DEPARTMENT OF VETERANS AFFAIRS
DEPUTY ASSISTANT SECRETARY FOR
ACQUISITION AND MATERIEL MANAGEMENT
WASHINGTON DC 20420

SEP 23 1993

RE: Calculation of FCP for New Drugs under P.L. 102-585

Dear Manufacturer:

During the Spring of this year, when the Department of Veterans Affairs (VA) returned your copies of the executed Master Agreement (MA) and Pharmaceutical Pricing Agreement (PPA), a letter setting forth VA's requirements for the addition of new covered drugs was included with the packet. (See enclosed copy of the letter.) VA has now partially revised that policy, and this letter is to inform you of VA's final policy in the matter.

The requirement that an initial, temporary Federal ceiling price (FCP) for a new covered drug be determined in most cases through the use of 30 days of wholesale sales or backorders (as set forth in the first paragraph of the enclosed letter) has not been changed. However, the requirements for recalculation of non-Federal Average Manufacturer Price (non-FAMP) and FCP (described in the second paragraph of the enclosed letter) have been revised.

From this date forward, for new covered drugs introduced to the market during the fourth calendar quarter of the year or during the first calendar quarter of the next year, the non-FAMP and FCP should be recalculated after one full calendar quarter of sales experience to get the first annual FCP. As in the past, recalculations of non-FAMP and FCP for new covered drugs must always include all wholesale sales from the date of introduction. For covered drugs introduced to the market in the second or third calendar quarters of the year, the non-FAMP and FCP need not be recalculated after one quarter of sales experience. Instead, for these new drugs, when the following year's non-FAMP and ceiling price described in 38 U.S.C. 8126(a)(2)&(d)(2) are calculated in November, that newly calculated ceiling will be immediately effective as the final FCP for the first year. (That ceiling may also become the FCP for the next year of the multiyear contract if it is lower than the multiyear cap prescribed in 38 U.S.C. 8126(d)(1).)

In compliance with the MA, the recalculations must be reported to VA no later than 30 days after the last day of the calendar quarter included in the calculations (or by the due date for annual recalculations, November 15, if the new drug was introduced in the second or third quarters). Manufacturers will also be required to ensure that their FSS price lists (or dual price lists for VA, DoD and PHS if that election was made) reflect all recalculated FCPs.

Thank you for your cooperation with our efforts to implement P.L. 102-585. If you have any further questions, please do not hesitate to call our Office of General Counsel at (708) 216-2505.

Sincerely,

for Nancy L. Dan.
Gary J. Krump

Enclosure

DEPARTMENT OF VETERANS AFFAIRS
DEPUTY ASSISTANT SECRETARY FOR
ACQUISITION AND MATERIEL MANAGEMENT
WASHINGTON DC 20420

Dear Manufacturer:

As you are aware, Public Law 102-585 requires a manufacturer of "covered drugs" to enter into a Pharmaceutical Pricing Agreement for each "covered drug" and make them available for procurement on the Federal Supply Schedule (FSS). The statute provides that the Secretary of Veterans Affairs will set an appropriate time period for determining the non-Federal Average Manufacturer Price (non-FAMP) in the case of a "covered drug" for which sufficient data is not available, i.e., new drugs. In order to comply with the statute, a manufacturer of new "covered drugs" will be required to provide the Federal Ceiling Price (FCP) and non-FAMP information based on the first 30 days of sales and to offer the drug for procurement on the FSS contract after this first 30-day period. If you want to place your new "covered drugs" on the FSS without waiting for 30 days of sales to occur, we will negotiate terms and conditions with you for the interim period until 30 days of sales become available.

We understand that when a "covered drug" is first put on the market, the initial 30 days of sales may not be indicative of the eventual market price. Therefore, in the second calendar quarter following the introduction of a new drug, the Department of Veterans Affairs will require that the non-FAMP and the FCP be recalculated based on sales during the time period between the date of introduction until the last day of the second full quarter following introduction of the product. For instance, if a product is introduced February 1, 1993, the price should be recalculated through September 30, 1993, the end of the second full quarter. This calculation must include the first 30 days of sales on which the initial FCP was based. In compliance with Section 8126(e) and Section D(2) of the Master Agreement, this information must be reported no later than 30 days after the last day of the second calendar quarter. You will also be required to submit a modification to your FSS contract changing the price. This adjustment will allow for fluctuations in the market price and will adjust your FCP accordingly.

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 our Office of General Counsel at 708-216-2505.

Sincerely,

Gary J. Krump