

From page 2 of the OMB Supporting Statement:

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the Food and Drug Administration (FDA) to conduct research related to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

FDA regulations require that advertisements that make claims about a prescription drug include a “fair balance” of information about the benefits and risks of advertised products, in terms of both content and presentation. Ads can present information in ways that can optimize or skew the relative balance of risks and benefits. Both healthcare providers and consumers have expressed concerns to FDA about the effectiveness of its regulation of manufacturers’ prescription drug advertising directed to consumers (DTC), especially as it relates to assuring balanced communication of risks compared with benefits.

FDA has long fielded questions from stakeholders about the definition of “fair balance” in DTC advertisements and how to implement it in practice. As such, FDA proposes a research project to address the issue empirically. In any empirical investigation, researchers must operationalize concepts such as fair balance specifically in order to measure them accurately. The proposed research in this packet is one such operationalization. FDA recognizes that there is a tradeoff between the specificity and control of the research setting, and consequently the utility of the findings, and the generalizability of the findings to the field as a whole. As an evidence-

based Agency, FDA proposes to begin the process of investigating this issue scientifically. This research will inform the direction that FDA will follow. The results of this study will help FDA determine whether additional research is necessary, if there are additional questions to be answered, and what direction future discussions will take. The study is one piece of the puzzle that will help FDA fulfill its mission to protect public health from false and misleading DTC prescription drug advertisements.

One characteristic of DTC television broadcast ads that has raised continuing concern is the use of compelling visuals...