



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Division of Advertising Practices

August 21, 2007

Jodie Z. Bernstein, Esq.
Dana B. Rosenfeld, Esq.
Bryan Cave LLP
700 Thirteenth Street, N.W.
Washington, D.C. 20005-3960

Re: Monsanto Company Complaint on rBST-Related Claims
FTC Matter No. 072-3080

Dear Ms. Bernstein and Ms. Rosenfeld:

As you know, the submission that you filed with the Commission on February 27, 2007 on behalf of Monsanto Company, various dairy producers, and other interested parties was referred to the Division of Advertising Practices for review. I am writing to inform you of the staff's resolution of this matter.

Monsanto requested that the FTC investigate allegedly misleading advertising and labeling claims relating to recombinant bovine somatotropin ("rBST"), a synthetic growth hormone manufactured by Monsanto and approved by FDA for use in dairy cows to increase milk production. While Monsanto acknowledges that milk processors and retailers "have the right to inform customers about the use or non-use of rBST," it expresses concern about advertising and labeling claims that it believes may mislead consumers about the health and safety implications of rBST-use. Monsanto submits that consumers are being charged a premium for milk and other dairy products from cows not treated with rBST based on misleading claims that such milk and dairy products are healthier or safer for consumers than dairy products from cows treated with rBST.

The staff has completed its review of your original submission and subsequent filings in this matter and has conducted an independent review of web sites and other marketing materials by the milk processors and other parties that were referenced in those filings. The staff has also reviewed FDA's 1994 "Interim Guidance on the Voluntary Labeling of Milk and Milk Products

From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin”¹ and has consulted with FDA staff regarding the agency’s policy on rBST-related labeling claims.²

In approving rBST use to increase milk production, FDA determined that milk from rBST-treated cows is safe for human consumption and that there is “no significant difference between milk from treated and untreated cows.” Under its current policy, FDA does not object to food companies making labeling claims that they do not use rBST, provided the claims are truthful and that, in the context of the entire label, they do not mislead consumers to believe that milk from cows not treated with rBST is safer or of higher quality. To avoid misleading implications, FDA suggested in its 1994 interim guidance that claims about rBST be accompanied by information that puts the claim in its proper context. For example, a statement that milk is “from cows not treated with rBST” might be accompanied by the statement “No significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows.” The guidance, however, does not require this accompanying statement and recognizes that proper context could also be achieved by conveying a firm’s reasons (other than safety or quality) for choosing not to use milk from cows treated with rBST, so long as the label is truthful and not misleading.

The FTC staff agrees with FDA that food companies may inform consumers in advertising, as in labeling, that they do not use rBST, but should be careful not to suggest a human health or safety benefit. At this time, there does not appear to be an adequate scientific basis for claims that milk from cows treated with rBST presents health or safety risks to consumers. In the absence of such scientific evidence, claims that suggest either directly or by implication any link between rBST use and human health and safety would be unsubstantiated and thus deceptive.³ The “no significant difference” disclaimer is one possible approach to ensure that statements that rBST has not been used do not convey misleading claims about health or safety.

The FTC staff has reviewed rBST-related claims for all of the companies referenced in the Monsanto submission and subsequent filings. Although many companies reference rBST in product labeling and on company web sites, the staff did not find any examples of national or

¹ The 1994 Interim Guidance is available on FDA’s web site at <http://www.cfsan.fda.gov/~lrd/fr940210.html>.

² As you are aware, the FTC shares jurisdiction with FDA over food marketing. Under a liaison agreement between the two agencies, FDA has primary authority over the regulation of claims made in labeling and the FTC has primary authority over claims made in advertising.

³ Because all milk naturally contains hormones, including natural BST, it could also be deceptive to suggest that the milk or dairy product itself, rather than the production process, is rBST-free or hormone-free.

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significant regional advertising campaigns that made express or implied claims linking rBST to human health and safety. In addition, the majority of web sites for companies cited by Monsanto as making rBST-related claims appear to include some variation of the "no significant difference" disclaimer.⁴ The staff did identify, however, a few instances of companies making unfounded health and safety claims about rBST, primarily on their web sites. Some of these companies appear to be small, locally operated businesses. The staff has conveyed its concerns to the companies at issue, and those companies are in the process of revising their marketing materials.

Given the limited nature and scope of advertising making rBST-related health and safety claims and the willingness of the companies contacted by staff to make modifications to their advertising, we have determined that formal investigation and enforcement action is not warranted at this time. Please feel free to contact me if you have any questions regarding this matter.

Very truly yours,

A handwritten signature in black ink, appearing to read "Mary K. Engle". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Mary K. Engle
Associate Director

⁴ Some of these web sites have already been modified since Monsanto's original submission to remove safety discussions and to include the "no significant difference" disclaimer.