

FDA's VMAC Sets Public Hearing On BST

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prevent BST from ever being approved.

Representatives of the National Farmers Union, the Consumers Union and the National Family Farm Coalition, reportedly met with members of the staff to Vice President Al Gore to plead for intervention in what the organizations foresee as pending FDA approval.

There is no indication of how much influence on FDA's decision the White House could make. Also, the Clinton Administration's position on BST is also not known.

There was no media announcement of a public hearing on BST coming from FDA. The March 5 memorandum that notified of the meeting was apparently not intended for the media.

According to the memorandum, the Veterinary Medicine Advisory Committee (VMAC) to the FDA has scheduled the meeting to run from 8:30 a.m. to 5 p.m., with a period set from 9:30 a.m. to 3 p.m. to allow for public comment.

According to the news release, "During the open committee discussion (from 8:30 a.m. to 9:30 a.m., and from 3 p.m. to 5 p.m.), VMAC will discuss whether the increased incidence of mastitis in dairy cows treated with Monsanto Company's bovine somatotropin product — Somatotrope-zinc complex (Somatotrope) — as an aid in increasing milk production, and the potential concomitant increase in antibiotic use, represents a risk to human health."

However, the memorandum also states that the CVM has already determined that the con-

cern for human health is not merited. Though the agency did note that it did not treat the issue raised by the GAO frivolously in making its assessment.

"Data in the New Animal Drug Application for Somatotrope and in the published literature shows that the increase in mastitis for Somatotrope-treated cows is much less than the normal variation in mastitis incidence related to physiological and environmental changes; nevertheless, any increase in mastitis could still result in an overall increase of antibiotic use that could pose a risk to human health if it raised beyond lawful levels, the amount of antibiotics found in milk or meat.

"In this particular case, however, the Center for Veterinary Medicine has reached an initial conclusion that concern regarding potential additional risk to humans resulting from an increased incidence of mastitis due to Somatotrope is not warranted. The basis for the center's conclusion will be discussed with the advisory committee."

It is too late for those who have not already registered with the CVM to make public comment.

According to Gary E. Stefan, with the Center for Veterinary Medicine, as of the March 24 deadline, he had already received more requests to address the VMAC than there is scheduled time to allow.

The CVM also would not release a list of those scheduled to speak during the hearing, because of a policy it follows to protect the scheduled speakers from unnecessary harassment or approach.

The anti-BST organizations reported on their efforts to gain the interest of the White House. According to a news release from the NFU, "The Food and Drug Administration' apparent willingness to approve a controversial growth hormone for dairy cows could seriously damage American dairy farmers by undermining consumer confidence in milk quality."

According to the release, "Polls have shown that consumers do not want to buy dairy products produced from cows injected with the synthetic hormone.

"In addition, the government's investigative agency, the General Accounting Office (GAO), earlier this month repeated its concern that the FDA has not answered all of the questions surrounding the impact of synthetic (BST) on dairy herds."

The Farmers Union has opposed BST because its members perceive a devastating impact on the dairy economy, based on consumers' reaction to the drug.

There are also those who oppose approval out of fear that BST will drive family farmers out of business, because they suspect use of the drug will cause a glut of milk and lower on-the-farm milk prices.

These people can't see any reason for using a product that makes the cow work harder than she already is.

As a hormone, BST acts within the body of the cow to direct nutrients to the milk-making area of the cows, resulting in the manufacture by the cow, of more milk. Nutritional requirements by the cow also increase with the manufacture of more milk.

There is no method to detect the difference between milk from a

cow treated with BST and milk from a cow not treated.

In some cases, groups have sought to bypass this lack of ability to make a distinction between the milks. One group has recommended forcing dairies to put consumer warning labels on milk containers if they use any milk coming from farms where BST is used.

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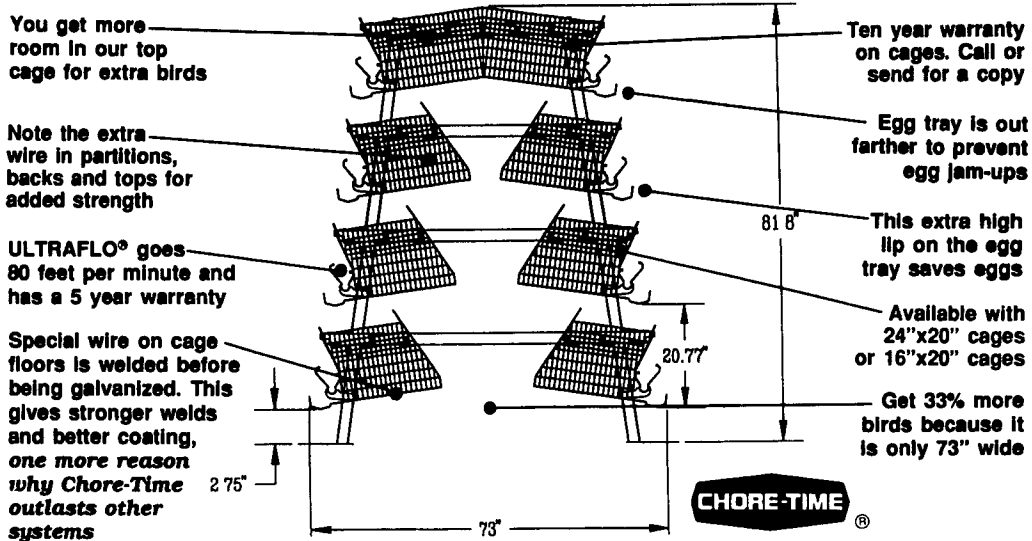
Applications are available at the Lebanon County Conservation District Office, 2120 Cornwall Road, Suite 5, Lebanon, PA 17042.

Seedling forms can also be obtained at Zweier's (Lebanon), Dutchway (Schaefferstown and Myerstown), Wertz Candies (Lebanon), Leed's Corner (Campbelltown), Jonestown Market, and Collin's Market (Colbrook).

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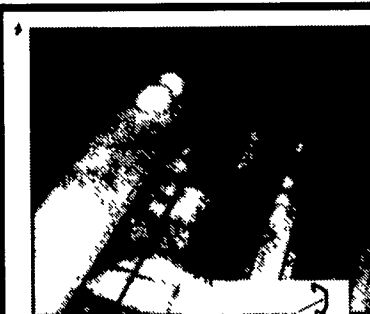
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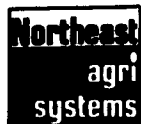
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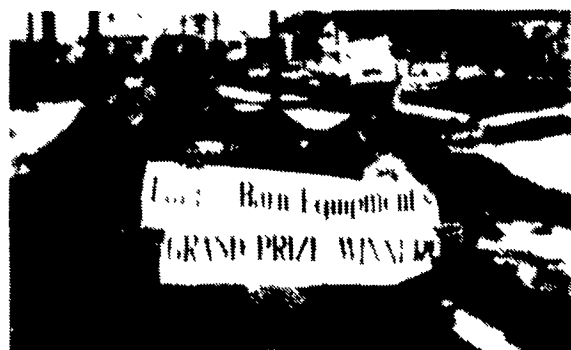
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