

Posilac Quality Control Problems Persist, Inventories Running Out

by Pete Hardin

The end of a misbegotten era looms for the U.S. dairy industry. Good riddance, Posilac.

Posilac supplies are running out because quality-control problems at the Austrian plant producing Monsanto's synthetic cow growth hormone have not been corrected.

IF these problems cannot be corrected by the end of April 2004, Monsanto will exhaust current Posilac inventories and have virtually nothing left to sell to dairy farmer customers using the drug.

IF Posilac sales cease because Monsanto has no remaining inventories, the impact will further depress already struggling U.S. farm milk production ... causing even greater milk shortages across the nation.

IF the quality control problems in Posilac manufacture cannot be resolved, then look for an announcement from Monsanto by sometime in May that Posilac is *kaput*. Monsanto has already curtailed Posilac sales by 50% and dramatically reduced the Posilac sales force.

Posilac supply already cut by 50%

Posilac customers have already been struggling with half their normal allocations of the milk-stimulating, biotech hormone drug in recent weeks. That 50% cutback is one factor, among several, causing serious declines in U.S. milk production.

In January, Monsanto announced it would re-

duce Posilac sales by 50%, effective March 1. But numerous dairy producers reported half-orders delivered as early as late January and early February.

Monsanto cited quality control problems as the reason for reducing Posilac distribution. The February 2004 issue of *The Milkweed* printed records of FDA inspector Rebecca Rodriguez' visit to the Austrian plant owned by pharmaceutical giant Sandoz. That inspection, conducted in November 2003, revealed long term, quality-control problems in the production of Posilac. Incidents cited by the FDA inspector included:

- Corrective actions for repeated sterility failures in Posilac production, occurring from 2001 through 2003, did not effectively improve quality control.
- Contamination was repeatedly found in the environmental samples of the manufacturing areas. "Batches manufactured around the same period of time and under the same conditions of the affected lots have been released to the market.," Rodriguez' inspection report noted.
- Sterility failures in the packaging of Posilac into hypodermic needles occurred repeatedly.
- Representative samples of batches of Posilac were not examined at least once a year for evidence of deterioration.

FDA's Division of Manufacturing Technologies shut down 15% of Posilac sales on December 19, 2003. That was the same day that inspector Rodriguez' reports were received by that Bureau. The "logic" behind FDA's 15% Posilac sales cutback was never clear. Either a drug is safe, or not. Posilac has been previously described by Monsanto as the largest-selling veterinary drug in the U.S.

Rodriguez' report noted that batches of Posilac, produced at the same time as other batches later de-

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CCC Halts NFDM Sellbacks

Without explanation, the Commodity Credit Corporation suspended resale of surplus nonfat dry milk on April 13. Industry sources guess that remaining surplus NFDM is more than six months to one year of age.

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Posilac's Run May Be Over

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terminated to be contaminated, had been commercially sold by Monsanto. A Monsanto spokesperson has vigorously denied that any quality-impaired Posilac has been sold to U.S. dairy farmers. Monsanto has historically been "truth-challenged."

Word in the industry tells of widespread terminations among Monsanto's Posilac sales force. In March, sources say, the company held a big meeting of its sales force, at which about 20 positions were terminated. Other Posilac sales persons have either quit voluntarily, or are aggressively looking for their next gravy train.

At this meeting, sources say, company executives laid out the problems of continuing quality control problems and reported that inventories were dwindling to the point where, if Posilac production is not restored by the end of April 2004, no inventories will remain to sell.

All Posilac commercially sold has been made in Austria. Quality control problems have persisted throughout the drug's history. The September 1993 issue of *The Milkweed* printed an internal Monsanto document showing nearly one ton of Posilac had to be destroyed due to contamination, only weeks before FDA approved commercial sale of the biotech drug.

Treated cows dependent upon Posilac injections

Dairy cows treated with the milk-stimulating biotech veterinary drug are reported to gain eight to twelve pounds of daily milk production from Posilac injections. Problem is: injections of Posilac suppress cows' natural production of growth hormone. Thus, when regular Posilac injections are halted in midst of a cow's lactation cycle, the decline in her milk production will likely be greater than the increased milk output she gained from use of the drug. Posilac-injected cows become dependent upon the drug.

Some dairy farmers have found that cows that

have been regularly injected with the drug have their daily milk output "crash" when the injections stop.

Before cutback, over 20% of cows injected

Spread that "crashing" milk output problem among roughly 22% of the U.S. dairy herd that has been receiving Posilac injections ... and the worsening problem of U.S. milk shortages becomes apparent. U.S. milk production has itself become dependent upon Posilac, and pending withdrawal of the remaining 50% of Monsanto's biotech drug will create even greater milk shortages than already anticipated.

In the analysis of , loss of the remaining 50% of Posilac sales will impact widely on the U.S. dairy industry:

- Lower overall milk production. These production declines will obviously impact dairies based upon the number of animals they have injected with Posilac. According to various studies, Posilac use correlates with larger dairies, and also increases as one moves east to west across the country.
- A run on low-end dairy cull cows to slaughter. Absent Posilac, there are a lot of dairy cows that will be sent to slaughter because they cannot produce efficient levels of milk without the drug. Posilac has been popularly used on "tail-enders" (low producers) and "no-breeders."
- Dramatic increases in values of female dairy calves and heifers. The pending loss of Posilac, the milk production derived from injected cows ... and indeed, many of those injected cows ... will result in dramatic shortages of milk cows in the U.S. Shortages of dairy's fundamental resource will drive up prices.

End of a misbegotten era

For the past two decades in dairy, Monsanto and Posilac have best symbolized most of what was wrong with the U.S. dairy industry. Monsanto funneled money to many industry "experts" preaching the gospel of bigger dairies, more debt, more milk per cow ... and biotechnology. Cash flow, rather than husbandry, became the idol for too many.