

For Immediate Release

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Coalition for Healthcare Communication Seeks New Prescription Medicine Advertising Rules

Citizen Petition to FDA also Proposes New FDA Standing Communication Advisory Committee

Washington, D.C., March 31, 2006 – The Coalition for Healthcare Communication filed a Citizen Petition with the U.S. Food and Drug Administration (FDA) today asking the FDA to formulate new rules governing consumer advertising of prescription medicines. The goal of the proposed new rules is to make consumer advertising simpler and clearer, and to stimulate better dialogue between patients and physicians.

The Coalition also asked the FDA to create a standing advisory committee of academic and professional experts in consumer behavior to advise the agency on communication policy.

“Recent strides by the pharmaceutical industry vastly have improved prescription medicine ads,” said John Kamp, Executive Director of the Coalition for Healthcare Communication. “We are encouraging the FDA to take the next step by modernizing the rules. Our goal is simpler, clearer messages that communicate both the risks and benefits of prescription medicines, more informed doctor/patient dialogue, and improved patient compliance.” The Coalition represents trade associations that specialize in medical communications, marketing, advertising and publishing.

The Petition proposes three new specific requirements that would appear in both broadcast and print advertising. The three core messages that would have to appear in every consumer ad relate to prescription medicine risks, the need for a professional consultation and prescription, and the patient’s role in those consultations. At present, Kamp said, FDA’s prescription medicine advertising rules require complicated information that many consumers cannot understand or use on a practical basis.

“Great advertising requires clear, consistent messages,” said Ron Pantello, CEO of EURO RSCG Life Worldwide and immediate past chairman of the Executive Committee of the Coalition.

“Advertising agencies, their clients, the FDA and the public all want better ads. Pharmaceutical companies have moved in the right direction by adopting the new PhRMA self-regulatory direct-to-consumer (DTC) advertising principles. Now it’s time for the FDA to assert its national

leadership and exclusive regulatory authority in prescription medicine marketing. New FDA rules informed by an expert advisory committee will make it happen.”

“This FDA recognizes the proven power of prescription medicine advertising to promote awareness of treatable medical conditions and treatment options,” said Harry Sweeney, Chairman of Dorland Global Health Communications and chair of the Coalition Executive Committee. “But, new rules can enhance this power and accelerate its benefits to both advertisers and the public health.”

The Coalition’s petition asks that the FDA begin a formal administrative process, including rule-making and a public comment period so that consumers and other interested parties can provide their own views on how prescription medicines can best be depicted in consumer advertising.

Advisory Committee

The Petition also recommends that the FDA create an advisory committee like those used in the prescription medicine approval process that would advise the FDA on marketing and communications issues. In particular, the committee would bring to the FDA other government advertising experts, academic behavioral scientists and communication professionals to help guide the FDA’s decisions in regulating prescription medicine marketing, and also in communicating risk information itself. The committee would ensure that the best available minds across government, academia and the communications industry help guide and inform FDA policy. The committee process would bring additional expertise to the FDA and help it avoid new policies and rulings that would violate the speech protections of the First Amendment.

Background

FDA DTC advertising policy is largely an artifact of the five-decades-old rules of the FDA designed for print advertising in professional journals. Those rules were originally adopted in the 1960’s after FDA was given authority to regulate prescription medicine advertising.

The identical rules were applied to consumer advertising, without a formal rulemaking, when consumer advertising of prescription medicines started. The Coalition recommends that the FDA recognize that 1960’s rules applied to print advertising in medical journals may not be applicable in the 21st century.

Further, research on consumer advertising gives us greater insight into how information about prescription medicines should be conveyed, and the Coalition urges that the new rules be based on a scientific understanding of consumer behavior and a full understanding of both the potential and the limits of consumer advertising.

Prescribers and consumers have a different role in the prescribing decision, need different information, and require ad rules designed to fit their needs. For example, consumers must be given enough information to stimulate appropriate discussions of therapeutic options with their physicians, but that same information should not confuse or scare them away from asking questions or remaining compliant with current treatment. *DTC advertising should not be, and should not appear to be, a substitute for patient-physician interaction, and sound prescription medicine selection by trained physicians.*

The Coalition for Healthcare Communication

The Coalition for Healthcare Communication defends the right of health professionals and consumers to receive truthful information regarding pharmaceuticals and medical products, as safeguarded by the Constitution of the United States. Founded in 1991, the Coalition represents organizations, rather than individuals, dedicated to assuring the free exchange of scientific information without undue government interference.

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