DEPARTMENT OF VETERANS AFFAIRS
Office of General Counsel
PO Box 76
Hines IL 60141

September 25, 1995

In Reply Refer To (025NAC)

Dear Manufacturer:

As you may have learned, pursuant to 38 U.S.C. 8126(e)(3) (section 603(e)(3) of the Veterans Health Care Act of 1992), the Department of Veterans Affairs (VA), Office of Inspector General (OIG), Contract Audit and Review Division, has been visiting covered drug manufacturers to assess their level of compliance with the above Act. These reviews are designed to determine if the Manufacturers' policies and procedures, as written and described, are adequate to provide assurance that the requirements of the Act are being met and to determine if the policies and procedures are implemented accurately. In the course of several reviews, the OIG has seen repeated instances of inadequate compliance policies and procedures, as well as several instances of the same errors occurring in Non-FAMP/FCP calculation methods.

In order to assist unreviewed manufacturers to correct any compliance deficiencies before they are visited by Government auditors, VA is relaying the following OIG observations:

a. **Policies and Procedures Were Not Adequate.** OIG reviewers found that some Manufacturers' policies and procedures were not adequate to ensure that Manufacturers' management and the Government could rely on the Manufacturers complying with the requirements of the Act. Policies and procedures should be in writing, be approved by management, and be in sufficient detail to enable employees to understand responsibilities and to perform their duties as required by those responsibilities. Further, the policies and procedures should incorporate internal controls sufficient to ensure that errors will have a strong probability of not occurring or, if they do occur, of being detected and corrected in the normal course of work.

b. **Prompt Payment Discounts were Applied Incorrectly.** The Master Agreement states that all weighted average price computations will be net of all cash discounts and similar price reductions. For some of the non-FAMP calculations submitted, the reviews revealed that the Manufacturers adjusted sales to wholesalers for the 2 percent prompt payment discount; however, they applied the discount to the net sales rather than the gross sales. The incorrect formula often used was (wholesale gross sales minus chargebacks) times 98 percent. The correct formula that should be used is (wholesale gross sales times 98 percent) minus chargebacks.

c. **Entire Federal Government Transactions not Excluded from Non-FAMP Calculation.** The Act states that any prices paid by the Federal Government are not to be taken into account when calculating the non-FAMP. Reviewers found that some Manufacturers excluded the chargebacks related to the Government sales from their FCP calculations; however, they did not exclude the entire wholesale transaction (both sales and units).

d. **Non-Wholesale/Direct Sales Used for Non-FAMP Calculation.** The Act defines wholesaler as a merchant middleman, who sells chiefly to retailers, other merchants, or industrial, institutional, and commercial users mainly for resale. OIG found that some Manufacturers included some customer class codes in their calculations that did not meet the definition of wholesaler. OIG also found that some Manufacturers that sold product through wholesalers, as well as directly to retailers, incorrectly included the direct sales to retailers in their non-FAMP calculations.

e. **VA Policy for New Drugs was not Fully Implemented.** Some Manufacturers did not fully implement VA policy on calculating non-FAMPs and FCPs for new drugs. In the Spring of 1993, VA issued policy regarding new drugs. This policy was revised per September 23, 1993 guidance. Reviews revealed that some Manufacturers did not submit the non-FAMP data following all the appropriate guidance. Reviewers found that some Manufacturers did not identify all covered drugs or submitted the FCPs in an untimely manner. As one example, a Manufacturer submitted FCPs for several drugs in October 1993; however, the drugs were on the FSS since 1992. This resulted in a refund to the Government for the units purchased at the higher FSS prices.

f. **Some FSS Prices Erroneously Exceeded PPA Prices.** To determine if the prices of the covered drugs on the FSS contract were correct, OIG compared the prices in the issued FSS pricelists (for VA, DoD, and PHS) to the FCPs in the PPAs. Reviewers found some drugs where the FSS prices to the above three agencies exceeded the PPA prices in violations of the Act.

g. **FSS Prices Extended to Qualifying Federal Agencies were Higher than to Non - Qualifying Users.** For Manufacturers with dual pricing, OIG compared the FSS pricelist used by qualifying agencies (VA, DoD, and PHS) to the FSS pricelist used by non-qualifying agencies (agencies other than VA, DoD, and PHS) to ensure that the FCPs that the Manufacturer extended only to qualifying agencies did not exceed the FSS contract prices extended to non-qualifying agency users. Reviewers found some drugs where the prices charged qualifying agencies exceeded the prices extended to non-qualifying agencies.

h. **Relevant Records were not Retained.** During its reviews OIG could not always substantiate the accuracy of Manufacturers' original non-FAMP submissions. The Master Agreement requires Manufacturers to retain all relevant records used to generate and report the annual FCPs for not less than 5-years from the date of creation. Reviewers found that some Manufacturers did not have a process to archive sales data that was used to create the non-FAMPs and FCPs originally submitted to VA in prior years.

i. **Rounding Inconsistencies in Non-FAMP/FCP Inputs.** During its reviews, OIG recalculates all FCPs using the two decimal place non-FAMPs reported by the Manufacturers to DPPM and compares results to the Manufacturers' reported FCPs. In some cases OIG was unable to recalculate the exact FCP as submitted. DPPM guidance requires the non-FAMP calculations to

be submitted and rounded to two decimal places. However, OIG found some Manufacturers did not reprogram their computer systems to calculate the FCPs using strictly the two decimal place non-FAMPs but instead they used four, five, or six decimal place non-FAMPs.

OIG recommends that Manufacturers review and identify any similar errors in their FCP calculations from inception of the Act in 1992. Manufacturers that acknowledge to DPPM any of these good faith errors by December 15, 1995, recalculate their FCPs, submit payment for any overcharges collected since January 1, 1993, and submit a current voluntary price adjustment may avoid interest or penalty assessments.

Questions regarding these observations may be addressed to the OIG by phoning 202-523-1730, or may be addressed to the undersigned by calling 708-216-2505. Thank you for your assistance in our efforts to implement the Veterans Health Care Act of 1992.

Sincerely,

M. A. Noel, Jr.

Melbourne A. Noel, Jr.