

DDMAC Warning Letter Summary

Date	Company	Product	Vehicle	Violation
March 2006	InterMune	Infergen – Hepatitis C	Journal Ad	<ul style="list-style-type: none"> ▪ Overstated Efficacy – Ad stated that “only Infergen” offered treatment to non-responders, however since the studies were conducted that demonstrated Infergen efficacy for non-responders at a time before newer therapies came to market, a claim that it was the “only” alternative was not proven by the studies upon which the claim relied. ▪ Minimization of Risk – Label contained specific warnings for cardiovascular patients that were not mentioned in the ad journal.
February 2006	Mayne Pharma	M.V.I 12 - Prevention of Vitamin Deficiency (Multi-vitamin infusion without Vitamin K)	Promotional Mailing	<ul style="list-style-type: none"> ▪ Omission of Risk Information - The promotional mailer included a reference to the full prescribing information; this statement, however, was not deemed sufficient to provide appropriate qualification or pertinent information for claims made in the mailer. For the piece to be truthful and non-misleading, it must contain risk information in each part as necessary to qualify any safety or effectiveness claims made in that part. Because the piece makes effectiveness claims but contains no risk information, it is false or misleading.
February 2006	Palatin Technologies	Neutrospec – Radiopharmaceutical for diagnostic purposes	4 Professional Digital Exhibit Panels; Video posted to Web site	<ul style="list-style-type: none"> ▪ Product not on the market at the time due to safety concerns, yet still received Warning Letter ▪ Omission of Risk Information – The detailed risk information in the PI was not included in the digital billboards. ▪ Overstatement of Efficacy – The digital billboards contained efficacy figures that differed from the study results outlined in the PI. They also applied the term “rapid” to the product, without defining it and the agency felt that the video claiming that a diagnosis could be made in 5-6 minutes overstated PI findings of 60 minutes. The video characterized the procedure as “simple” while the agency sees it as involved, demonstrating that the use of terms to characterize a result without setting context is a danger area. Lastly, the company used physician POV to state that they didn’t need another test, overstating the role of the product.

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January 2006	Sankyo	Benicar – High Blood Pressure	Sales Aid	<ul style="list-style-type: none"> ▪ Overstatement of Efficacy/Superiority – the sales aid made reference to superiority, but the studies that it relied on to do so were open-label, meta analyses, titration studies or trials that did not compare drugs at their maximum prescribed doses. ▪ Minimization of Risk – serious risks of use during pregnancy were minimized in the package and largely referred physicians to the PI, though the aid did have a copy of the box warning in it.
January 2006	Duramed	Cenestin - estrogens	Journal Ad	<ul style="list-style-type: none"> ▪ Minimization of Risk – Material from the boxed warning on the PI not included in the ad. Additionally a 2-12 fold increase in cancer rates among certain patients was characterized by the ad as creating conditions that “may” lead to increased cancer risk. ▪ Implied Superiority Claims – By presenting unique characteristics of a product packaged together, or to suggest that these benefits offer a particular uniqueness may be construed by the agency as implying superiority.
January 2006	Medicis	Shampoo	Electronic Brochure on Web site	<ul style="list-style-type: none"> ▪ Broadening of Indication – Language that stated “routine” use or making the product part of a “regular routine” implied long-term use was proven safe and effective, though studies were not available to that end. ▪ Omission of Risk – most serious risks listed in PI were not seen by the agency in the promotional materials.

Prepared by Eye On FDA (www.eyeonfda.com/).