

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0209]

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Certifier R. BEDESMA

Request for Comment on First Amendment Issues

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to September 13, 2002, the comment period for original comments and is extending to October 28, 2002, the comment period for responses to those comments relating to FDA's Request for Comment on First Amendment Issues published in the **Federal Register** of May 16, 2002 (67 FR 34942). The agency is taking this action in response to requests for an extension.

DATES: Submit written or electronic comments on the Request for Comment on First Amendment Issues by September 13, 2002, and submit written or electronic responses to those comments by October 28, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Catherine Lorraine, Office of Policy, Planning, and Legislation (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 16, 2002 (67 FR 34942), FDA published a document entitled "Request for Comment on First

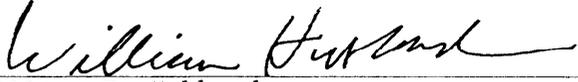
Amendment Issues.” In this document FDA asked the public to comment on a number of questions to help ensure that the agency’s regulations, guidances, policies, and practices continue to comply with the governing First Amendment case law. Recent case law has emphasized the need for not imposing unnecessary restrictions on speech. The document also stated the agency’s wish to learn what empirical evidence exists concerning, among other things, the effect of commercial speech on the public health.

The agency received three letters requesting that the agency extend the comment period for 60 days until September 30, 2002, for the submission of comments and until November 13, 2002, for the submission of responses to the comments. The three requests cited the need for additional time because of the complexity and importance of the subject matter to be commented on. The requests also stated an extension was needed to enable consultation with a variety of individuals, including social science and other experts, as well as business partners. One request pointed out that summer vacation schedules would make this consultation even more difficult. FDA has determined that it is appropriate to grant these requests. However, FDA believes that an additional 45 days will be sufficient time to allow for the consultations discussed and the preparation of comments.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the document requesting comment on First Amendment issues by September 13, 2002, and responses to comments by October 28, 2002. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this

document. Comments and responses to comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 3, 2002.



William K. Hubbard,
Senior Associate Commissioner for Policy,
Planning, and Legislation.

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