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

October 19, 2001

In Reply Refer To:

Dear Manufacturer of Covered Drugs:

In previous years, we have written to you concerning observations by this Office and the Office of Inspector General regarding errors and/or inadequate compliance policies that have been encountered during reviews of manufacturers' non-Federal Average Manufacturer Price (non-FAMP) calculation methods under the Veterans Health Care Act of 1992, Section 603 (VHCA) (P.L. 102-585; 38 U.S.C. 8126). During the past fiscal year, several matters surfaced outside of the compliance review process that require the Public Law 102-585, Section 603 (P.L.) Policy Group to issue additional guidance regarding the Department of Veterans Affairs' (VA) interpretation and enforcement of the statute.

1. It appears that covered drug and biological originators are more frequently licensing the right to label and distribute their products to companies that are primarily generic manufacturers or specialized distributors. These licenses are frequently non-exclusive and allow the licensee to price and market the product as it wishes. In recent months, the VA National Acquisition Center and other branches of the VA Office of Acquisition & Materiel Management have learned that covered drugs or biologicals are being marketed and distributed by licensees to commercial and Government customers without first complying with the VHCA. It should be noted that the definition of "manufacturer" in the VHCA (38 U.S.C. 8126(h)(4)) includes not only companies that compound or process prescription drug products, but also companies that package, repackage, label, re-label or distribute such products. The only entities clearly excluded by the definition are wholesale distributors of drugs and retail pharmacies licensed under State law. Thus, a vendor that repackages, re-labels or distributes covered drugs or biologicals under license is considered a "manufacturer" for purposes of the VHCA and must comply with its requirements or bear the financial consequences described in 38 U.S.C. 8126(a)(4).

In order to promote compliance with the VHCA, VA requests that already compliant manufacturers that enter into licensing agreements for the repackaging, re-labeling and/or distribution of their covered products inform the prospective licensees of their obligations to comply with the statute. VA also requests that all compliant manufacturers develop a list of distribution licensees of their covered products sometime prior to the end of 2001 and provide that list to Carole O'Brien at the National Acquisition Center.

2. After reviewing the Interagency Agreement between the HHS Division of Immigration Health Services (DIHS) and the Immigration and Naturalization Service of the Department of Justice, the P.L. Policy Group has determined that DIHS' purchases of drugs for use in their clinics are procurements of covered drugs by a subdivision of the Public Health Service that qualify for VHCA pricing.

3. After receiving input from the HHS Office of Pharmacy Affairs (OPA) and industry representatives concerning the operation of the pharmaceutical prime vendor (PPV) program by OPA, pursuant to the requirements of Section 602 of P.L.102-585, the P.L. Policy Group has acceded to OPA's request. The Group agrees that all sales of covered products to Section 602 covered entities at prices negotiated by the Section 602 PPV can be excluded from a manufacturer's non-FAMP calculations, even when those prices are below the Section 602 statutorily calculated price. If manufacturers choose to exclude such sales made through the Section 602 PPV in their 2001 annual report, they must recalculate their third quarter 2000 non-FAMP data (the "old non-FAMP"), employing the same exclusion process in order to obtain a consistent application of newly excluded prices. This approval for excluding from non-FAMP all sales made to covered entities at Section 602 PPV negotiated prices is prospective only, beginning with the 2001 annual report due on November 15, 2001.

4. Finally, effective October 1, 2001, the P.L. Policy Group, in response to industry requests, has reconsidered its policies regarding the generation of non-FAMPs and Federal ceiling prices (FCP) for newly introduced covered drugs and biologicals. In addition to temporary FCPs and permanent FCPs that are required for new covered drugs as outlined in the Dear Manufacturer letter of September 23, 1993, VA will now prospectively recognize as statutorily acceptable "provisional FCPs". These are FCPs determined by the manufacturer and the VA contracting officer (CO) at the time of a new drug's launch, prior to having 30 days of wholesale sales history upon which to base a temporary FCP. Provisional FCPs must be based on the new drug's wholesale acquisition cost, less any percentage cash discount, less the 24 percent basic discount required by the VHCA. A provisional FCP is to be in effect only until such time as the new drug manufacturer obtains sales data needed for calculating the temporary non-FAMP and FCP and reports it to the VA CO and the PBM Data Base Manager.

In other words, those manufacturers that choose to employ the provisional FCP approach in order to get their new products on contract at launch will be obliged to follow a three-step reporting process rather than the standard two-step process. The three steps are: 1) agree on provisional FCP with CO; 2) calculate and report temporary non-FAMP and FCP based on 30 days of wholesale sales; 3) after one full quarter of experience, calculate and report a permanent non-FAMP and FCP effective for the remainder of the year, according to the guidance in the September 1993 letter. Beginning on October 1, 2001, manufacturers employing provisional FCPs in the manner approved above need not tender to "Big Four" ordering activities the difference between the provisional FCP and the temporary FCP, when the latter is lower than the former.

If you have any questions concerning the above points, you may telephone the undersigned at (708) 786-5167. Once again, thank you for your cooperation with VA's efforts to enforce the VHCA.

Sincerely yours,

M. A. Noel, Jr.

Melbourne A. Noel, Jr.