

**Petition Seeking the Withdrawal of the New Animal Drug Application Approval for
Posilac - Recombinant Bovine Growth Hormone (rBGH)**

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Mike Leavitt
Secretary of Health and Human Services
U.S. Department of Health and Human Services

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

Dockets Management Branch
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

Citizen Petition

The undersigned submits this petition on behalf of the Cancer Prevention Coalition, Samuel S. Epstein, M.D., Chair; the Organic Consumers Association, Ronnie Cummins, Executive Director; Family Farm Defenders, John Kinsman, President; Arpad Pusztai, PhD, FRSE; Institute for Responsible Technology, and Jeffrey M. Smith, Executive Director.

This petition is based on scientific evidence of increased risks of cancer, particularly breast, colon, and prostate, from the consumption of milk from cows injected with Posilac®, the genetically modified recombinant bovine growth hormone (also known as rBGH, sometribove, recombinant bovine somatotropin, or rbST). Posilac® is the trademark for Monsanto's rBGH product, registered with the U.S. Patent and Trademark Office, and is approved for marketing by the Food and Drug Administration (FDA). This petition is also based on abnormalities in the composition of rBGH milk, resulting from the recognized veterinary toxicity of rBGH, particularly increased levels of IGF-1.

The undersigned submit this petition under section 512(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e)(1)(A)), to request the Secretary to immediately suspend approval of Posilac® based on imminent hazard; and under section 21 U.S.C. 321 (n), 361, 362, and 371 (a), 21 CFR 740.1, 740.2 of 21 CFR 10.30 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of the Food and Drug Administration to label milk and other dairy products produced with the use of Posilac® with a cancer risk warning.

A. AGENCY ACTION REQUESTED

This petition requests the Secretary and the Commissioner to take the following action:

Suspend approval of Posilac®, and/or require milk and other dairy products produced with the use of Posilac® to be labeled with warnings such as, “Produced with the use of Posilac®, and contains elevated levels of IGF-1, a major risk factor for breast, prostate, and colon cancers.”

B. STATEMENT OF GROUNDS

1. The Veterinary Toxicity of Posilac®

Evidence of these toxic effects was first detailed in confidential Monsanto reports, based on records of secret nationwide rBGH veterinary trials, submitted to the FDA prior to October 1989 when they were leaked to one of the petitioners, Dr. Epstein. He then made these reports available to Congressman John Conyers, Chairman of the House Committee on Government Operations. On May 8, 1990, Congressman Conyers issued the following statement. “I find it reprehensible that Monsanto and the FDA have chosen to suppress and manipulate animal health test data” (1). Details of these toxic effects were subsequently admitted by Monsanto and the FDA, and disclosed on the drug’s veterinary label (Posilac) in November, 1993. These include injection site lesions, a wide range of other toxic effects, and an increased incidence of mastitis, requiring the use of medication and antibiotics, and resulting in their contamination of milk.

2. Abnormalities in rBGH Milk

In a Monsanto Executive Summary, Posilac, January 1994, it was claimed that “natural milk is indistinguishable” from rBGH milk and that “There is no legal basis requiring its labeling.” However, there are a wide range of well-documented abnormalities in rBGH milk, apart from increased IGF-1 levels (2-11). These include: reduction in casein; reduction in short-chain fatty acid and increase in long-chain fatty acid levels; increase in levels of the thyroid hormone triiodothyronine enzyme; contamination with unapproved drugs for treating mastitis; and frequency of pus cells due to mastitis.

3. Increased Levels of IGF-1 in rBGH Milk

A wide range of publications have documented excess levels of IGF-1 in rBGH milk (10-22), with increases ranging from four- to 20-fold. Based on six unpublished industry studies, FDA admitted that IGF-1 levels in rBGH milk were consistently and statistically increased, and that these were further increased by pasteurization (16); these increases were also admitted by others (17, 18). Included among these is one by Lilly Industries, in its application for marketing authorization to the European Community Committee for Veterinary Products, admitting that rBGH milk may contain more than a 10-fold increase in IGF-1 levels (20). It should also be noted that pasteurization increases IGF-1 levels by

a further 70% (16), presumably by disrupting protein binding, and since standard analytic techniques for IGF-1 in rBGH milk may underestimate its levels by up to 40-fold (9, 15).

4. IGF-1 is Readily Absorbed from the Intestine into the Blood

Contrary to Section 2 of FDA's 6/8/2000 Docket No. 98P-1194 response to the December 5, 1998 Citizen Petition of the Center for Food Safety, IGF-1 is a peptide and not a protein, and as such is readily absorbed into the blood. Even more compelling is evidence of marked growth promoting effects following short-term feeding tests in rats (16, 22). FDA's Section 2 thus reflects a misunderstanding relating to "the possibility of IGF-1 surviving digestion."

5. Increased IGF-1 Levels Increase Risks of Breast, Colon and Prostate Cancers

Thus, increased levels of IGF-1 have been shown to increase risks of breast cancer by up to seven-fold in 19 publications (23-41), risks of colon cancer in 10 publications (42-51), and prostate cancer in 7 publications (52-57).

6. Increased IGF-1 Levels Inhibit Apoptosis

Of generally unrecognized, critical importance is the fact that increased IGF-1 levels block natural defense mechanisms against the growth and development of early submicroscopic cancers, known as apoptosis or programmed self destruction (53, 58, 59).

7. Bovine Growth Hormone Increases Twinning Rates

An increased rate of twinning in cows injected with rBGH was admitted by Monsanto on its November 1993 Posilac label. rBGH increases ovulation and embryo survival, and increases the incidence of fraternal twins (60). "Because multiple gestations are more prone to complications such as premature delivery, congenital defects and pregnancy-induced hypertension in the mother than singleton pregnancies, the findings of this study suggest that women contemplating pregnancy might consider substituting meat and dairy products with other protein sources, especially in countries that allow growth hormone administration to cattle." (61).

8. The International Ban on the Use and Imports of rBGH Dairy Products

Based on the veterinary and public health concerns detailed in this Petition, the use and import of rBGH dairy products has been banned by Canada, 29 European nations, Norway, Switzerland, Japan, New Zealand, and Australia.

It should further be noted that on June 30, 1999, the Codex Alimentarius Commission, the United Nations Food Safety Agency representing 101 nations worldwide, ruled unanimously not to endorse or set a safety standard for rBGH milk.

9. The FDA Policy on Labeling rBGH Milk

The FDA has misled dairy producers and consumers with regard to its requirement for labeling of rBGH milk, to the effect that "No significant difference has been shown between milk derived from rBST-treated and non-rBST treated cows." This, however, is misleading in extreme as the "FDA has determined it lacks the basis for requiring such labeling in its statute." This was admitted in a 7/27/94 letter by Jerold R. Mande, Executive Director to the FDA Commissioner, to Harold Rudnick, State of New York Department of Agriculture and Markets.

C. CLAIM FOR CATEGORICAL EXCLUSION

A claim for categorical exclusion is asserted pursuant to 21 CFR 25.24 (a)11.

D. CERTIFICATION

The undersigned certify (page 9), that, to their best knowledge and belief, this petition includes all information and views on which the petition relies, and also that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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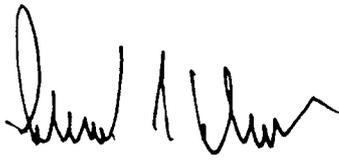
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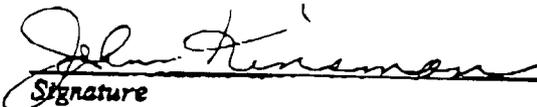
Signature

Samuel S. Epstein, M.D.
Cancer Prevention Coalition
c/o University of Illinois at Chicago
School of Public Health, MC 922
2121 West Taylor Street
Chicago, IL 60612
312-996-2297; epstein@uic.edu



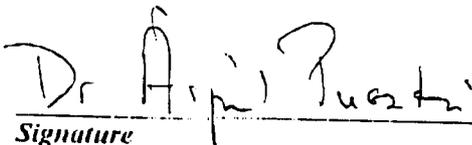
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Ronnie Cummins
Organic Consumers Association
6771 South Silver Hill Drive
Finland, MN 55603
218-349-3836; ronnie@organicconsumers.org



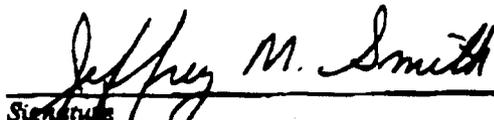
Signature

John Kinsman
Family Farm Defenders
P.O. Box 1772
Madison, WI 53701
608-986-3815; jepeck@students.wisc.edu



Signature

Arpad Pusztai, PhD, FRSE
Consultant Biologist
6 Ashley Park North
Aberdeen AB10 6SF
Scotland
44-1224-594954; a.pusztai@freenet.co.uk



Signature

Jeffrey M. Smith
Institute for Responsible Technology
P.O. Box 469
Fairfield, IA 52556
641-472-8338; jeffrey@seedsofdeception.com

This Petition is submitted by:

Samuel S. Epstein, M.D.
Chairman, Cancer Prevention Coalition
c/o University of Illinois at Chicago
School of Public Health, MC 922
2121 West Taylor Street
Chicago, IL 60612
312-996-2297; fax 312-413-9898
e-mail epstein@uic.edu