



We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

*ISI*  
Douglas L. Sporn  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research