



**BlueCross BlueShield  
Association**

An Association of Independent  
Blue Cross and Blue Shield Plans

May 7, 2004

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

1310 G Street, N.W.  
Washington, D.C. 20005  
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**Re: Docket No. 2004D-0042**

Dear Sir or Madam:

The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to provide the FDA with comments on the agency's two draft guidance for industry entitled, "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements," and "Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Forms," (69 FR 6309).

BCBSA is a federation of 41 independent, locally operated Blue Cross and Blue Shield Plans that collectively provide health care coverage to over 88 million Americans. BCBSA strongly supports the Food and Drug Administration's (FDA's) effort to clarify communications of risk information for prescription drugs advertised directly to consumers.

**I. BCBSA Recommendations in response to the Guidance on "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements"**

BCBSA agrees with the FDA's draft guidance that the brief summary requirement is being fulfilled in a manner that is less than optimal for consumers due to the technical nature, volume and format of the information, making the information less comprehensible to consumers.

While the practice of reprinting the risk-related sections of the approved product labeling exactly as written for health professionals satisfies the FDA regulation, it requires consumers to scrutinize technical medical data, presented in small type, to glean critical drug risk information.

**BCBSA recommendations:**

1. Require FDA-approved patient labeling, when available and appropriate, to make information more understandable for the consumer;
2. When patient labeling is not available, require "Highlights of Prescribing Information," as suggested in the guidance, in addition to the professional labeling. This information should be placed in a prominent location at the beginning of the advertisement in a format, typeface and size that is legible and understandable for most consumers. The

models provided in the guidance provide a good illustration of how the most critical information could be provided to consumers; and

3. Require a tagline in the highlights section that encourages consumers to consult with their health care professional for additional information on other alternative medications or treatment options.

FDA should continue to ensure that ads targeting consumers do not overstate the benefits of the drug and appropriately disclose the risks associated with the drug.

## **II. BCBSA Recommendations in response to the Guidance on “Help-Seeking and Other Disease Awareness Communications by or on Behalf of Drug and Device Forms”**

BCBSA agrees with the FDA guidance that drug and device firms should ensure that their disease awareness communications and reminder promotional pieces or product claim pieces are sufficiently distinctive in terms of their thematic, graphic, visual and other presentation elements so they will not be perceived as a single promotional piece.

### **BCBSA recommendations:**

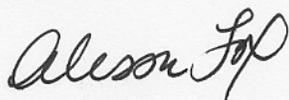
1. When help-seeking communications employ common elements, where a consumer would likely perceive the two communications in common, the communications should be required to meet FDA’s requirements for promotional communications; and
2. Disease awareness communications should be required to include a statement that patients should consult their health care professional for options available to treat the condition.

FDA’s vigilant scrutiny over disease awareness communications will ensure that the benefits of increased disease awareness communications are not abused by product manufacturers to promote specific products without adhering to appropriate FDA regulation and oversight.

### **Summary**

BCBSA believes that the two FDA draft guidances will help provide consumers with more understandable information, because the information will be more ‘consumer-friendly’ and ‘help-seeking’ communications will ensure that product manufacturers appropriately comply with both the letter and intent of FDA regulations. We applaud the FDA for addressing these critical health care issues and support the agency in its endeavors. If you have any questions regarding these comments, please contact Nan North at (202) 626-8649.

Sincerely,



Alissa Fox  
Executive Director, Policy  
Office of Policy and Representation