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April 7, 2000

Commissioner Jane Henney
Food & Drug Administration
Parklawn
5600 Fishers Lane
Rockville, MD 20857

Delivered by fax: (301) 443-3100

RE: Citizen Petition 99P-4613

Dear Commissioner Henney:

FDA will soon be making a final determination on my petition to revoke the use of *Posilac*, based upon evidence that the formula for Monsanto's hormone was altered subsequent to FDA's exhaustive review.

TIMELINE

On August 24, 1990, FDA published a review of bovine somatotropin in *Science*. As a result of FDA's review of Monsanto's application, FDA made three determinations:

1. FDA incorrectly determined that pasteurization destroyed the majority of the bovine growth hormone in milk so that it was not necessary for Monsanto to develop an assay.
2. FDA incorrectly determined that pasteurization destroyed the majority of the bovine growth hormone in milk so that Monsanto was relieved from performing further toxicology studies.
3. FDA assigned a "zero-day withdrawal" for rbST-treated milk. After FDA's determination that rbST treated milk was safe to drink for humans, the one remaining issue was whether or not it would be safe or ethical to use on dairy cows.

In 1992, Monsanto learned that five "freak" amino acids were produced during the manufacturing process for rbGH. Since the review for human safety had already been completed, Monsanto withheld that information from FDA. Monsanto did not reproduce previously submitted research with the changed formula.

99P 4613

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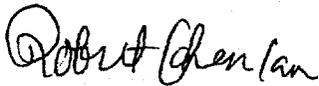
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By late 1993, Monsanto had successfully invented a state of the art filtration process removing proteins containing the "freak" amino acids. Monsanto neither revealed evidence of those errors nor their method of "fixing" those errors to the FDA.

It is clear that the milk hormone now on the market has never been tested. One may incorrectly assume that by "fixing" the problem, one has eliminated possible future adverse effects. Such an assumption may seem logical, but that conclusion cannot be supported by research, for there is none. FDA was deceived by Monsanto and such a deception should be punished. Should FDA not take action against such an unprecedented act, that would represent a deception against the American people.

Very truly yours,



Robert Cohen

RC/am

cc: Linda Suydam, Senior Associate Commissioner - FDA (Fax: 301-443-5930)
cc: Andrew Beaulieu, Deputy Director - CVM (Fax: 301-594-1830)

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