

**Washington Legal Foundation
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Washington, DC 20036
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August 7, 2006

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Re: Citizen Petition Regarding Review of Policies and Practices of DDMAC and OCBQ to Ensure Compliance with First Amendment and Statutory Mandate

CITIZEN PETITION

The Washington Legal Foundation (WLF) hereby submits this Petition under Section 502(a) and (n) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 352(a), (n), to request the Commissioner of Food and Drugs to direct the Division of Drug Marketing, Advertising and Communications (DDMAC) within the Center for Drug Evaluation and Research, and the Office of Compliance and Biologics Quality (OCBQ) within the Center for Biologics Evaluation and Research to review their respective policies and practices for consistency with their statutory authorities and with the First Amendment, and as a result of that review, to take steps to ensure that future actions are both legally authorized and appropriate.

WLF is a public interest law and policy center headquartered in Washington, D.C., with supporters in all 50 States. WLF devotes a substantial portion of its resources to defending and promoting free enterprise, individual rights, and a limited and accountable government. WLF has been involved in numerous government proceedings relating to FDA regulation. For example, WLF successfully challenged the constitutionality of FDA restrictions on speech regarding off-label uses of FDA-approved products. Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998), appeal dismissed, 202 F.3d 331 (D.C. Cir. 2000). As part of its effort to ensure that federal regulators comply with First Amendment rights, WLF carefully monitors (and, as appropriate, responds to) letters sent by DDMAC and OCBQ officials objecting to promotional communications by or on behalf of prescription drug manufacturers.

A. Action requested

WLF requests that the Commissioner of Food and Drugs direct DDMAC and OCBQ, with appropriate support and oversight by the Office of the Commissioner, the Office of the Chief Counsel, and the CDER Office of Medical Policy, to undertake a comprehensive, systematic review of their respective policies and practices relating to prescription drug advertising and promotional labeling for consistency with their statutory authorities and with the First Amendment. WLF requests, further, that appropriate proceedings (e.g., rulemaking, guidance development, withdrawal of draft guidances) be initiated to implement the results of that review.

Four years ago, FDA issued a Request for Comment on First Amendment Issues, in an effort to ensure that its “regulations, guidances, policies, and practices continue to comply with the governing First Amendment caselaw.” 67 Fed. Reg. 34,942 (May 16, 2002). Despite receiving 173 comments from interested persons, FDA has not yet systematically reviewed its policies and practices. We request that the agency, and particularly DDMAC and OCBQ, do so now.

B. Statement of grounds

WLF’s review of warning and untitled letters issued by DDMAC and OCBQ from June 2005 through June 2006 reveals the many legal and policy issues raised by FDA’s regulation of prescription drug promotion. Such letters are clearly being used to establish policy. This is suspect from a legal perspective, because federal law and FDA’s own regulations generally require the agency to provide notice and an opportunity for interested parties to comment before the agency communicates new regulatory expectations for the first time. The policies themselves are also troubling, as a legal matter and from a public health perspective.

In particular, the letters reveal that the agency has a firmly established policy of allowing drug manufacturers to make promotional claims only if those claims meet regulators’ overly narrow definition of “substantial evidence.” DDMAC and OCBQ essentially require companies to have the same type and quantity of evidence required for the drug to have been approved in the first instance before they can speak. Thus, even statements that are truthful and non-misleading are banned if they are based on clinical investigations or other sources of information that agency officials deem inadequate.

It is also apparent that there is an established policy of not allowing companies to employ disclaimers to address any potential of a statement to mislead, despite the First Amendment requirement that the government refrain from imposing a blanket ban on potentially misleading speech when any such potential can be obviated through use of disclaimers. “[T]he collective effect of FDA’s conduct has been to discourage manufacturers from disseminating information that they would otherwise have chosen to distribute. The result is that doctors . . . have been prevented from receiving information which they claim to have an interest in receiving.” Washington Legal Found. v. Kessler, 880 F. Supp. 26, 35-36 (D.D.C. 1995).

DDMAC and OCBQ also have established a policy of requiring drug manufacturers to include duplicative risk information in printed promotional materials, such as scientific journal advertisements aimed at health care practitioners. Under this policy, manufacturers are required to communicate publicly about their products in ways that overemphasize the risks of drug use and underemphasize their benefits. This is contrary to recent FDA policy statements focusing on the importance of tailoring risk information to health care practitioners and consumers to avoid “information overload” and to ensure that risks are discussed in the context of clinical benefits. There are also sound legal reasons to question the validity of the “double disclosure” policy for risk information.

WLF’s review of 2005-2006 warning and untitled letters also shows that DDMAC and OCBQ have now firmly established a policy of requesting corrective advertising in every warning letter issued with respect to prescription drug promotion. Corrective advertising

is a drastic measure, because it effectively compels a private party to make statements to the public with which it might disagree. FDA has never performed a systematic analysis of the effects of corrective advertising. There is good reason to believe that use of this tactic in the drug promotion context might actually contribute to consumer confusion. Moreover, DDMAC and OCBQ do not determine that an advertisement actually has misled consumers or health care practitioners before they request corrective advertising. Consumers could therefore be misled by the very advertising that regulatory officials intended to be corrective.

Although FDA characterizes the “regulatory letters” and other statements of FDA officials as merely “advisory,” these communications have real practical consequences. As we discuss in greater detail in Exhibit A, WLF has determined that the current regulation of prescription drug promotion by DDMAC and OCBQ:

- Deprives patients and consumers of truthful, non-misleading scientific information without adequate justification and in violation of the First Amendment;
- Irrationally compels drug manufacturers to disclose drug risk information twice in the same advertisement, misleading consumers and health care practitioners into believing that products are riskier than they actually are; and
- Improperly relies on corrective advertising, which FDA has never determined to be effective in addressing misleading promotion and which is used routinely by FDA without any analysis of whether the allegedly deceptive manufacturer advertisement was, in fact, misleading.

The grounds for the Petition are set forth in greater detail in Exhibit A.

C. Environmental impact

A claim for categorical exclusion from the requirement of submission of an environmental assessment is made pursuant to 21 C.F.R. § 23.31.

D. Economic impact

WLF will submit information upon request of the Commissioner. WLF believes that DDMAC’s and OCBQ’s maintenance of policies that suppress manufacturer dissemination of truthful information about FDA-approved products is raising health-care costs and having harmful economic impact on patients and their doctors. Conversely, granting this Petition, WLF believes, will result in the more effective use of available therapies and therefore have a favorable economic impact.

D. Certification

The undersigned certify that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

Respectfully submitted,

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cc: Hon. Michael O. Leavitt, Secretary, U.S. Department of Health and Human Services
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