

August 1, 2007

Mary K. Engle Associate Director, Division of Advertising Practices Federal Trade Commission 600 Pennsylvania Ave., N.W. Washington, D.C. 20580

Re: Labeling of Milk from Cows Not Treated with rBST

Dear Ms. Engle,

On behalf of the Center for Food Safety ("CFS"), we write to respond to a letter sent from the Monsanto Company on February 22, 2007, signed by Brian Robert Lowry. Monsanto requested an agency investigation in regard to milk labels, alleging that dairy labels are misleading consumers. We urge you to deny Monsanto's request.

CFS is a non-profit, membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and other forms of sustainable agriculture.²

We strongly disagree with the assertion that there is a crisis in milk labeling. Monsanto's position, that labels implying health claims deceive consumers into paying more for an equivalent product and present an economic threat to dairy farmers, is misguided. We disagree that current labels imply deceptive claims. Many scientific studies have raised valid health issues, substantiating concerns about rBST, the synthetic bovine growth hormone also known as rBGH. Consumers have strong opinions on the issue, and for good reason. Their concerns are more likely due to valid, informed opinions than labeling statements. Moreover, Monsanto's allegations of harm to the consumer and the industry are simply false and unfounded.

We also note that Monsanto does not object to rBST labeling *per se*. Indeed, Mr. Lowry pointed out that "milk processors and retailers certainly have the right to inform customers about the use or non-use of rBST."³

¹ Letter from Brian Robert Lowry, Associate General Counsel, Office of Policy, Stewardship, Regulation and Government, Monsanto Company, to Ms. Mary K. Engle, Associate Director, Division of Advertising Practices, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580 (February 22, 2007) (herein after "Monsanto's February 22, 2007 letter to FTC").

² See generally www.centerforfoodsafety.org.

Health Claims About rBST Are Substantiated.

Recent science associates serious health risks with rBST and ample evidence supports health claims about rBST-free milk. It is appropriate for businesses to make reasonable statements explaining the basis for their decisions to use or not to use rBST. Such statements are substantiated if they are reasonably based on current scientific studies.⁴ Although Monsanto may not like opposition to its product, it has failed to show that claims on labels are actually unsubstantiated or misleading.

There have been a number of scientific studies documenting valid health concerns associated with rBST, particularly since the Food and Drug Administration's (FDA) 1993 approval and subsequent 1999 review of the product. Many studies, including Monsanto's own studies, show rBST raises levels of insulin-like growth factor 1 (IGF-1) in milk. IGF-1 is associated with several cancers including breast, colon, and prostate cancers. In the 1990s FDA approved rBST and subsequently in 1999 noted that there was no science showing that the IGF-1 could be absorbed into the bloodstream, and that the amounts of IGF-1 in milk were insignificant. However, recent studies show that IGF-1 in milk does survive digestion, and that the amount of IGF-1 in milk is enough to affect human health. Moreover, cancer is just one of the many health risks that have been raised; others include risks to reproductive health and the creation of antibiotic resistant bacteria.

³ Monsanto's February 22, 2007 letter to FTC at p. 1.

⁴ See, e.g., In re Cliffdale Assoc., Inc, 103 F.T.C. 110, 1984 FTC LEXIS 71, 79–80 (1984) ("The basic question is whether the advertiser 'acted upon information which would satisfy a reasonable prudent businessman' that the representations are true and that he thus acted in 'good faith'.").

⁵ Miller M. et al., unpublished report MSL 8673, Monsanto Agricultural Company, 1989; White T. et al., unpublished report MSL 8671, Monsanto Agricultural Company, 1989; Juskevich J. and Guyer G., Bovine Growth Hormone: Human Food System Evaluation, Science, Aug. 24, 1990, 249(4971): 879-883; Torkelson A. et al., Concentration of IGF-1 in Bovine Milk, Journal of Dairy Science, 1988, 71(52).

⁶ See, e.g., Yu, H, Rohan, T, Role of the insulin-like growth factor family in cancer development and progression, Journal of the National Cancer Institute, Sept. 20, 2000, 92(18):1472-1481.

⁷ See, e.g., Hankinson, S, Willett, W, Colditz, G, Hunter, D, Michaud, D, Deroo, B, Rosner, B, Speizer, F Pollak, M, Circulating concentrations of insulin-like growth factor-I and risk of breast cancer, The Lancet, May 9, 1998.

⁸ See, e.g., Giovannucci, E, Insulin, insulin-like growth factors and colon cancer: a review of the evidence, Journal of Nutrition, Nov. 2001, 131:3109S-3120S.

⁹ See, e.g., Chan, JM, Stampfer, MJ, Giovannucci, E, Gann PH, Ma, J, Wilkinson, P, Hennekens, CH, Pollak, M, *Plasma insulin-like growth factor-I and prostate cancer risk: a prospective study*, Science, Jan. 23, 1998, (279):563-566.

¹⁰ Food and Drug Administration, Report on the Food and Drug Administration's Review of the Safety of Recombinant Bovine Somatotropin, February 10, 1999.

¹¹ Anderle, P. et al, *In Vitro Assessment of Intestinal IGF-1 Stability*, Journal of Pharmaceutical Sciences, Jan. 2002, 91:1.

¹² Steinman G, *Mechanisms of twinning: VII: Effect of diet and heredity on the human twinning rate*, Journal of Reproductive Medicine, May 2006, 51(5).

¹³ *Id*

¹⁴ rBST increases rates of disease in cows, which is often treated with antibiotics. *See*, Kronfeld, D, *Recombinant bovine somatotropin and animal welfare*, Journal of the American Veterinary Medical Association, June 1, 2000, 216(11):1719-1720.

Regardless of whether the FDA approves or bans rBST, scientific studies published in peer reviewed journals substantiate serious health risks and show that consumers' concerns are legitimate. Governing bodies around the world, including the United Nations, ¹⁵ all countries of the European Union, ¹⁶ Japan, Australia and New Zealand have declined to declare that rBST is safe. The potential for cancer risk is valid and pertinent to consumers. Health risks should not be dismissed across the board simply based on the FDA's 1993 approval of rBST. ¹⁸

Additionally, Monsanto's assertion that milk products with or without rBST are equivalent is misleading. The products are clearly different in process, and the products are physically different. rBST is a genetically engineered hormone structurally different from a cow's natural hormone. Because, as Monsanto notes, growth hormones in cows are passed into the milk, ¹⁹ the milk itself will contain altered hormone. Also, milk produced by cows injected with rBST contains elevated levels of pus²⁰ and IGF-1.²¹ To deny, ignore, or gloss over differences such as these misses the point of scientific and consumer concern.

Milk Labels Do Not Generally Imply Health Claims About rBST.

Monsanto overreaches by arguing that labels or advertisements deceive consumers. Even according to FDA and Monsanto, a dairy may claim that it does not use rBST.²² It is unwarranted to argue that every label asserting that its milk is healthy, and that its milk is rBST-free is likely to mislead a reasonable consumer.

For example, the Dean statement which Monsanto references is a website stating that Dean does not use rBST.²³ Dean's website goes on to discuss the geographic area that is farmed, states that Dean produces milk with certain health benefits, and then discusses animal husbandry. It is appropriate to view such claims in context of this entire

²³ Monsanto's February 22, 2007 letter to FTC, Attachment D.

Center for Food Safety, Letter to FTC re: Milk Labeling

¹⁵ Codex Alimentarius Commission, Report – Twenty-third Session, Consideration of Draft Maximum Residue Limits for Bovine Somatotropin (BST), Rome, June 28-July 3, 1999, p. 13-14.

¹⁶ The European Commission, Scientific Committee on Veterinary Measures Relating to Public Health, *Report on Public Health Aspects of the Use of Bovine Somatotropin*, March 15-16, 1999, Section 2.4.2.1. ¹⁷ Health Care Without Harm, *Position Statement on rBST*, available at www.noharm.org/us/food/issue (last link under "Key Resources") (last viewed July 31, 2007).

¹⁸ We incorporate by reference the recent letter from Oregon Physicians for Social Responsibility, which elaborates on the scientific basis for the concerns over rBST. Letter from Rick North, Project Director—Campaign for Safe Food, and Martin Donohoe, MD, Chief Scientific Advisor, Oregon Physicians for Social Responsibility, to Sheldon T. Bradshaw, Chief Counsel, Food and Drug Administration, and Mary k. Engle, Associate Director, Division of Advertising Practices, Federal Trade Commission (July 14, 2007).

¹⁹ Monsanto's February 22, 2007 letter to FTC at p. 3.

²⁰ Food and Drug Administration, *Animal Drugs, Feeds, and Related Products; Sterile Sometribove Zinc Suspension*, November 12, 1993, 58 Federal Register 59946.

²¹ Supra, note 5

²² Food and Drug Administration, *Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin*, February 10, 1994, 59 Federal Register 6279; Monsanto's February 22, 2007 letter to FTC, p.1.

website.²⁴ As such, these paragraphs do not make negative claims about qualities of rBST, rather the paragraphs make positive claims about the healthfulness of Dean's own product—claims which Monsanto has never contested. There is no precedent for Monsanto's argument that a health claim on a healthy food is deceptive because it might imply that other foods are unsafe.

Indeed, most labels are simply a response to consumer concerns and do not imply a claim about rBST. Monsanto has taken milk, a product symbolically associated with wholesomeness, and introduced into it a synthetic substance which consumers are concerned about, and about which science has raised the specter of risk. Consumers have responded in large numbers by avoiding conventional milk.²⁵ This market climate represents the larger "course of dealings" within which an advertisement needs to be considered. 26 It is appropriate for dairies to woo back cautious consumers by advertising that their product avoids any risk that concerns the consumer. In this context, the labels are only claiming that their product avoids risk; they are not making health claims about rBST. It is particularly clear that these labels are not making claims about rBST when they include the disclaimer that the FDA has found no significant difference in the products, which Monsanto admits most labelers do include.²⁷

For example, Monsanto references the website for Alta Dena, which is clearly responding to consumer preferences to avoid rBST.²⁸ The website describes rBST and states that consumers have raised health concerns about the product. The website then discusses cow health and milk, concluding with the excerpt Monsanto quotes: "By not using rBST, we protect the health of our cows, their milk and our customers."²⁹ The label is accurate to discuss animal welfare and the impacts it may have on milk. ³⁰ The statement does not make claims about harm from rBST, rather it verifies that a risk is avoided, and asserts the healthfulness of the product being marketed. It is ultimately a legitimate market response to consumer demand.

²⁴ FTC Policy Statement on Deception, letter from James C. Miller III, Chairman, Federal Trade Commission, to Honorable John D. Dingell, Chairman, Committee on Energy and Commerce, U.S. House of Representatives (October 14, 1983) ([T]he Commission will evaluate the entire advertisement, transaction, or course of dealing....").

²⁵ Letter from Rick North, Project Director—Campaign for Safe Food, and Martin Donohoe, MD, Chief Scientific Advisor, Oregon Physicians for Social Responsibility, to Sheldon T. Bradshaw, Chief Counsel, Food and Drug Administration, and Mary k. Engle, Associate Director, Division of Advertising Practices, Federal Trade Commission (July 14, 2007), at 5.

²⁶ FTC Policy Statement on Deception, *supra* note 24.

²⁷ Letter from Brian Robert Lowry, Associate General Counsel, Office of Policy, Stewardship, Regulation and Government, Monsanto Company, to Sheldon T. Bradshaw, Chief Counsel, U.S. Food and Drug Administration (February 22, 2007) (submitted to the FTC as an attachment to Monsanto's February 22, 2007 letter to FTC) at 6 ("To their credit, most purveyors of deceptive labels do include the ... quote.").

²⁸ Monsanto's February 22, 2007 letter to FTC, Attachment B.

²⁹ Id

³⁰ Claims about rBST's impact on cows, and that it increases pus in milk, are not disputed. See, Food and Drug Administration, Animal Drugs, Feeds, and Related Products; Sterile Sometribove Zinc Suspension, November 12, 1993, 58 Federal Register 59946.

Also, like Dean's statement, Alta Dena's statements are found on the website, not the label. The statements are only accessed by consumers seeking information about the dairies' rBST use. In determining such a claim, it is appropriate to view the entire context of the statement, including the unique audience it targets.³¹ In context, these are accurate responses to consumers desiring to avoid risk, not statements making negative health claims about rBST.

Labels may properly differentiate products based on grounds besides human health. In the FDA's 1993 approval, serious health impacts on cows³² and a difference in pus counts in milk were associated with rBST use.³³ Additionally, consumers may feel that synthetic hormones in their products are unnatural, and avoid rBST on that basis alone.³⁴ A label is not wrong or misleading if it implies correct quality, health or safety claims based on any of these issues.

For example, Alta Dena's rBST statement falls in this category. The label only makes claims about the health of Alta Dena's cows, and the naturalness of their product. "No rBST in all of our products mean (*sic*) better health and happier cows. Alta Dena uses all natural products, no artificial sweeteners, artificial colors, flavors or stabilizers." ³⁵

Even labels about animal health or naturalness are not necessarily making the claims Monsanto implies. For example, it's untenable for Monsanto to assert that the representation of rBST on Dutch-Way labels implies animal harm simply because the symbol of a syringe is not in proportion to the label's picture of a cow.³⁶

Finally, Monsanto attacks comments consumers have written congratulating a dairy's decision to avoid rBST.³⁷ We note that these are not labels, and may not even constitute advertisements because they merely document customer feedback. Also, these statements only appear on a website, and are accessed by customers affirmatively seeking information. Anonymous web statements by customers would not reasonably be taken by a rational viewer to represent a scientific health claim made on behalf of a company. "A representation does not become 'false and deceptive' merely because it will be unreasonably misunderstood by an insignificant and unrepresentative [few]." In sum, Monsanto has not demonstrated that the implications it suggests will actually be inferred, let alone that such implications are likely to mislead.

³¹ FTC Policy Statement on Deception, *supra* note 24.

³² *Id.*; see also, Monsanto package insert for Posilac®.

³³ Food and Drug Administration, *Animal Drugs, Feeds, and Related Products; Sterile Sometribove Zinc Suspension*, November 12, 1993, 58 Federal Register 59946.

³⁴ See, Food and Drug Administration, Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms 56 FR 60421, 60466 ("In its informal policy..., the agency has considered "natural" to mean that nothing artificial or synthetic ... is included in, or has been added to, the product that would not normally be expected to be there.).

³⁵ Monsanto's February 22, 2007 letter to FTC, Attachment B.

³⁶ *Id.* at 11.

³⁷ *Id.* at 7–8.

³⁸ In re Heinz W. Kirchner Trading as Universe Co., 63 F.T.C. 1282, 1963 FTC LEXIS 71, 17 (1963).

Consumer Demand for rBST-free Milk Is Attributable To Informed Opinion Rather Than Misleading Labels.

The market shift away from rBST use in milk production is due to legitimate consumer demand, not manipulative labels. Monsanto's argument relies on the assumption that milk labels are the force behind consumers' avoidance of rBST. In reality, dairies' marketing "rBST-free" is a response to consumer demand, not a manipulation of the marketplace. Monsanto has not shown that consumer aversion to rBST is actually caused by labeling.³⁹ Monsanto's own evidence suggests otherwise.

Monsanto's studies show consumers have negative associations with rBST, but the studies do not show that those associations are caused by the labels. Monsanto's studies actually demonstrate that consumers are informed before interpreting the labels. For example, one of Monsanto's studies shows that when a dairy advertises that its cows were given rBST, most of the consumers who see this as a difference view this fact negatively. 40 This study does not show that labeling is misleading; rather it makes the point that consumers have prior impressions about rBST, synthetic hormones, and synthetic food additives.

Indeed, Monsanto's argument would prove too much. Were it true that statement such as "rBST-free" implied health claims, even simply labeling milk as "from cows not treated with rBST" could be a trade violation by making health claims—yet such labels are clearly allowed. Monsanto agrees that "milk processors and retailers certainly have the right to inform customers about the use or non-use of rBST...."41

The newspaper articles Monsanto references likewise show that consumer demand drives labeling, not vice-versa. The article in the Boston Globe states that dairies are avoiding synthetic hormones because consumers "are not comfortable with them." The article in the Worcester Telegram and Gazette says that dairies' switch away from rBST is based on "consumer interest in milk being a natural product." Similarly, Monsanto cites several consumer comments congratulating a dairy for switching to rBST-free. 44 These demonstrate that consumer concerns are driving labeling, not the other way around.

³⁹ The study Monsanto quotes in its letter to the FTC correctly states that claims of "hormone free" or "no hormone" are misleading. Because there are hormones in all milk, we agree that these statements are not accurate. However, none of labels Monsanto addresses in its letter make a "hormone free" claim. ⁴⁰ Letter from Brian Robert Lowry, Director, Industry Affairs, Monsanto Company, to Daniel E. Troy,

Chief Counsel, U.S. Food and Drug Administration (May 9, 2003) (on file with the Center for Food Safety), at footnote 16 (summarizing a May 1993 study by Westgate Research Inc., BST Label Interpretation Study).

⁴¹ Monsanto's February 22, 2007 letter to FTC, p. 1.

⁴² Bruce Mohl, Stores hike prices on milk free of synthetic hormones, Boston Globe, October 10, 2006

⁽cited in Monsanto's February 22, 2007 letter to FTC, p. 13, note 14).

43 James F. Russell, *Certified milk is not aiding dairy farmers*, Worcester Telegram & Gazette, November 5, 2006 (cited in Monsanto's February 22, 2007 letter to FTC, p. 2, note 2). 44 Monsanto's February 22, 2007 letter to FTC, p. 7–8.

Ultimately, a number of consumer groups have publicized their concerns about rBST and prominent studies have also raised questions about rBST.⁴⁵ The issue has received much media coverage.⁴⁶ With so much information now available to consumers, it defies logic to conclude that consumer demand for rBST-free milk is based on milk labels, let alone dairy websites.

Current Labels Do Not Harm Consumers.

Monsanto's claim that rBST-free labels harm consumers through deception is unsupported. To show deception, Monsanto must show that the labels contain unsubstantiated claims, the claims are likely to mislead a reasonable consumer, and the claims are material such that they are to the consumer's detriment or injury. Monsanto has not made such a showing. To the contrary, as discussed above, health claims about rBST are substantiated, most labels do not even imply claims about rBST, and rBST-free labels are not the cause of consumer opinions. Further, it is not true that there is any detriment to either consumers or the industry.

Monsanto claims that consumers are harmed because they may pay more for rBST-free milk. Consumers are not harmed because they prefer a product that might be slightly more expensive than another. Even if there were no valid health concerns, a consumer could get value by preferring the process of rBST-free milk (no artificial hormones, less impact on animal welfare). Ultimately there is no harm in drinking rBST-free milk—indeed there is significant peace of mind in avoiding risks.

Monsanto presents no sound, verifiable evidence to support its assertion that consumers are "ripped off." The contention is the opinion of farmer Richard W. Kimball, quoted by Monsanto to support the erroneous scientific claim that there is no difference between milk produced with, and without, rBST. While the farmer opinion can be considered, it is not a firm economic and scientific foundation for an FTC investigation. It appears that Monsanto is waging a publicity campaign for its product. For example, Monsanto's further support refers to a newspaper article, which cites a Monsanto spokesman for its main claim that "consumers are paying more for nothing."

Additionally, it is not clear that rBST-free milk increases milk prices. The brands Monsanto highlights are mostly well recognized name brands such as Borden and Deans. It is normal for these companies' milk to have a higher price point than generic brands. Also, milk that is rBST-free is often organic, which regularly sells for more than

⁴⁵ See, e.g., www.centerforfoodsafety.org /rbgh_hormo.cfm; www.oregonpsr.org/programs/campaignSafeFood.html; www.noharm.org/us/food/issue (last link under "Key Resources");

http://www.foodandwaterwatch.org/food/dairy/bovine-growth-hormone/rbgh-fact-sheet.

⁴⁶ See, e.g., Letters to the editor, *Bioengineered Milk? No Thanks*, N.Y. Times, July 5, 2007, available at http://topics.nytimes.com/top/opinion/editorialsandoped/letters/ (Op-Ed on rBST drawing strong response from several diverse interests).

⁴⁷ FTC Policy Statement on Deception, *supra* note 24.

⁴⁸ Monsanto's February 22, 2007 letter to FTC, p. 2.

⁴⁹ Bruce Mohl, *supra*, note 42.

conventional milk. So even if rBST-free milk is more expensive on average, that does not show that labels indicating rBST-free drive up prices.

Monsanto also asserts that milk produced with rBST would become less available, however Monsanto shows no evidence for this, nor shows how it would be harmful to consumers.

As noted above, milk with and without rBST is different in both process and product. Where consumers prefer one product over another for any number of reasons, whether it be the risk of health implications, animal welfare concerns, or desire for natural foods, there is no cognizable harm when the consumer purchases accordingly.

Current Labels Do Not Harm The Industry.

Monsanto claims that the labeling of rBST-free milk is harming the industry because farmers will not be paid enough for their product. The contrary is true—farmers are paid a premium for rBST-free milk, and the evidence does not support Monsanto's contention that their product saves farmers money. The Center for Food Safety's mission to promote a safe and sustainable food supply depends on the vitality of healthful farming practices. Due to serious health concerns, consumer aversion, and negative economic impacts of rBST, we believe the synthetic hormone is bad for the industry, and we believe Monsanto's claim is unfounded.

Monsanto contends that profits are not passed along to farmers. This is flatly contradicted by Monsanto's statement that farmers are paid a premium for rBST-free milk. 50 Moreover, Monsanto presents no causational evidence linking milk labels to any documented harm to farmers, and ultimately, the price negotiated between farmers and dairies is not contingent upon labeling.

Monsanto's claim that farmers are denied profits by not using rBST is likewise dubious. It is not clear that using rBST actually helps farmers. The only large national study on the subject contradicts the claim that rBST can reduce milk prices and save on grain use.⁵¹ Dairy farming is an occupation well established in society; it is unfounded to claim that the industry now needs Monsanto's product to be successful. Indeed, were all of Monsanto's claims true (rBST could increase milk production and thereby decrease milk prices) it seems likely that the amount farmers are paid for their milk would go down—a situation good for Monsanto's business, but not necessarily a farmer's.

⁵⁰ Monsanto's February 22, 2007 letter to FTC, p. 13.

⁵¹ William D. McBride, Sara Short, Hisham El-Osta, The Adoption and Impact of Bovine Somatotropin on U.S. Dairy Farms, Review of Agricultural Economics 26 (4) (2004), 472–488.

Conclusion: FTC Investigation Is Not Appropriate.

Monsanto's request for an investigation is unwarranted. While Monsanto clearly has a business interest is silencing opposition to its product, its interest is at odds with consumer concerns and scientific evidence. Monsanto has not shown that any advertisements or labels are actually wrong, let alone misleading. Monsanto has not produced any evidence that consumers are deceived by labels, nor has it demonstrated harm from advertising. On the other hand, recent scientific studies have raised serious, verifiable concerns about the use of rBST, and consumers have demonstrated a legitimate interest and concern in the matter.

If anything, FDA's rBST guidelines are out of date because they do not represent the current science that milk derived from cows treated with rBST is materially different and should be under a mandatory labeling requirement. Nonetheless, labelers continue to comply with the existing guidance, ⁵² even though FDA itself has asserted that it has no authority to require comparative labeling statements. ⁵³

To describe the labelers and industry as a whole as deceptive is simply not accurate. The accuracy of labels and advertising is important to society, and is best served by allowing substantiated health and safety concerns to be communicated in the marketplace. We urge the FTC to respect the consumers' concerns, and not to take action against labelers accurately informing consumers about a dairy's own product.

Sincerely,

Kevin Golden Staff Attorney

Shawn Eisele Law Clerk

Letter from Brian Robert Lowry, Associate General Counsel, Office of Policy, Stewardship, Regulation and Government, Monsanto Company, to Sheldon T. Bradshaw, Chief Counsel, U.S. Food and Drug Administration (February 22, 2007) (submitted to the FTC as an attachment to Monsanto's February 22, 2007 letter to FTC) at 6 ("To their credit, most purveyors of deceptive labels do include the ... quote.").
 Letter from Jerold R. Mande, Executive Assistant to the Commissioner, Food and Drug Administration,

⁵³ Letter from Jerold R. Mande, Executive Assistant to the Commissioner, Food and Drug Administration, to Harold S. Rudnick, Director, Division of Milk Control, State of New York Department of Agriculture and Markets (July 27, 1994) (on file with the Center for Food Safety).