

Bayer HealthCare  
Pharmaceuticals



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August 18, 2004

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

**Re: Docket No. 2004D-0042  
Response to FDA Call for Comments  
Draft Guidance for Industry on Improving Information About  
Medical Products and Health Conditions**

Dear Sir or Madam:

Bayer Pharmaceuticals Corporation ("Bayer") would like to provide comments on Docket No. 2004D-0042 referenced above. We support comments that PhRMA has already submitted on these draft guidances and seek to supplement those comments with our own. Bayer applauds the FDA's effort to establish clear advice to prescription drug companies on rules applicable to certain communications directed to consumers and health care practitioners. The intent of the proposed guidance is understood, yet Bayer has several suggestions for approaches that would improve efforts in guiding or regulating the industry on the topics covered in two of the three draft guidance documents.

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**Brief Summary: Disclosing Risk Information in Consumer-Directed  
Print Advertisements**

The agency strongly encourages the use of consumer-friendly language in all consumer-directed promotional materials. Until issuance of this guidance, many manufacturers presumed that the use of FDA-approved

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patient labeling was sufficient to maintain compliance to fulfill the brief summary requirement in consumer directed print advertisements.

It seemed safe to simply reprint FDA-approved patient labeling especially in view of the FDA guidance issued on April 23, 2001 entitled *Using FDA-approved Patient Labeling in Consumer-Directed Print Advertisements*.

It is suggested in this draft guidance that the proposed amended regulation published in 2000, regarding the format and content of FDA-approved professional labeling would contain an introduction section called "Highlights". The agency considers that the "Highlights" section would be translated from language appropriate for a professional audience into language easily understood by the average consumer. This draft guidance did not convey whether or not the "translation" would occur before or after FDA approval of a proposed label (*i.e.* would be a part of the approved label) or whether separate review by DDMAC and or the appropriate review division prior to use would be required.

It could also be inferred from this draft guidance issued February 4, 2004, that if any such consumer-friendly "Highlights" section were developed, then the patient information section of the package insert – the patient labeling-might be redundant. Further, implementation of the proposed rule requiring a "Highlights" section would require major revisions for existing drug package inserts, and so would create a labor-intensive burden for many sponsors.

Bayer recommends that FDA should revise its draft guidance to delete any reference to the "Highlights" section of a proposed rule. Instead the draft guidance should make clear that either format, an approved patient information section of the package insert or a conversion of the brief

summary to consumer –friendly language will satisfy the brief summary requirement.

FDA recommends that a statement accompany consumer-directed print advertisements directing consumers to a free telephone number or web site address for comprehensive information (lines 118-121 annotated version). However, this draft guidance stopped short of recommending what constitutes the comprehensive information that should be provided. Also, FDA should state if there is any instance other than a solicitation by a consumer in which the manufacturer is obligated to provide the FDA-approved professional labeling to the consumer. These concerns could be adequately addressed by promulgating regulation to cover direct to consumer (“DTC”) print advertisement fulfillment of the brief summary requirement to include relevant definitions for clarity.

**Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms**

As an initial matter, Bayer understands and appreciates that FDA believes disease awareness communications can provide important health information to consumers and health care practitioners. Yet, FDA acknowledges that disease awareness communications are not subject to the requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations. Moreover, FDA’s guidance documents do not establish legally enforceable responsibilities. Bayer respectfully suggests that some regulation would be preferable to a guidance document that may be ambiguous and is not enforceable.

On the matter of combining disease awareness communications with reminder or product claim promotion Bayer agrees that a definition

explaining “close physical or temporal proximity” must be clearly established. As these terms might be considered elements of the behavior in question, then Bayer recommends a test be developed to determine additional discreet factors and criteria associated with combining disease awareness communications with reminder or product claims. Generally, a standard should be agreed upon so that the test is an effective tool that can be used to enforce appropriate use of each communication through guidance or regulation as FDA pleases.

In closing, Bayer appreciates the opportunity to comment on these important draft guidances. We support the FDA’s objectives to create a consumer-friendly brief summary and appropriate use of help-seeking and disease awareness communications as well as appropriate use of each in combination with reminder or product claim advertising. Please let us know how we can continue to support this effort.

Sincerely,

A handwritten signature in black ink, appearing to read "Tammara M. Lewis", with a stylized flourish at the end.

Tammara M. Lewis  
Deputy Director Regulatory Affairs  
Bayer Pharmaceuticals Corporation