard. Marketers need to rethink how they review unbranded creative, offline and online. A holistic view of the communication and the user experience will be vital to ensuring that the lines between unbranded and branded are not crossed.

- If creating HCP unbranded content, completely separate consumer unbranded site by URL and design. Compare unbranded and branded sites from a consumer perspective, not a professional consumer (HCP) perspective.
- Do not reference indication on links between unbranded and branded sites if there is no competition.
- While each page should be considered as an experience in itself, be sure to look at each page as a part of a whole — including HCP and consumer if on the same URL, and connected websites owned by the brand.

To review the Novartis warning letter, please visit <http://tiny.cc/fdaletter2>. For more reviews on 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>.