

Unbranded Web Sites: FDA Finds Violative Promotional Practices

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User-generated content is gaining momentum and pressures are mounting to take advantage of Web-based opportunities. At the same time, guidance to industry on the use of the Internet and Web 2.0 remains outstanding. This article focuses on the intensity demonstrated by the Division of Drug Marketing, Advertising and Communications (DDMAC) in its interpretation of two Web sites sponsored by Novartis Pharmaceuticals Corp. (Novartis).

Misleading Product Claim Websites

The FDA issued a warning letter on April 21, 2010, to Novartis regarding two unbranded Web sites, www.gistalliance.com and www.cmlalliance.com (alliance Web sites), that included disease state information and clinical data about gastrointestinal stromal tumors (GIST) and chronic myeloid leukemia (CML). DDMAC concluded that the alliance Web sites represent branded promotional material for the drug Gleevec and that the alliance Web sites are false and misleading because they promote Gleevec for an unapproved use, fail to disclose the risks associated with the use of Gleevec and make unsubstantiated dosing claims, which can put patients at higher risk of experiencing adverse events.

DDMAC's review is a cascade of intensity that ends with a request that Novartis submit a comprehensive plan of action to disseminate truthful, non-misleading and complete corrective messages to the audiences that received the violative promotional materials, as well as provide the full details of its involvement with and control over the www.bloodleveltesting.com Web site.

In concluding that the alliance Web sites effectively promoted the use of Gleevec, DDMAC relied on the following combination of factors:

- The alliance Web sites are “perceptually similar” to the Gleevec Web site, incorporating the distinct orange color, design layouts and other elements.
- The alliance Web sites are clearly marked with the Novartis Oncology name and logo and discuss sponsorship by Novartis Pharmaceuticals Corp.
- The healthcare professional-directed Web page on the CML alliance Web site provides a direct link to the Gleevec product Web site, and the patient-directed Web page provides a link to a Novartis-sponsored Web site, “My CML Circle Program,” which discusses Gleevec as a treatment for CML.
- The alliance Web sites present data from imatinib clinical studies and provide the corresponding literature references that include the drug name in the listed publication titles, and one of the publications recounts a pivotal clinical trial submitted to FDA in support of the approval of Gleevec in the adjuvant treatment of GIST.
- The alliance Web sites discuss the use of tyrosine kinase inhibitor (TKI) for first-line treatment of GIST and CML; Gleevec is the only TKI approved for first-line treatment of chronic phase CML and the only TKI approved for first-line treatment of GIST, product details “well known” in the oncology community.



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- The alliance Web sites contain numerous references to the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology, which recommend the use of Gleevec exclusively for the first-line treatment of CML and GIST.
- The alliance Web sites are registered to Novartis AG.

Unsubstantiated Dosing Claims

DDMAC's drill down around the unsubstantiated dosing claims includes comments that the alliance Web sites heavily promote the "CML & GIST Alliance™ Blood Level Testing Program," which encourages physicians to test patients for "suboptimal" plasma levels of imatinib. Avantix Laboratories is noted as explicitly recommended to provide the corresponding testing services, and hyperlinks are provided for physicians to access the recommended services. Further noted is the associated Web site dedicated to the imatinib blood level testing program, www.bloodleveltesting.com, as making numerous unsubstantiated claims about the use of blood tests to optimize outcomes specifically in patients with GIST or CML who are taking imatinib mesylate.

The following observations by DDMAC are notable:

- Although clicking on the prominently displayed links on the CML Alliance and GIST Alliance Web sites leading to www.bloodleveltesting.com produces a pop-up window disclaimer stating that you are "moving to an external Web site independently operated and not managed by the Novartis Pharmaceuticals Corp.," we note several indicators that Novartis is, in fact, responsible for the content of the Web site. For example, the Web site is registered to Novartis AG, contains the CML Alliance and GIST Alliance logos, and makes repeated reference to Novartis.
- The Web pages within www.bloodleveltesting.com provide hyperlinks to the CML Alliance and GIST Alliance home pages. The Web site does not mention any TKIs other than imatinib, nor does it mention pharmaceutical manufacturers other than Novartis.
- Novartis provides the blood level testing program at no cost to healthcare providers. Thus, it appears that Novartis may be at least partly responsible for the content on this Web site.

This warning letter comes at a time when many in the industry are looking for ways to create a community with patients and physicians amid an environment overshadowed by legal and regulatory considerations.

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