BST Gets Thumbs Up

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At the end of the day-long hearing, the advisory board concluded, though not without dissent, that although there is a real increase in the incidence of mastitis in dairy cows treated with Sometribove (BST), it is insignificant and managable and does not present any increased risk to the consumer.

The 13-member board consisted of seven representatives from various fields of applied veterinary medicine, six consultants and an executive secretary, Richard Geyer, deputy director for the Office of Surveillance and Compliance for CVM.

The dissent came from Dr. Debra Aaron, with the Department of Animal Sciences, University of Kentucky, and Dr. Howard Rosenfeld, a consumer representative from Lawrenceville, N.J.

Aaron said she had started her career in Washington D.C. working for Consumers Union, one of the organizations which has protested the approval of the product. She also said she didn't know anything about cows, though she still issued concern.

Both Aaron and Rosenfeld called for the committee to delay issuing a decision, for up to six

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months or more.

However, after taking several polls of committee members, is was unanimously agreed that enough data and research had been presented by Monsanto that no further amount of information would be necessary in making a decision.

It was noted by several that the only additional information that could possibly be enlightening would be to have a 20- to 30-year study done to examine any possible, though not indicated, long term dangers to humans.

The committee meeting was structured so that during the first hour, members of the FDA CVM, which had already issued a tentative position that it did not find a significant risk to humans, were permitted to present the reasoning behind their findings.

Dr. Guest outlined the structure and the purpose.

'CVM has tenatively concluded that indirect risk relating to public health is not significant, because it can be managed," he said, but then added that theirs was a tentative finding and that it was up to the committee to find its own position.

CVM's Dr. Pamela Chamberlain discussed the specifics of

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establishing safety parameters for toxicology to humans, since the product was being reviewed for possible effects on humans. She showed in her presentation how overly cautious the standards are: standards are set so that average milk consumption is increased by three times normal for the highestconsuming age group; the potential human sensitivity to antibiotics is exaggerated by a minimum of 100 times, up to 1,000 times; minimum withdrawl times are also extended beyond normal residue to further reduce any possible subcomponent residue.

Dr. G. A. Mitchell discussed the federal milk monitoring program which has been established to prevent antibiotics from getting into milk.

He reviewed the program from the labeling of all drugs, the regulations for testing, that 100 percent of all tankers are tested for antibiotics, etc.

Dr. Robert Condon, also with the CVM, reviewed the data on the incidence of mastitis and showed that while there was a statistical

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increase in the amount of cases, the real difference was not significant considering all the causes of mastitis. He said that the weather has a far greater impact on the number of mastitis cases than BST.

The doses of BST suggested for commercial use would be a 500 mg injection every 14 days starting from the ninth week into lactation for a period of about 252 days total during a 305-day lactation.

Currently, the majority of all cow illnesses, mastitis included, show up before BST would be injected, mainly because the cow

is most vunerable then, with a drastic change in feed, environment and metabolism.

Of the public testifying, 26 people presented opinions.

Those testifying against its approval included U.S. Rep. Bernard Sanders, Vt., who, despite the request to keep testimony relevant, decried the need for BST because of its impact on the dairy family farm and because it didn't cure anything.

Also opposing BST were Dr. Michael Hansen with the Consum-

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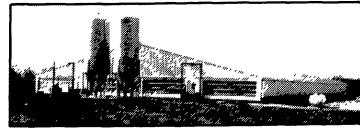


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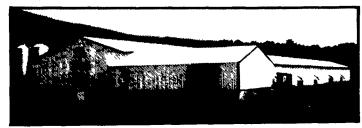
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