FDA makes "Quantitative Summary of the Benefits and Risks of Prescription Drugs: A Literature Review" available for comment

December 13, 2011

On December 13, 2011, FDA announced the availability of a draft report entitled “Quantitative Summary of the Benefits and Risks of Prescription Drugs: A Literature Review” for public comment. The literature review was conducted pursuant to section 3507(a) of the Patient Protection and Affordable Care Act (Affordable Care Act) which required the Secretary of Health and Human Services (HHS), acting through the Commissioner of Food and Drugs, to determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in standardized format (e.g., similar to the “Drug Facts” on over-the-counter-products) to the promotional labeling or print advertising of such drugs would “improve health care decision-making by clinicians and patients and consumers.”

To fulfill this requirement, FDA commissioned a review of scientific studies related to communication of quantitative benefit and risk information and is providing a comment period for interested parties to comment on the literature review report as it relates to section 3507 of the Affordable Care Act. FDA’s literature review will be available for public comment until February 13, 2012.

More information regarding the literature review report, including information regarding how to submit comments, is available here.