

# FDA Proposes "Experimental Study of Comparative Direct-to-Consumer Advertising"

December 9, 2011

On December 9, 2011, the Food & Drug Administration (FDA) issued a notice announcing that a proposal to collect information for a "Experimental Study of Comparative Direct-to-Consumer Advertising" had been submitted to the Office of Management and Budget (OMB). FDA is required to submit the proposal to OMB for review and clearance under the Paperwork Reduction Act of 1995. FDA's submission reveals its intent to study direct-to-consumer marketing of FDA-regulated products, with a focus on prescription drug advertising.

According to FDA, research findings on the effects of comparative versus noncomparative ads on purchase intentions indicate that comparative ads result in greater purchase intentions than noncomparative ads. Given the prevalence of comparative advertising, "FDA is embarking on the proposed research to ensure that it has adequate information to assess whether prescription drug comparative DTC ads provide truthful and nonmisleading information to consumers."

Through the study FDA "aims to investigate how consumers interpret and react to DTC comparative drug ads." The two-phase study will explore drug efficacy comparisons and other evidence-based comparisons, such as dosing, mechanism of action, and indication. The goal of Phase I is to (1) explore how consumers understand and interpret print and broadcast ads that explicitly compare the efficacy of two similar drugs; and (2) learn whether named comparisons are more likely than unnamed comparisons to promote accurate recall, comprehension, and perceptions. The goal of Phase II is to (1) determine if consumers infer that one drug is better or more effective than another from ads that include different types of drug label comparisons (i.e., indication, dosing, mechanism of action, drug risk), and (2) if consumers consider switching medications based on these comparisons in advertisements.

FDA also intends to apply existing comparative literature to DTC advertising, beginning with a large compendium of information on the comparative effectiveness of medical treatments in 14 priority medical conditions (including arthritis, cancer, dementia, depression, diabetes, and substance abuse). The compendium is being secured by the Agency for Healthcare Research and Quality, which also is funding a set of CHOICE (Clinical and Health Outcomes Initiative in Comparative Effectiveness) studies designed to explore comparative effectiveness.

More information regarding FDA's proposal can be found [here](#).