



DEPARTMENT OF VETERANS AFFAIRS

Office of General Counsel

Post Office Box 76

Hines IL 60141

December 30, 1992

Via Facsimile & U.S. Mail

In Reply Refer To:

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Dear Manufacturer:

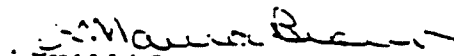
We have received your request for an increase in the Federal ceiling price of your pharmaceutical product pursuant to the requirements of the Veterans Health Care Act of 1992 (the "Act"). The Act at 38 U.S.C. 8126(a)(2) states that the price paid by the specified Federal agencies "...may nominally exceed..." the Federal ceiling price (FCP) "if found by the Secretary to be in the best interests of the Department or such Federal agencies". VA has determined that, in most instances, the statutory term "nominally exceed" does not allow any increase that exceeds 10% of the most recently reported annual non-FAMP.

In order to initiate the processing of a request for nominal increase in the Federal ceiling price, a manufacturer must submit a detailed written request justifying the increase for each separate covered drug item and a certification by its President stating that the FCP is below the production cost of that covered drug and selling at that price would cause the manufacturer to lose money on its overall business. The manufacturer also must agree to make full disclosure of relevant company records to enable VA to verify the accuracy of the certification (see enclosed certification).

Should the Secretary decide to grant the ceiling price increase, this amount will be added to the FCP. If the addition of the nominal amount does not result in a positive number, the ceiling price will be set at \$.01.

Thank you for your cooperation with our efforts to implement the new Act. If you have any further questions, please do not hesitate to call (708) 216-2505.

Sincerely yours,


William E. Thomas, Jr.
Assistant General Counsel

CERTIFICATION

I, _____, (President of the company), hereby certify that I am the President of _____ (the Manufacturer), _____ (address) and that I have the authority to execute this certification for, and on behalf of _____ (Manufacturer). I certify that the current Federal ceiling price of _____ (fill in name of product) is below the cost of producing this covered drug.

I certify that selling the above covered drug product to the Department of Veterans Affairs, Department of Defense, and Public Health Service, including the Indian Health Service at this price will cause _____ (Manufacturer) to lose money on its overall business.

I further certify that _____ (Manufacturer) I will make full disclosure of relevant financial records and that any representatives of the Government shall have the right to examine and audit any and all records and related documents necessary to verify the validity of my statements.

Signature

Date

Title