



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

0326 04 MAR 10 10 46

The Honorable Russell D. Feingold  
United States Senate  
Washington, D.C. 20510-4904

MAR 8 2004

Dear Senator Feingold:

Thank you for your January 26, 2004, letter expressing your concern about the Food and Drug Administration's (FDA or the Agency) July 2003 interim guidance relating to qualified health claims in dietary supplement and conventional food labeling.

We have reviewed your letter but are unable to respond at this time because FDA is involved in litigation related to these issues. See *Center for Science in the Public Interest et al. v. FDA*, No. 03-1962 (RBW) (D.D.C. filed September 24, 2003).

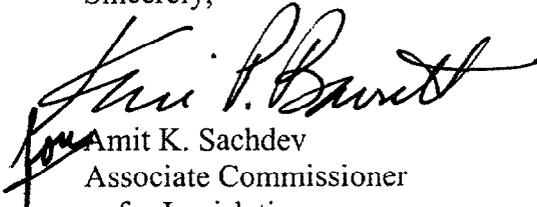
As you know, the Agency issued an advance notice of proposed rulemaking on November 25, 2003, soliciting comments on ways to manage qualified health claims, including the First Amendment concerns raised in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) and subsequent decisions. FDA is seeking comments in three broad areas:

- Alternatives for regulating health claims that do not meet the significant scientific agreement standard,
- Other issues related to health claims, and
- Dietary guidance statements on conventional food and dietary supplement labels.

We are forwarding your correspondence to the public docket so that your comments will be considered during our review of this issue.

Thank you again for contacting us about this matter. If you have further concerns or questions, please let us know.

Sincerely,

  
Amit K. Sachdev  
Associate Commissioner  
for Legislation

cc: Dockets Management Branch, HFA-305  
(Docket No. 03N-0069)

03N-0069

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RUSSELL D. FEINGOLD  
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DEMOCRATIC POLICY COMMITTEE

# United States Senate

WASHINGTON, DC 20510-4904

January 26, 2004

Dr. Mark McClellan, M.D. Ph.D.  
Commissioner  
Food & Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857-0001

Dear Dr. McClellan,

I am writing to express my concern about the Food and Drug Administration's (FDA) announcement of guidelines which allow for qualified health claims on human foods. The existing statute establishes a relatively strict standard for food labels, but it appears that the guidance issued in July 2003 intends to permit the use of claims based on a lower standard of scientific evidence. I am also concerned that the guidance will diminish the ability of the public to comment.

Under FDA's July announcement, the agency will assess the quality of evidence for a health claim, and depending upon the level of scientific support, will take no enforcement action against labels with claims that are not supported by "significant scientific agreement as long as certain disclaimers are used. As a result, the agency will apparently no longer apply the significant scientific agreement standard established in the 1990 Nutrition Labeling and Education Act. I am concerned that the new lower standard may result in the use of health claims that are subsequently found to have little or no scientific support. The July guidance also provides new procedures for public comment that appear to circumvent established notice-and-comment rulemaking procedures.

I am concerned that the change may encourage the use of unreliable and misleading labels on foods and may exceed the agency's statutory authority. Further, changes to the public comment process could compromise the ability of the public to provide input into the agency's regulatory actions.

I look forward to receiving a response addressing these concerns. Thank you for your attention to this matter.

Sincerely,



Russell D. Feingold  
United States Senator

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FROM THE OFFICE OF  
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DATE: 1/26/04

TO: FDA  
301-443-5897

FROM: Erica Pagel

Total Pages (including this cover page): 2

FYI - Here is a copy of a letter that Senator Feingold sent to Dr. McClellan today.

04-549

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