

103<sup>D</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 4669

To amend the Federal Food, Drug, and Cosmetic Act to require labeling for milk and milk products produced from cows which have been treated with synthetic bovine growth hormone, to direct the development of a synthetic bovine growth hormone residue test, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 28, 1994

Mr. SANDERS (for himself, Mr. ANDREWS of Maine, Miss COLLINS of Michigan, Mr. DEFAZIO, Mr. DELLUMS, Mr. ENGEL, Mr. FOGLIETTA, Mr. GONZALEZ, Mr. GUTIERREZ, Mr. HINCHEY, Mr. JOHNSTON of Florida, Mrs. KENNELLY, Mr. KLECZKA, Mrs. MINK, Mr. MORAN, Mr. NADLER, Mr. OBERSTAR, Mr. OBEY, Mr. OLVER, Mr. OWENS, Mrs. UNSOELD, Mrs. SCHROEDER, Mr. SHAYS, Ms. VELÁZQUEZ, Mr. VENTO, Mr. WASHINGTON, and Mr. YATES) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require labeling for milk and milk products produced from cows which have been treated with synthetic bovine growth hormone, to direct the development of a synthetic bovine growth hormone residue test, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Bovine Growth Hor-  
3 mone Milk Labeling and Residue Test Act”.

4 **SEC. 2. FINDINGS.**

5 The Congress finds the following:

6 (1) Synthetic recombinant bovine growth hor-  
7 mone (in this section referred to as “synthetic  
8 BGH”) is a product of genetic engineering and is  
9 the first food product of genetic engineering to be in  
10 direct widespread use in the consumer marketplace  
11 and to be ingested in significant amounts by infants  
12 and children.

13 (2) Synthetic BGH injections in dairy cows re-  
14 sult in a residue of synthetic BGH in the milk pro-  
15 duced by injected cows.

16 (3) Synthetic BGH injections of dairy cows re-  
17 sult in increased levels of bovine insulin-like growth  
18 factor in the milk produced by injected cows. Ac-  
19 cording to the American Medical Association and  
20 others, further studies are required to determine  
21 whether human ingestion of higher than normal lev-  
22 els of bovine insulin-like growth factor is safe.

23 (4) Synthetic BGH injections result in a variety  
24 of health problems in injected cows, including sig-  
25 nificant increases in mastitis (an infection of the  
26 cow’s udder that results in visibly abnormal milk).

1           (5) The cow health problems resulting from  
2 synthetic BGH injections will result in a significant  
3 increased use of antibiotics in injected cows. Many  
4 of the antibiotics used to treat mastitis in dairy cows  
5 are not detected in the usual milk monitoring proc-  
6 ess. The Food and Drug Administration determined  
7 that synthetic BGH poses a “manageable risk” to  
8 consumers because of the increased risk of anti-  
9 biotics entering the consumer milk supply.

10           (6) Consumers are concerned about hormones  
11 and antibiotics in their food and humane treatment  
12 of animals and have shown overwhelming support  
13 for labeling of milk and milk products produced with  
14 synthetic BGH.

15           (7) According to the Office of Management and  
16 Budget, synthetic BGH use will result in an increase  
17 in Federal budget costs of over \$500,000,000 in the  
18 next 5 years and a decrease in overall dairy farm in-  
19 come of \$1.3 billion dollars in that same period.

20           (8) As of 1994, the European Community had  
21 a moratorium on the commercial use of synthetic  
22 BGH and the Canadian Parliament had rec-  
23 ommended a similar moratorium. Australia and New  
24 Zealand, where one quarter of the world’s milk is  
25 produced, refused to approve synthetic BGH.

1           (9) Consumers have a right to know if the milk  
2 they consume has been produced with synthetic  
3 BGH.

4           (10) Both States and individual companies have  
5 begun to take actions to label products produced  
6 with synthetic BGH.

7           (11) Confusion surrounding label claims and  
8 regulations have resulted in lawsuits against States  
9 and companies who have implemented label pro-  
10 grams.

11           (12) There is a need for a common label to pro-  
12 vide consumers across the country with a simple and  
13 accessible means of identifying milk produced with  
14 synthetic BGH.

15           (13) A synthetic BGH residue test is needed to  
16 validate label claims in order to ensure consumers  
17 that the labels are truthful and not misleading.

18           (14) A residue test is generally required when  
19 a drug is found to leave a residue in a human food  
20 product.

21           (15) Scientific organizations, including the  
22 American Medical Association and the Consumers  
23 Union, have stated that a synthetic BGH residue  
24 test can be devised. Much of the preliminary re-  
25 search for a test has already been completed. Claims

1 have been made that a test already has been suc-  
2 cessfully developed in a lab.

3 **SEC. 3. LABELING.**

4 Section 403 of the Federal Food, Drug, and Cosmetic  
5 Act is amended by adding at the end the following:

6 “(s)(1)(A) If it is milk that—

7 (i) is intended for human consumption; and

8 (ii)(I) is produced by cows that have been in-  
9 jected with synthetic BGH; or

10 (II) has been commingled with milk pro-  
11 duced by such cows,

12 unless the labeling of the milk bears the following  
13 statement: ‘This milk was produced by cows injected  
14 with synthetic BGH.’

15 “(B) If it is a milk product that is intended for  
16 human consumption and is derived from milk described  
17 in subparagraph (A), unless the labeling of the milk prod-  
18 uct bears the following statement: ‘This milk product was  
19 derived from milk produced by cows injected with syn-  
20 thetic BGH.’

21 “(2)(A) A person who sells synthetic BGH, purchases  
22 the hormone, distributes the hormone, or injects the hor-  
23 mone into a cow shall prepare and maintain records that  
24 comply with the regulations issued by the Secretary under  
25 subparagraph (B).

1 “(B) Not later than 30 days after the date of enact-  
2 ment of this paragraph, the Secretary shall issue regula-  
3 tions that require—

4 “(i) persons who sell synthetic BGH;

5 “(ii) persons who purchase synthetic BGH;

6 “(iii) persons who distribute synthetic BGH;

7 and

8 “(iv) persons who inject synthetic BGH into  
9 cows,

10 to create and maintain records that contain the applicable  
11 information specified in subparagraph (C).

12 “(C) Regulations issued under subparagraph (B)  
13 shall require records to contain a description of—

14 “(i) the quantity and source of the synthetic  
15 BGH obtained (by manufacture, purchase, or any  
16 other means);

17 “(ii) the date on which the hormone was ob-  
18 tained; and

19 “(iii) the identity of each person to whom the  
20 hormone was sold or otherwise distributed, the cows  
21 into which any portion of the hormone was injected,  
22 and each person who has an operator or ownership  
23 interest in the cows.

1       “(3) Not later than 30 days after the date of enact-  
2 ment of this paragraph, the Secretary shall issue regula-  
3 tions that establish—

4             “(i) requirements with respect to the sale, dis-  
5 tribution, and administration of synthetic BGH; and

6             “(ii) such other requirements with respect to  
7 the use of synthetic BGH as the Secretary may de-  
8 termine to be necessary to carry out the objectives  
9 of this Act.

10       “(4) As used in this paragraph—

11             “(i) The term ‘synthetic BGH’ means—

12                 “(I) a substance described as bovine  
13 somatotropin, bST, BST, bGH, or BGH; and

14                 “(II) a growth hormone, intended for use  
15 in bovine animals, that has been produced  
16 through recombinant DNA techniques.

17             “(ii) The term ‘cow’ means a bovine animal.”.

18 **SEC. 4. RESIDUE TEST.**

19       (a) IN GENERAL.—At the earliest possible date, the  
20 Secretary of Health and Human Services (acting through  
21 the Commissioner of Food and Drugs) shall develop a sci-  
22 entifically valid synthetic BGH residue test to—

23             (1) detect the presence of the residue of syn-  
24 thetic BGH in milk produced from cows injected  
25 with such hormone, and

1           (2) assure compliance with section 403(s) of the  
2       Federal Food, Drug, and Cosmetic Act.

3 After the test is developed the Secretary shall make the  
4 test available to public health and agricultural agencies of  
5 the States and commercially available at the lowest pos-  
6 sible cost to dairy producers and processors.

7       (b) DEFINITIONS.—As used in subsection (a):

8           (1) The term “synthetic BGH” means—

9               (A) a substance described as bovine  
10       somatotropin, bST, BST, bGH, or BGH; and

11               (B) a growth hormone, intended for use in  
12       bovine animals, that has been produced through  
13       recombinant DNA techniques.

14           (2) The term “cow” means a bovine animal.

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