Drug Firms Explain Safety Of BGH

Four animal drug firms, Elanco Products, American Cyanamid, Monsanto and Upjohn, have joined forces to explain to the Food and Drug Administration, and Department of Agriculture, and Congress that bovine growth hormone (BGH) can be used in lactating cows without endangering the quality or safety of milk.

Representatives of the four firms met with FDA officials to give their joint presentation recently, according to a memorandum of the meeting prepared by Dr. Woodrow M. Knight of FDA's Center for Veterinary Medicine.

In addition to saying BGH poses no danger to the environment and is not biologically active in humans, the firms' representatives also stated that it will not endanger the ability of the small dairy farmer to compete with the larger farmers, Knight reported.

Meanwhile, American Cyanamid has written FDA that use of bovine growth hormones will have no impact on the environment and urged the agency to reject a coalition's petitioned denial of a New Animal Drug Application for somatotropin bovine growth hormone (BGH) based on environmental concerns.

American Cyanamid rejected the petition's interpretation of the "true nature" of BGH and its status under FDA regulations, saying that it is "not a new genetic bacterial material, only another purified pharmaceutical preparation." It continued:

"Cyanamid suggests that, because of this crucial distinction, the concerns of the petitioners are without foundation and that an EIS (Environmental Impact Statement) is not needed and there is no reason based on genetic concerns for denying any applications for approval of such products. Indeed other pharmaceuticals similar to bovine somatotropin, e.g., human insulin, human interferon and human somatotropin, have been approved by FDA, manufactured and sold without environmental impact."

The firm said the petitioners, the Foundation on Economic Trends and its president, Jeremy Rifkin, the Humane Society of the U.S., the Wisconsin Family Farm Defense Fund, and the Secretary of State of Wisconsin, fail to make clear the status of these products at FDA or to relate their requests "to past and present FDA regulations governing animal drugs (and human drugs as noted above) and environmental considerations which are in place and are operative."

Noting the agency's Investigational New Animal Drug Application (INAD) regulations for testing and approving new animal drugs and revoking applications when facts warrant revocation, it added, "The FDA thus has ample authority to take whatever action is needed to protect both human and animal health and, indeed, environmental safety."

Additionally, American Cyanamid pointed out that the agency revised its environmental regulations in 1985 and stated that INAD's "are categorically exempt from the requirements of the preparation of environmental assessment (EA)," continuing:

"Thus, an environmental assessment is not required for an INAD if the drug is intended to be used for clinical studies 'in which waste will be controlled or the amount of waste expected to enter the environment may reasonably be expected to be non-toxic.' Thus, at this stage, not even an environmental assessment is routinely required, much less an Environmental Impact Statement."

FDA's environmental regulations state that no category of FDA action "routinely significantly affects the quality of the human environment and... therefore automatically requires an EIS," American Cyanamid said, adding that "no FDA actions, including, perforce, NADA's and INAD's routinely require EIS's."

"But the FDA has gone on to rule," it continued, "that before the FDA approved any application to permit the marketing of these products, it will require the preparation of an environmental assessment."

Petitioners' Requests "Premature"

American Cyanamid said, "Given this pattern of regulation the petitioners' requests are clearly premature," adding that "FDA might not approve bovine somatotropin on grounds totally unrelated to environmental considerations," and noting that certain of the petitioners "have already been judicially instructed that their requests for EA's and EIS's indevelopmental research projects are misplaced."

FDA exhibited its awareness of public concern for "the orderly progress of new technologies in harmony with environmental safety," it said, in requesting American Cyanamid to submit an EA covering the investigational use of the firm's bovine somatotropin and it complied with the request.

Impact on Dairy Farmers

The firm said the adverse economic impact of bovine somatotropin on the dairy farmer forecast by the petitioners is also "in error," and that the petitioners reliance on a Cornell University study on the economic impact of BGH as the basis of their economic allegations is "a severe misuse of the Cornell scientists' work and... without foundation."

The Cornell study, American Cyanamid said, made it "abundantly clear" that it is the federal milk price support system "that has and will continue to affect the dairy industry in the most significant way in the years to come." Potential removal of these price supports to achieve a natural balance of supply and demand "will cause the number of dairy farms to decrease significantly, again independent of any actions taken with respect to bovine somatotropin," the firm said, contending that "it is clearly the potential future changes to the government surplus system that is the prime concern to petitioners, not bovine somatotropin."

Petitioners' concerns on increased total feed requirements were also rejected by American Cyanamid as a misinterpretation of the Cornell study findings, saying that the study's conclusion that feed requirements of individual cows producing increased amounts of milk may increase "does not support the apparently intended inference that the total feed requirements for the entire U.S. dairy herd nationwide will increase."

"In fact, total feed requirements to produce the total U.S. milk supply will decrease slightly with bovine somatotropin use as compared to such requirements without use of bovine somatotropin," American Cyanamid commented, saying, "The simple fact is that all the studies published to date reveal that when bovine somatotropin is used, less feed is required per pound of milk produced."

The petitioners' citing of the Cornell study as linking bovine somatotropin use with an estimate that "...between 25 percent and 30 percent of all dairy farms in the U.S. will be forced out of business... Within five years nearly one out of every two... will be eliminated," has been refuted by the senior author of the report as "totally off the wall... There is nothing in our study that says anything remotely like this," American Cyanamid said.

Additionally, the firm questioned the petition's allegations on the adverse effects of BGH on the health of dairy cows, stating, "No scientific authority is cited for any of these allegations." The company contended that scientific studies conducted to date demonstrate "exactly the opposite." American Cyanamid cited a study by Bauman et al. which concluded that treatment with the product:

"...obviously ...did not stress the animals adversely. The animals were in good health through the study... We have never observed any health abnormalities or evidence of stress... In fact, the dramatic increases in efficiency we have observed with BGH treatment would have never occurred if cows were unhealthy or stressed in any way."

American Cyanamid noted also that the Cornell study "demonstrated that under conditions of market equilibrium there would be essentially no increase in New York State milk production projected with the use of bovine somatotropin over the level expected without bovine somatotropin or government price supports."

"The sole undeniable fact," according to the firm, "is that bovine somatotropin will allow the U.S. dairy industry to produce that volume of milk which is socially, economically and politically acceptable to the nation as a whole utilizing less feed and at less cost to the farmer, large or small."

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