



MAY 27 2004

Food and Drug Administration
Rockville MD 20857

Mr. Robert Cohen
560 Oradell Avenue
Oradell, NJ 07649

Re: Docket 00P-0177

Dear Mr. Cohen:

This is the final response from the Food and Drug Administration (FDA) to your Citizen Petition dated January 10, 2000 and filed on January 11, 2000.

Your petition requests that FDA refuse to approve an application by Upjohn for approval of a recombinant bovine growth hormone (rbGH) product. You assert that Upjohn has submitted an application for approval of rbGH. You also state that FDA has determined that Upjohn's version of genetically engineered bovine growth hormone is identical to the naturally occurring pituitary extract. You disagree with this determination, presumably because of your assertion that new evidence suggests that "freak amino acids" are produced when the bovine growth hormone is recombined with *E. coli* bacteria. You also maintain that FDA has developed a "substantial equivalence" policy that eases the burden on applicants for approval of genetically modified organisms, but you argue that the policy should not apply to Upjohn's application.

For these reasons, you contend that Upjohn has the burden of conducting the same testing and research that was required of Monsanto in its application for approval of its rbGH product, Posilac®.

We are denying your petition. Under our regulations, 21 C.F.R. § 514.11(b), we cannot disclose the existence of a New Animal Drug Application (NADA) unless such existence has previously been publicly disclosed or acknowledged by a sponsor. We are not aware that the existence or nonexistence of an NADA has been previously disclosed or acknowledged. Obviously, we could not grant your petition when our regulation does not allow us to disclose the existence or nonexistence of an NADA.

To clarify, however, Upjohn (or any other sponsor) could not receive an approval of an abbreviated application for an rbGH product based on FDA's determination that their product is identical to pituitary-derived bGH. The Generic Animal Drug and Patent Term Restoration Act (GADPTR) authorizes approval of a new animal drug based on, among other things, a demonstration of equivalence to an approved new animal drug. However, pituitary-derived bGH is not the subject of an NADA approval.

Also, Upjohn (or any other sponsor) could not receive an approval under GADPTR based on the approval of Monsanto's Posilac®. This is because Congress determined that new animal drugs that are primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques are not eligible for generic copying. Pub. L. No. 100-670, § 106, 102 Stat. at 3984. Therefore, any sponsor would need to submit all data required in an NADA in order to obtain approval for an rbGH product.

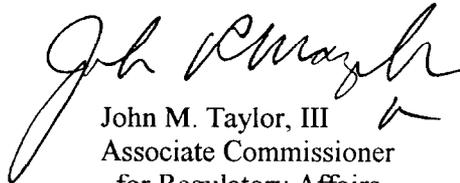
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The remaining assertions in your petition are irrelevant to our decision on your petition. However, we do wish to correct several of the scientific and factual assertions that you made. First, rbGH is not an organism and therefore cannot be a genetically modified organism. Further, FDA does not have a "substantial equivalence" policy that applies to animal drugs, whether the drug is an organism, a chemical or of some other composition. Also, rbGH is not produced by recombination with *E. coli* bacteria. Finally, the amino acid modifications of Posilac® (which you refer to as "freak amino acids") were known by FDA's Center for Veterinary Medicine and determined to be biologically inconsequential before the Center approved Posilac®. Therefore, your assertion that the hormone that is on the market is different from the one reviewed and approved by FDA is incorrect. This is explained more fully in my letter to you of April 20, 2000, denying your petition Citizen Petition 99P-4613, at pages 5-7.

For the reasons stated above, FDA denies your Citizen Petition requesting that FDA refuse to approve an application by Upjohn for approval of an rbGH product.

Sincerely yours,



John M. Taylor, III
Associate Commissioner
for Regulatory Affairs

Cc: HFA-305 (Docket 00P-0177)