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June 12, 2002

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. 02N-0209; Request for Extension of Comment Period**

Dear Madam or Sir:

Pfizer Inc respectfully requests that the Commissioner of Food and Drugs extend the time for the public to submit comments in the following matter.

*A. Proceeding Involved*

The specific proceeding for which Pfizer seeks an extension is FDA's May 16, 2002 request for public comment on the extent to which its regulations, guidances, policies, and practices comply with governing First Amendment case law ("First Amendment inquiry"). See *Request for Comments on First Amendment Issues*, Docket No. 02N-0209, 67 Fed. Reg. 34942, 34942-43 (May 16, 2002).

*B. Action Requested*

Pfizer seeks an extension from July 30, 2002 until and including September 30, 2002 by which to respond to FDA's First Amendment inquiry and a corresponding extension from September 13, 2002 until and including November 13, 2002 by which to respond to comments submitted by others in the initial round.

*C. Statement of Grounds*

The requested extensions of the initial comment deadline and response comment deadline will enable all commenters to more thoroughly address the complex issues raised by the agency, which in turn will support development of a more complete administrative record and enable FDA to reach more fully substantiated conclusions. Moreover, the requested extensions would apply uniformly and therefore prejudice no individual participant in the proceeding. For these reasons, discussed in more detail

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below, the requested extensions would serve the public interest and therefore should be granted.

As the agency can well appreciate, responding to the First Amendment Inquiry will be neither a simple nor a quick undertaking. FDA broadly solicits comments “to ensure that its regulations, guidances, policies, and practices continue to comply with the governing First Amendment case law” and poses a wide range of questions that could implicate the 96-year foundation of the agency’s entire regulatory regime. *See Request for Comments on First Amendment Issues*, Docket No. 02N-0209, 67 Fed. Reg. 34942, 34942-43 (May 16, 2002). FDA’s queries touch on virtually every aspect of its jurisdiction; they call not only for comment on the ramifications of recent case law on the rules governing discrete categories of regulated products but also seek input on whether and how these discrete sets of rules should be harmonized. In addition, the First Amendment Inquiry explicitly invites public comment beyond the specific questions posed, stating that the “questions are not meant to be exhaustive. Rather, they are meant to spur the public to provide FDA with comments that will help FDA safeguard the public health while fulfilling all its legal obligations.” *Id.* at 34943.

Pfizer welcomes the opportunity to provide thorough and well-reasoned responses to FDA’s questions. Doing so, however, will require that the company invest a great deal of thought, research, and time in order to formulate the most useful input possible. Pfizer hopes and intends that its submissions will significantly assist FDA in addressing the ramifications of recent First Amendment jurisprudence for the agency’s future operations. As an institutional matter, Pfizer is committing substantial time and resources to reviewing and responding to the notice. An extension of time would greatly assist Pfizer’s ability to produce and refine its submissions.

Moreover, Pfizer takes seriously FDA’s many questions inviting commenters to address relevant professional literature and to consult with experts on various evidentiary issues. For example, FDA seeks input on (1) whether the agency’s approach to advertising regulation is “consistent with empirical research” on the effects of advertising on consumers; (2) the “relevant authority or social science research” on the effectiveness of disclaimers; and (3) the “evidentiary basis” for distinguishing between speech directed to “learned intermediaries” and that directed to consumers. These and other questions in the First Amendment Inquiry appropriately reflect the constitutional requirement that FDA, like other government agencies, not “rely upon mere speculation or conjecture,” *Edenfield v. Fane*, 507 U.S. 761, 770 (1993), to justify restraints it may impose on commercial speech. Locating and analyzing pertinent studies and other professional literature that attempt to answer these questions also will be a complex and time-consuming effort. Moreover, Pfizer intends to consult with various experts concerning many of these questions in order to prepare more fully informed comments, which will better assist FDA in its inquiry. An extension of time therefore will assist Pfizer and other commenters to more thoroughly analyze pertinent social science literature and

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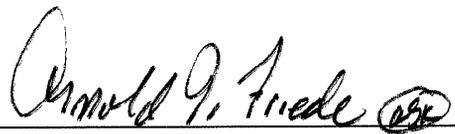
result consult with experts in order to address FDA's questions more thoroughly and effectively.

Finally, the requested extensions will not harm anyone. To the contrary, they will benefit FDA and participating commenters. With additional time in which to respond to FDA's comments, commenters will be in a far better position to address FDA's questions and concerns more fully. The end result will be a more comprehensive administrative record upon which FDA may determine its future course of action. Pfizer expects that the ultimate beneficiary of a fully developed record should be the public, on whose behalf FDA regulates.

Accordingly, Pfizer respectfully requests an extension of time until and including September 30, 2002, by which to file initial comments in response to the First Amendment Inquiry, and a corresponding extension of time until and including November 13, 2002, by which to respond to comments submitted by others in the initial round.

Respectfully submitted,

PFIZER INC

By:  \_\_\_\_\_  
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