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Comments of Pfizer Inc  
On the Current Status of Useful Written Prescription  
Drug Information for Consumers

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Comments Submitted Electronically to [fdadockets@oc.fda.gov](mailto:fdadockets@oc.fda.gov)

Pfizer Inc ("Pfizer") is pleased to submit these written comments on the current status of the private sector's efforts to provide useful written prescription drug information to consumers.

Written point-of-purchase prescription drug information is an important component of a comprehensive health information regime, a primary goal of which should be to empower patients to engage meaningfully with physicians and other health care providers so that patients can make decisions about their own health and well-being. Pfizer's commitment to quality health care means providing patients with responsible, motivating, and easy to understand health information that patients can comprehend and act on in consultation with their physicians. In our view, a better informed consumer makes for a healthier person.

To this end, Pfizer believes that pharmaceutical companies should be active participants in helping to deliver the best possible information to consumers to foster better health outcomes. Pfizer also believes that in order to continue to enhance consumers' understanding of their prescription medicines, there should be consistency between consumer health information and a greater use of FDA regulated written materials. These efforts should continue on a voluntary basis. And to achieve the Year 2006 goal, such voluntary

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efforts should include a strong partnership between the pharmaceutical industry and information providers.

## General Overview

With these points in mind, and before addressing the four specific questions posed by FDA in the Federal Register notice, it is important to note how point-of-sale prescription medicine information fits into the overall information environment where consumers are both active and passive information users.

Consumers use a variety of sources to obtain information about prescription medicines.<sup>1</sup> Pfizer recognizes that pharmacists are an integral part of the multi-source prescription medicine information continuum that has burgeoned significantly over the last several years. Nevertheless, in assessing the “usefulness” of prescription medicines information that is currently being provided to consumers, Pfizer believes that FDA and the public should also take into account the other information sources and private sector efforts that are aimed at ensuring that patients receive useful, truthful medicine information. More specifically, the point-of-sale leaflet – albeit a critical information source – is one of many venues in which patients today are receiving information on prescription medicines.

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<sup>1</sup> Specifically, in assessing what individuals who suffer from at least one health condition consider to be the “best” source of advice about prescription medication, the Yankelovich Monitor (2000) found the following percentage breakdown: 65% from physicians; 32% from pharmacists; 11% from FDA; 8% from other people who use the medication; 9% from nurses; 6% from non-profit health organizations; 5% from media reports; 5% from drug companies; and 4% from alternative medicine practitioners. Similarly, as recently confirmed by research conducted by Harvard Medical School and Harris Interactive in assessing individuals who receive health care information “often,” the following is the percentage breakdown of the sources where these individuals obtain their health information: 28% from their physician; 26% from advertisements; 20% from family and friends; 15% from television and radio; 13% from pamphlets in a physician’s office; 11% from pharmacists; and 8% from the Internet. Weissman, Blumenthal, Silk, Zapert, Newman and Leitman, “The Public Health Impact of Direct-to-Consumer Advertising of Prescription Drugs,” Harvard Medical School and Harris Interactive (Feb. 2003).

For example, “learned intermediaries” (e.g., physicians and pharmacists) continue to be the critical, primary source of information for consumers. In addition, and with guidance from the learned intermediaries, direct-to-consumer (DTC) ads have further enabled care-givers and patients to learn more about the medical options available to them. This has enabled consumers, where appropriate, to take more control of their own health care; has improved health outcomes; and has created economic benefits for consumers and society. Moreover, there are a variety of reputable publications which offer a vast array of useful information on prescription medicines to consumers.

In sum, thanks to this multi-source information environment, the growing and positive trend is toward a more sophisticated and educated consumer. Therefore, we should not lose sight of the tremendous progress that has been made by the private sector when evaluating one “piece of the puzzle”— point-of-sale materials. Rather, the focus should be on the value and content of all sources of health information, with the key aims being consistency in such information and a greater use of FDA regulated materials.

With this in mind, Pfizer will now address the following four questions posed by FDA.

***1. What steps is the private sector [e.g., Pfizer] taking to improve the usefulness of the written information patients receive with prescription drugs and to meet the Year 2006 goal?***

Pfizer strongly supports, and has been intimately involved with creating, the current multi-source informational environment that provides patients with accessible, truthful, and understandable information. This information about our medicines helps consumers, in consultation with their physicians, to determine the risks and benefits associated with a medication, and how to use prescription products appropriately and safely. Information is distributed through many channels, including through physicians, pharmacists, patient package inserts (PPIs), DTC ads, disease management programs distributed by Pfizer or in partnership with voluntary health organizations and managed care companies, Internet sites etc.

Specific Pfizer initiatives include developing easy to read materials that are available in English and Spanish. Pfizer believes that it has made, and will continue to make, great strides towards improving the usefulness of prescription medicine information that is provided to consumers.

### **Pfizer's Clear Health Communication Initiative**

Specifically, looking to make health information more accessible to a broad consumer audience, Pfizer set out to meet an ambitious goal of having all of Pfizer's consumer materials meet its "Principles for Clear Health Communication" ("the Initiative"), including being written at the 6th grade level.

While people at all literacy levels often have trouble understanding health information and would prefer that it was easier to read, those with limited literacy are at an even greater risk for not understanding. Known as low health literacy – the ability to read, understand, and act on health information – this lack of understanding has been shown to impact health outcomes. In fact, research shows that people with limited literacy are more likely to be hospitalized, make more medication and treatment errors, and are less likely to seek preventive care.

Pfizer launched the Initiative in 2001. Working closely with health literacy experts, Pfizer developed guidelines (Principles for Clear Health Communication) and trained Pfizer teams and creative agencies on how to produce easy-to-read and understandable consumer communication. A review process was developed for monitoring progress.

The established goal is that all of Pfizer's consumer materials meet the Principles for Clear Health Communication, including being written at the 6<sup>th</sup> grade level. With 50% of adults in the U.S. reading at or below the 8<sup>th</sup> grade level, and 50% of seniors reading at or below the 5<sup>th</sup> grade level, Pfizer understands the impact this goal could have on effectively reaching our consumers.

Over the past two years since the launch of the Initiative, there has been impressive progress made towards Pfizer's goal. As 2003 progresses, and moving toward 2006, Pfizer is committed to ensuring that all its consumer communications meet the Principles for Clear Health Communication.

In addition, a unique program that Pfizer has initiated are "easy reads," available in English and Spanish, that focus both on Pfizer product information and disease states; these should become available to physicians, pharmacists, and consumers starting in 2004. Moreover, capitalizing on the success of the Initiative for printed consumer communication, Pfizer is committed to improving communications on Pfizer medicines beyond traditional printed materials, e.g., through the Internet and other electronic communications.

### **Pfizer Strategic Partnership Efforts**

Moreover, as part of Pfizer's efforts to raise awareness of the health literacy issue and to develop real-world solutions, Pfizer has supported research (in both academic and clinical settings) to gain a greater understanding of the scope and impact of the low health literacy problem and to begin to develop solutions focused on clear health communication.

Creating strategic partnerships is a crucial element in Pfizer's Clear Health Communication Initiative. The company has partnered with the American Medical Association (AMA) Foundation to raise awareness and understanding of health literacy among physicians and to develop tools that will improve communication with patients. Pfizer has awarded a grant to the AMA Foundation that was used to develop a tool kit, a Web site, and grants to support physician-focused clear health communication programs and media outreach efforts. The AMA's distribution network will be utilized to reach a significant percentage of the AMA membership with clear health communication messages, educational programs, and tools for use in the clinical setting.

In addition to this provider-focused effort, Pfizer supports programs to build the health literacy research base, to provide training on health literacy issues, and to raise awareness of health literacy to patients. Some of the company's clear health communication efforts include:

- The Florida Health Literacy Study, a clinical trial at the University of South Florida designed to determine the most effective interventions for improving health outcomes for patients with diabetes or hypertension.
- Community-based initiatives with national patient advocacy groups in association with the National Health Council and other health-related organizations.
- Sponsoring a national conference on health literacy.
- Awarding research grants to health care and academic institutions to develop and test health literacy interventions.

Pfizer is also committed to multicultural educational efforts aimed at addressing the diagnosis and treatment gaps among Hispanics and African Americans. One example is the *Sana La Rana* program designed to empower Hispanic consumers to help them control their health. Specifically, this multi-dimensional, bi-lingual program is designed to provide information and answer questions about important diseases, including high cholesterol, high blood pressure, diabetes, and depression. To that end, Pfizer is working with local physicians and clinics to distribute patient education materials.

To extend the reach of *Sana La Rana*, Pfizer has partnered with the National Council of La Raza (NCLR), who will train Spanish-speaking community volunteers to educate their communities about these diseases and treatment options.

All these initiatives represent Pfizer's commitment to clear and culturally relevant health communication.

**2. What barriers exist for the private sector to meet the Year 2006 goal, and what plans exist to overcome these barriers?**

We believe that the success that Pfizer has achieved with its Clear Health Communication Initiative, which includes the need to be

culturally relevant, underscores the private sector's ability and commitment to meeting the voluntary Year 2006 goal.

In this regard, Pfizer recognizes that pharmacists act as one of the important "safety links" in the medication distribution chain by providing oral and written information to patients. Nevertheless, pharmaceutical manufacturers such as Pfizer have not worked directly with the vendors who prepare the written prescription information that pharmacists distribute to patients. As a manufacturer of prescription medicines, and as a company that possesses a tremendous knowledge base in creating understandable written drug information for consumers, Pfizer believes that FDA should encourage vendors to involve drug manufacturers such as Pfizer in the drafting of the written prescription information that is provided to patients.

**3. What should the role of FDA be in assuring full implementation of the Action Plan to meet the Year 2006 goal?**

As discussed above, Pfizer believes that the Year 2006 goal is fully attainable through the continued voluntary efforts of the private sector. Nevertheless, an area where FDA may play a role is by encouraging vendors to work directly and voluntarily with pharmaceutical manufacturers in the preparation of the written information that is provided by pharmacists to patients.

**4. What other initiatives should FDA consider for providing patients with useful written drug information about prescription drugs as endorsed by Public Law 104-180? Such initiatives could include the possibility of FDA requiring manufacturers to provide authorized dispensers with the means to distribute useful written information approved by FDA.**

As discussed above, Pfizer is willing to partner with vendors on a voluntary basis to ensure that written prescription medication information that is provided by pharmacists to consumers is accessible and understandable. This should contribute to better health outcomes.

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Thank you for considering Pfizer's comments. Pfizer is committed to the efforts of providing patients with useful prescription drug information. We are confident that that goals of the Action Plan can and will be met by 2006.

Respectfully submitted,

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