



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

October 18, 1999

Dear Manufacturer of Covered Drugs:

In previous years, we have written to you concerning the Office of Inspector General's (VAOIG) observations regarding the errors and/or inadequate compliance policies that they had encountered during reviews of manufacturers' non-Federal Average Manufacturer Price and Federal Ceiling Price (non-FAMP/FCP) calculation methods. During the fiscal year ending September 30, 1999, the VAOIG Contract Review & Evaluation Division completed reviews of 22 covered drug manufacturers' efforts to comply with the Veterans Health Care Act of 1992, Sec. 603 (VHCA; 38 U.S.C. 8126). IG auditors continue to find errors and gaps in company compliance plans, including many that had been discussed in letters previously sent to all manufacturers of covered drugs. In some instances, employees responsible for compliance had never seen VA's guidance letters from 1995, 1996, and 1997. To assist manufacturers in correcting deficiencies before they are visited by Government auditors, we are re-issuing the above guidance letters. Copies of these letters are attached for your use.

Additionally, IG auditors and this office have observed that mergers and buy-outs of manufacturers have sometimes resulted in the elimination or replacement of staff positions that had carried the responsibility for VHCA reporting and compliance monitoring. This has led to VHCA obligations falling between the cracks of the corporate structure and to erroneous calculations being filed. VA would like to remind all signatories of Master Agreements (MA) that the VHCA prescribes penalties for filing untimely or false data. As stated in Part IV of the MA, the statute prescribes a penalty of \$10,000 per day for failure to timely file information required by 38 U.S.C. 8126(e)(1) and a penalty of up to \$100,000 for knowingly providing false information covered by the Agreement. VA believes that a manufacturer who knowingly provides annual reporting data that has been calculated in a manner contrary to the MA's requirements or contrary to formal VA guidance is subject to the \$100,000 penalty for each erroneous submission. When in doubt as to the proper way to perform a calculation, a manufacturer's representatives should phone Marci Vineyard in the Contract Review & Evaluation Division at 202-565-5444 or the undersigned at 708-786-5167. Any requests for short filing extensions should be in writing, supported by an explanation of significant, unavoidable reasons, and sent via fax to the undersigned at 708-786-5165 prior to November 15, 1999.

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.