



DEPARTMENT OF VETERANS AFFAIRS  
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From Mel Noel

per your request  
GENERAL SERVICES ADMINISTRATION

Dear Manufacturer:

Between December 1, 1992, and the present date, we have received from your company either a complaint concerning unreasonably low Federal Ceiling Price (FCP) of your covered drug product(s) calculated under the provisions of the Veterans Health Care Act of 1992 (the Act) or a formal request for an increase in an FCP. On December 30, 1992, we issued a letter to all interested manufacturers describing the Department of Veterans Affairs' (VA) policy regarding requests for increases in FCPs. Since that time, we have had occasion to reconsider the policy expressed in the December 30 letter and the accompanying "Certification". This letter sets forth VA's revised policy concerning FCP increase appeals, and the new Certification enclosed herein supersedes the one enclosed in the December 30 letter.

The Act at 38 U.S.C. 8126(a)(2) states that the price paid by the specified Federal agencies as calculated under the Act "...may nominally exceed..." the FCP "...if found by the Secretary to be in the best interests of the Department or such Federal agencies". As we previously stated, VA has determined that, in most instances, the statutory "nominally exceed" does not allow any increase in FCP that exceeds 10% of the most recently reported annual non-FAMP.

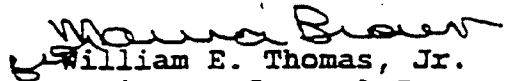
In order to initiate the processing of a request for nominal increase in the FCP, a manufacturer must submit a detailed written request justifying the increase for each NDC item for each period. The request should set forth the financial problem which allegedly exists with the calculated FCP, should compare the amount of Government sales for the NDC item with the amount of non-Government sales and should explain how it would be in the best interests of VA or another Federal agency to pay more for a covered drug product than the statutory formula specifies. VA will not consider that sale of an isolated NDC item(s) to the Government at an amount below standard cost is, standing alone, directly relevant to the interests of VA or another Federal agency. Along with the written request, the President of your company must submit a certification requesting the increased FCP and agreeing to make full disclosure of relevant company records to enable VA to verify the accuracy of statements made in the written justification (see enclosed Certification).

2.

Should the Secretary or his designee decide to grant the ceiling price increase, this amount will be added to the calculated FCP. If because of a large additional discount impact on the calculated FCP, adding a nominal amount does not result in a positive number, the ceiling price will be set at \$.01. (VA has determined that for bookkeeping convenience and other reasons, all negative FCPs will be recorded as \$.01.)

Thank you for your cooperation with our efforts to implement Act. If you have any further questions, please do not hesitate to call General Counsel attorneys serving the National Acquisition Center at (708) 216-2505.

Sincerely yours,

  
William E. Thomas, Jr.  
Assistant General Counsel

Enclosure

MAN:gsd

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(s) of \_\_\_\_\_ (name of the product and its NDC number(s)) is (are) \$ \_\_\_\_\_.

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 this product.

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