

# FDA Warning: Lipitor Warned for Linking Without Providing Risk Info

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## Top-Level Points

- Pfizer has received a warning letter from the FDA because its Lipitor website links to the products Caduet, Chantix and Norvasc, but does not mention any risk or prescribing information.
- The FDA itself did not catch these violations; they were submitted via the DDMAC Bad Ad program.
- One of the medications, Chantix, has a boxed warning and serious potential side effects. This makes the infraction even more serious in the eyes of the FDA.
- This warning letter comes on the heels of a previous citation in 2009, for featuring paid search ads for several of the same drugs without including any risk information.

## Summary

On August 31, 2011, the FDA released a [warning letter](#) to Pfizer regarding its Lipitor website. The “Online Resources” page on the site was cited for linking to branded pages for several Pfizer prescription medications and discussing their efficacy but failing to include any risk information. This violation was not caught by the FDA; it was submitted via the DDMAC Bad Ad program, and this is one of the first sites to be warned because of this program. This warning also comes on the heels of a previous warning letter from 2009, in which Pfizer’s sponsored links on search engines mentioned several of the same products with no risk information added.

## Key Information

The Lipitor website (www.lipitor.com) has an “Online Resources” page that offers more information on other Pfizer medications that can help treat heart disease. The page, when cited, contained the following copy:

- CADUET® (amlodipine besylate/atorvastatin calcium)  
Learn about a treatment for high blood pressure and high cholesterol in a single pill
- CHANTIX® (varenicline)  
Learn about a prescription drug to help people quit smoking
- NORVASC® (amlodipine besylate)  
Learn about a treatment for high blood pressure and the chest pain of angina

However, it fails to communicate the full prescribing information or any risk factors associated with these products. Several of these drugs have fairly serious contraindications and potential side effects, and Chantix actually carries a boxed warning for its neuropsychotic symptoms. Since these drugs are Pfizer products, fair balance laws go into effect each time these products are mentioned, even if it is on a website for another Pfizer medication.

The FDA previously warned the company in March 2009, when its sponsored links on search engines for several products, including Caduet and Chantix, discussed the efficacy of these medications but did not include any risk information. RTCRM discussed this in a previous POV, which can be found at: <http://bit.ly/E7knr>. According to the 2011 warning letter, “DDMAC is concerned that Pfizer is continuing to promote its products in a similarly violative manner.”

Since the “Online Resources” page of the Lipitor site is considered promotional material, it must include risk information that is relevant to the claims that are made about any Pfizer medications mentioned – regardless of the fact that the overall website is not promoting the medication named in the link. In the case of Chantix, this omission is particularly alarming because the product carries a boxed warning for serious neuropsychotic effects, such as suicidality. Although the copy for each of these medications contains a link to the product’s website, this is not enough to mitigate the omission of risk information from the originating site.



## Implications and Action Items

This warning letter demonstrates that for any pharma company trying to use one of its brands to promote another, any and all mentions of a product must include explicitly stated fair balance information. Implications and action items for this letter include:

- **Portfolio Sites:** For pharma companies that are promoting their portfolio of products or cross-selling across brand websites, all mentions of a prescription medication must contain fair balance information – even if the product is mentioned outside of its own site.
- **HCP Awareness:** Health care providers are aware of the regulations governing pharmaceuticals in marketing; even if the FDA misses a site, it can still be picked up via the Bad Ad program and submitted for a citation.
- **Promotional Material:** All promotional material that mentions the name of the product and its indication should mention risk factors and clearly link to more information.
- **Paid Search:** The FDA is concerned about a brand making efforts to unfairly represent its products by providing the indication and no risk information; if a brand has multiple offenses, the FDA will remember and comment on them.

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

