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**SUPPLEMENT TO CENTER FOR FOOD SAFETY CITIZEN PETITION**

**Docket No. 98P-1194**

**(Filed December 15, 1998)**

**BEFORE THE UNITED STATES**

**FOOD AND DRUG ADMINISTRATION**

*Dockets Management Branch*

*Food and Drug Administration*

*Department of Health and Human Services*

*Room 1-23, 12420 Parklawn Drive*

*Rockville, MD 20857*

**CENTER FOR FOOD SAFETY,**

a project of the

INTERNATIONAL CENTER FOR

TECHNOLOGY ASSESSMENT,

310 D Street, N.E.

Washington, DC 20002,

*et al.*

*Petitioners,*

vs.

**JANE HENNEY,**

in her official capacity as,

Commissioner

Food and Drug Administration

Parklawn Building, Room 1471

5600 Fishers Lane

Rockville, MD 20857

*Defendants.*

**Docket No. 98P-1194**

**SUPPLEMENT TO PETITION SEEKING THE WITHDRAWAL OF THE NEW  
ANIMAL DRUG APPLICATION APPROVAL FOR POSILAC® -  
RECOMBINANT BOVINE GROWTH HORMONE (rBGH)**

On December 15, 1998, petitioners filed a citizen's petition with the Food and Drug Administration seeking rulemaking and collateral relief under §360b of the Federal Food Drug and Cosmetic Act. As a result of the FDA's failure to adequately analyze several human health risks associated with the use of recombinant Bovine Growth Hormone (rBGH), the petitioners requested the Commissioner to undertake the following actions:

(1). Immediately suspend the approval of the new animal drug application for Posilac® - recombinant bovine growth hormone (rBGH);

(2). Immediately publish a Notice of Opportunity for an Evidentiary Hearing concerning "new evidence" related to the new animal drug application approval of Posilac® (rBGH) in the Federal Register;

(3). Upon completion of the hearing, issue an order withdrawing the approval of the new animal drug application for Posilac® (rBGH); *and*

(4). Revoke all regulations associated with the approval of Posilac® (rBGH) including those found at 21 C.F.R. § 522.2112.

Petitioners now supplement that request with the additional information that the use of Posilac® (rBGH) presents an imminent hazard to the health of animal.

## PETITIONERS

Petitioner **Center for Food Safety** (CFS), a project of the International Center for Technology Assessment, is located at 310 D Street, N.E., Washington, DC 20002. CFS was established in 1997 to address the increasing concerns about the impacts of our food production system on human health, animal welfare and the environment.

Petitioner **American Humane Association** (AHA) is located at 236 Massachusetts Ave., NE, Suite 203, Washington, DC 20002. Headquartered in Denver, CO, AHA is the national is a national, non-profit organization dedicated to protecting children and animals from cruelty, neglect and exploitation. It has 6500 organizational members and 160,000 individual members nationwide.

Petitioner **Breast Cancer Action Montreal** is located at 5890 Monkland Ave., Montreal, PQ H4A 1G2, Canada. It is a grassroots advocacy group run by women with breast cancer. It seeks to educate women about breast cancer prevention.

Petitioner **Community Nutrition Institute** (CNI) is located at 910 17th Street, N.W., #413, Washington, D.C. 20006. CNI is a non-profit organization founded in 1969 with a special focus on food policy. From the beginning, CNI has been a leading advocate for consumer protection, food program development and management, and sound federal diet

and health policies. The Institute provides policy analysis, information, and education to consumers, program managers, federal agencies, and lawmakers.

Petitioner **Corporate Agribusiness Research Project** is located at P.O. Box 2201, Everett, Washington 98203-020. Petitioner monitors corporate agribusiness from a public interest perspective .

Petitioner **Family Farm Defenders** is located at Box 581 Hillsboro, WI 54634. A coalition of organizations and individuals committed to the creation of farmer-controlled and consumer-oriented food and fiber production. We adhere to the principle of democracy by empowering farmers to speak for and represent themselves in the quest of economic justice and responsible sustainable agricultural policies.

Petitioner **Gateway Green Alliance** is located at PO Box 8094, St. Louis, MO 63156.

Petitioner advances environmental justice and economic equity, eliminates toxic hazards such as landfills and incinerators, and promotes political empowerment and fairness.

Petitioner **Greenpeace International** is located at Keizersgracht 176, 1016 DM Amsterdam, The Netherlands. It is one of the world's major environmental organizations with offices in 33 countries, including the United States, and over 3 million donating supporters worldwide. Greenpeace is a non-profit organization devoted to the protection of the environment with an emphasis on global environmental problems such as climate change and protection of the ozone layer, prevention of nuclear, chemical and biological pollution and the defense of biodiversity

Petitioner **Humane Society of the United States (HSUS)** is located at 2100 L Street, NW, Washington, DC 20037. The Humane Society of the United States is the nation's largest animal-protection organization, with more than 5 million constituents. The HSUS was founded in 1954 to promote the humane treatment of animals and to foster respect, understanding, and compassion for all creatures.

Petitioner **Institute for Agricultural and Trade Policy (IATP)** is located at 2105 1st Avenue South, Minneapolis, MN 55404-2505. IATP was established in 1986 as a nonprofit and tax exempt research and education organization. Our mission is to create environmentally and economically sustainable communities and regions through sound agriculture and trade policy. The Institute assists public interest organizations in effectively influencing both domestic and international policymaking.

Petitioner **Institute for Food and Development Policy (Food First)** is located at 398 60<sup>th</sup> Street, Oakland, CA 94618. Food First is a member-supported, non-profit "peoples" think tank and education-for-action center. Its work highlights root causes and value-based solutions to hunger and poverty around the world, with a commitment to establishing food as a fundamental human right.

Petitioner **LaMontanita Co-op** is located at 3500 Central Ave. SE, Albuquerque, NM 87106.

Petitioner **Mothers & Others for a Liveable Planet** is located at 40 West 20th Street, 11th Floor, New York, NY 10011-4211. Mothers & Others, a national nonprofit education organization, works to promote consumer choices which are safe and ecologically sustainable for this generation and the next. By providing strategies that can reduce individual and community consumption of natural resources, and by mobilizing consumers to seek sustainable choices, we aim to effect lasting protection of public health and the environment.

Petitioner **North American Farm Alliance** is located at P.O. Box 747, Covert, MI 49038.

Petitioner **Organic Trade Association** is located at P.O. Box 1078, Greenfield, MA 01302. The Organic Trade Association is the membership-based business association representing all sectors of the organic industry in North America. OTA's goal is to encourage global sustainability through promoting and protecting the growth of diverse organic trade. Petitioner **Rural Vermont** is located at 15 Barre Street, Montpelier, VT 05602. Founded in 1985, Rural Vermont is a farm and rural advocacy organization. One of its primary goals is to join the interests of farmers and consumers in order to support a healthy food supply, sustainable agriculture and strong rural economy.

Petitioner **Sierra Club, Virginia Chapter** is located at route 1, Box 1890, Palmyra, VA 22963. The Virginia Chapter of the Sierra Club is Virginia's branch of the nation's foremost grassroots environmental organization. With 11,000 members statewide, Chapter volunteers work to pass pro-environment legislation in the Virginia General Assembly, to advocate sound environmental policy at the state and local levels, and to assist the National Sierra Club in its work on federal issues.

Petitioner **Vermont Public Interest Research Group (VPIRG)** is located at 64 Main Street, Montpelier, VT 05602. Established in 1972, VPIRG has grown into Vermont's largest consumer and environmental organization with over 20,000 members. The Vermont Public Interest Research Group is a statewide non-profit organization dedicated to education, lobbying and advocacy on fundamental issues affecting Vermonters. They have prioritized the issues of environmental health, energy conservation and consumer protection.

Petitioner **Wisconsin Organic Crop Improvement Association**, Chapter #1 is located at RR 1, Box 1198, Soldiers Grove, WI 54655-9717.

Petitioner **Cissy Bowman** is located at 884 S SR 39, Clayton, IN 46118. Petitioner is Vice President of the Organic Farmers Marketing Association and owner of Center Valley Organic Farm. Petitioner represents the following organizations: Hoosier Organic Marketing Education (HOME) (a non-profit organization dedicating to providing educational information to the public about organic farming and food); Indiana Certified Organic, Inc. (ICO) (a certifier of organic operations); Organic Farmers Information and

Education Foundation (OFIEF) (a non-profit foundation whose purpose is to provide public information and education on organic farming to enhance food security and the environment); the Indiana Organic Peer Review Panel and the Indiana Farmers Union.

Petitioner **Judy Brady** resides at 62 Sussex Street, San Francisco 94131. She is a writer and political trainer for the Women's Cancer Resource Center in Berkeley, CA. She is also a board member of Green Action, an environmental justice organization.

## STATEMENT OF GROUNDS

### I. Statement of the Law

*A. 21 U.S.C. § 360b, in pertinent part, states:*

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to health of man or animals.

(1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) with respect to any new animal drug if the Secretary finds--

(A) that experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved or the condition of use authorized under subsection (a)(4)(A);

(B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated

together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that subparagraph (I) of paragraph (1) of subsection (d) applies to such drug;

(C) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(D) the patent information prescribed by subsection (c)(3) was not filed within 30 days after the receipt of written notice from the Secretary specifying the failure to file such information;

(E) that the application contains any untrue statement of a material fact; or

(F) that the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application. The supplemental application shall be treated in the same manner as the original application.

If the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such drug is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence to suspend the approval of an application shall not be delegated.

(2) The Secretary may also, after due notice and opportunity for hearing to the applicant, issue an order withdrawing the approval of an application with respect to any new animal drug under this section if the Secretary finds--

(A) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under subsection (1), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection;

(B) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

(C) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(3) Any order under this subsection shall state the findings upon which it is based.

*B. Administrative Procedure Act, 5 U.S.C. Section 706, Scope of Review.*

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the m