

# FDA Warning: Busulfex Warned for Misleading Content on Website

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## Top-Level Points

- Otsuka received a warning letter from the FDA because its Busulfex website omits and minimizes risk information and makes unsubstantiated and misleading claims.
- This warning letter indicates that the FDA is more aggressively examining aspects of websites where marketing language is used, including headlines and taglines.
- Many pages on the site omit information from the PI or make claims contrary to information from the PI, including a boxed warning.
- The FDA letter says the Busulfex website draws inaccurate conclusions, misinterprets data from studies and employs improper data calculation—all information must comply with the reporting standards established by the scientific community.

## Summary

On October 17, 2011, the FDA released a warning letter<sup>1</sup> to Otsuka America Pharmaceutical, Inc. (OAPI) regarding its health care professional website for Busulfex, which is a black box drug for leukemia treatment. The FDA concluded that the website violates compliance requirements by omission of safety information, minimization of risk information, unsubstantiated and misleading claims, and overstatements of efficacy across multiple pages.

## Key Information

According to the FDA, the Busulfex website suggests that the drug is safer than has been demonstrated by research or clinical evidence. In particular, dosage and administration for children is mentioned, but the site fails to convey all risk information and adverse events reported for children. Also, the Important Safety Information (ISI) section at the bottom of each page and some interior content does not include all facts regarding toxicity reported in the Prescribing Information (PI). Lastly, specific pages related to dosing and administration fail to discuss the need to take accompanying drugs prior to and throughout the course of treatment.



The warning letter further states that the Busulfex website makes deceptive claims regarding safety and efficacy. Several pages of the website claim “low incidence of severe toxicities” contrary to the toxicity information contained in a boxed warning. In addition, the site makes certain claims about the usage of Busulfex for seizures, contrary to observations reported in the PI. Likewise, the Busulfex website claims a “straightforward IV administration” even though there are several instructions that must be followed to properly administer the drug.

Moreover, the letter says the site overstates the efficacy of Busulfex by reporting misleading statistics: The site mentions statistics about the probability of overall survival and disease-free survival that have not been accurately calculated in accordance with scientific methodologies.

The FDA also cites the Busulfex tagline “Begin With Precision,” as well as numerous examples of claims and webpage headlines that use words like “precision,” “optimal,” “predictable,” and “controlled,” as being misleading. These claims imply a correlation between the drug and certain clinical benefits not supported by legitimate evidence. This is unusual, because elements like the tagline would have already been through rigorous legal review, and likely used on many other pieces of collateral.

<sup>1</sup><http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM278157.pdf>

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## Implications and Action Items

This warning letter demonstrates the importance of making accurate and fully supported claims and associations on pharmaceutical websites. As always the FDA is evaluating drug information for the most stringent accuracy, so it is best to:

- **Remember that all advertising language is subject to FDA surveillance.** This warning letter cited multiple examples of misleading language that appeared outside of the body copy in the webpage and section headlines, and in the website tagline. While there exists only one other instance of a similar warning,<sup>2</sup> marketers ought to bear in mind that this copy is subject to the same level of scrutiny as the body copy and this letter may mark the start of stricter FDA surveillance. All language that defines the brand identity and may appear across a variety of media and materials, such as the product tagline, ought to be carefully selected.
- **Be consistent with the PI.** All risk information reported in the PI ought to be reported on the website with accuracy and without omission of facts regarding risk.
- **Ensure data is complete.** Make sure that claims, associations and correlations between the drug and clinical outcomes are accurate and backed by legitimate evidence and accepted scientific methodologies.

For more insights into applying FDA regulations to digital marketing, see: <http://rtcrm.com/whitepapers/>.



The RTCRM Digital Integration and Innovation team is tasked with keeping track and making sense of the ever-changing digital world. It's our job to understand the nuances of how and why different types of people use technology and what that tells us about them. More importantly, it's our job to help our clients apply this knowledge to better communicate with their customers. We help clients translate business goals into marketing campaigns that build relationships with customers. In the 21st century, understanding how and why someone uses technology is as important as understanding where they live, what gender they are, and how old they are. That's where we come in. From ensuring that technological behavior is considered in the research phase, to tactical plans that align digital, print and broadcast tactics, we work with clients and internal partners to make sure it all works.

It's not about what's cool. It's about what works.

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<sup>2</sup><http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM260575.pdf>

