



WARNING LETTER

April 1, 2009

Jonathan Richman, Blogger
Dose of Digital
10 Main Street
Cincinnati, OH 45202

Products:

Dose of Digital Blog

Dear Mr. Richman:

This letter is in reference to your firm's continued writings as they appear on the blog called "Dose of Digital." Many of your posts are in violation of the Federal Food, Drug, and Cosmetic Act (the Act). In particular, your continuous posts regarding the FDA's practices are of greatest concern including the following:

- FDA Uses Social Media, But You Can't (<http://www.doseofdigital.com/2009/02/fda-uses-social-media-you-cant/>)
- How to Avoid FDA Regulations Using Mobile Marketing (<http://www.doseofdigital.com/2009/02/avoid-fda-regulations-mobile-marketing/>)
- The FDA Is Already Creating Digital Promotion Rules (<http://www.doseofdigital.com/2009/03/fda-creating-digital-promotion-rules/>)
- FDA Isn't Ready for Us...Stop All E-Marketing (<http://www.doseofdigital.com/2009/01/fda-isnt-ready-for-us-stop-all-emarketing/>)

As you are not a manufacturer, distributor, or seller of pharmaceutical products, we have limited jurisdiction over what you post. However, in cases like these, the Act allows us to assume executive powers as indicated under Section OU812 of the Act. These powers can only be assumed when FDA has determined that any marketing (as quoted from the Section in the Act) "makes it appear as though FDA is not a subject matter expert" or "infers that FDA is not in touch with the realities of the marketplace." Your blog posts violate both of these clauses.

FDA has only assumed powers via Section OU812 of the Act once before and we do not take this lightly. In that situation, Pharmed, another popular industry blog, had also commented on FDA's ability to regulate pharmaceutical marketing. We made it appear as though the editor, Ed Silverman, had a job change and was "choosing" to stop writing.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing regarding whether you plan to cease the violative activities described in this letter. If you no longer contribute, manage, edit, or write for the blog referenced in this letter, your response should so indicate, including the reasons that, and the date on which, you ceased production.

Your response to this letter should be directed to the attention of Mr. Gotham C. Welterweight, Consumer Safety Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Consumer Safety Officer, WO51 RM 5242, 10903 New Hampshire Avenue, Silver Spring, MD 20993.

Sincerely,

/s/

Trevor Manfranginsindin, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration