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

October 7, 1996

In Reply Refer To: 025NAC

Dear Manufacturer of Covered Drugs:

One year ago, we wrote to you concerning the Office of Inspector General's (VAOIG) observations concerning certain repeated errors and inadequate compliance policies discovered in manufacturers' non-FAMP/FCP calculation methods during visits by the VAOIG's Contract Audit and Review Division. Their efforts to assess the level of compliance with the Veterans Health Care Act of 1992, Section 603 (VHCA) (38 U.S.C. 8126) have continued in 1996. Additional compliance and calculation errors have been encountered this year by the IG and the Office of General Counsel, which prompt the Department of Veterans Affairs (VA) to state its positions regarding the following practices.

1. Some manufacturers have been excluding from their calculations of non-FAMP all covered drugs sold at a price equal to 10 percent or less of the last quarter's non-FAMP, regardless of the context of the sale. Generally, they have done this based upon the VHCA's definition of non-FAMP at 38 U.S.C. 8126(h)(5), which allows exclusion of "...any prices found by the Secretary to be merely nominal in amount." Although the Master Agreement has limited "nominal" prices to those which are no more than 10 percent of the previous quarter's non-FAMP, VA has never interpreted the VHCA to invite the Secretary to use his discretion to protect covered drug wholesale sales which reflect commercial market deep discounting practices to certain customers. The "nominal" pricing exclusion in the Act was not intended to protect incentive use schemes by eliminating from non-FAMP calculations all below-cost sales of a covered drug that result from customers' purchases of sizable quantities of packages at a standard commercial price. VA views "nominal" pricing as being pricing, usually below cost, designed to benefit the public by financially aiding disadvantaged, not-for-profit covered drug dispensaries or researchers using a

October 7, 1996

Dear Manufacturer of Covered Drugs:

drug for an experimental or non-standard purpose. Accordingly, low-price sales that do not fit this description may not be excluded from non-FAMP as sales made at a nominal price.

2. Although VA recognizes the legitimacy of "drug samples" allowed by 21 U.S.C. 353, VA does not agree that all "free" goods are exempt from inclusion in non-FAMP. Manufacturers who distribute covered drug samples in accordance with the letter and spirit of the above Statute may exclude such samples from the computation of their non-FAMPs. VAOIG auditors will verify that manufacturers have complied with the requirements of that Statute. Conversely, "free" goods contingent upon any written or verbal commercial agreements will not be considered exempt from inclusion in non-FAMPs. For example, "free" goods distributed to a customer as a result of its prior purchase of a certain quantity of those goods, e.g., a "buy one, get one free" scheme, must be included in the calculation of those covered products' non-FAMPs. Any distribution of "free" goods with the intent to circumvent the requirements of the VHCA will result in VA pursuing all available remedies under the VHCA.

3. Several manufacturers have inquired as to whether VA agrees with certain Department of Defense (DoD) TRICARE contractors who assert that the VHCA requires covered drug procurements made by TRICARE subcontractors for their mail order pharmacy and retail pharmacy network programs to be subject to Federal ceiling prices (FCP). An exchange of information between the Offices of General Counsel of DoD and VA has resulted in VA taking the position that the VHCA does not require manufacturers to make FCPs available to the presently awarded TRICARE contractors on orders placed by them or by their commercial pharmacy subcontractors for distribution through retail pharmacies. VA cannot conclude that such covered drug purchases under the TRICARE program, as presently structured, constitute covered drug procurements by the DoD within the wording of the Act. Major factors in this conclusion are the absence of any

October 7, 1996

Dear Manufacturer of Covered Drugs:

direct DoD payment for invoiced pharmaceutical products and the lack of any way to trace pharmaceuticals purchased by a TRICARE contractor or subcontractor back to DoD on an item-by-item basis.

On the other hand, VA stands by its previous statements that DoD's covered drug procurements accomplished through its CMOP demonstration project contractor and procurements by USTFs through DoD's pharmaceutical prime vendor contractors are subject to FCPs.

4. For similar reasons and based upon the Department of Health and Human Services (HHS) General Counsel's interpretation of the Indian Self-Determination and Education Assistance Act, Section 105k, Indian tribal health facilities operating under a compact or contract with the Indian Health Service (IHS) under Public Law 93-638 are not entitled to purchase covered drugs at FCPs. According to HHS General Counsel, such purchases may not be viewed under the Indian Self-Determination and Education Assistance Act as being made by the IHS or its agents.

We hope that the above statements regarding VA's interpretation of the VHCA will assist covered drug manufacturers to correct any compliance deficiencies without waiting for VAOIG intervention. Thank you for your cooperation with VA in its efforts to implement the VHCA.

Sincerely yours,

M. A. Noel, Jr.

Melbourne A. Noel, Jr.