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

October 26, 2007

Dear Manufacturer of Covered Drugs:

In recent months, the Department of Veterans Affairs (VA) has received several requests from individual manufacturers or their counsel for VA interpretations of 38 U.S.C. 8126 (P.L. 102-585, Sec. 603; Veterans Health Care Act or VHCA) and the statutory Master Agreement, regarding the proper calculation of non-Federal Average Manufacturer Prices (non-FAMP) and/or Federal Ceiling Prices (FCP). As we did last year at this time, we have summarized below the major inquiries and VA's responses in "Q & A" format, so that all manufacturers will be aware of them as they prepare their annual reports (due on Nov. 15, 2007).

1. Manufacturers may elect to participate in the General Services Administration's (GSA) new disaster recovery purchasing program that allows state and local governments to purchase (among other items) covered drugs from Federal Supply Schedule (FSS) contractors, pursuant to the Interim Rule published on Feb. 1, 2007, 72 Fed. Reg. 4649.

Q: Will FSS sales to state and local entities for advance disaster recovery purposes be considered to be sales to the Federal Government and, therefore, excludable from non-FAMP computations?

A: No. In a July 5, 2007 letter to a law firm, VA's Acting General Counsel stated that there is no specific authority in the Interim Rule and its underlying statute or in 38 U.S.C. 8126 that would permit the exclusion from non-FAMP of disaster recovery purchases by state and local governments. He opined that it was not possible to stretch the VHCA's exclusion of "any prices paid by the Federal Government" in the statutory definition of non-FAMP to include optional FSS purchases by state and local governments.

2. Q: If a manufacturer sells covered drugs through wholesalers to commercial vendors certified by the Centers for Medicare & Medicaid Services (CMS) as Competitive Acquisition Program (CAP) drug vendors for Medicare Part B, may such sales be excluded from non-FAMP computations as sales to the Federal Government?

2.

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A: No. VA's Public Law 102-585, Sec. 603, Policy Group recently decided that the same reasons that prevent CMS from permitting the exclusion of such sales from Average Manufacturer Prices also prevent VA from allowing the exclusion of CAP sales from non-FAMP computations. There is no provision in the relevant statutes that requires or suggests that CAP sales be treated as sales to the Federal Government.

3. Q: When performing the dual Federal Ceiling Price (FCP) calculation in the second or subsequent year of a multi-year contract (such as FSS contracts in 2008), may a Temporary Price Reduction (TPR) or Temporary FCP that is effective as the FSS contract price on Sept. 30 properly be used as the starting point of the dual calculation?

A: VA's annual report instruction letters from Pharmacy Benefit Management SHG to manufacturers have said that the dual calculation begins with "the permanent … (FSS) contract price of a covered drug in effect on September 30…" (emphasis in original). VA has previously stated that a TPR price is not to be considered the permanent contract price for this purpose. However, the P.L. 102-585, Sec. 603, Policy Group believes that a single-pricer's Temporary FCP on its FSS contract (a price that is based on sales reported to VA in a temporary non-FAMP report) is a proper starting point for the dual calculation.

4. In its Oct. 18, 2006 Dear Manufacturer Letter, VA OGC stated that certain described inventory management agreement (IMA) fees charged to covered drug manufacturers by general wholesalers are excludable from non-FAMP.

Q: Does VA agree that exclusion from non-FAMP is also proper for percent-of-sales fees offered to wholesalers by manufacturers as incentives for the wholesalers to adopt certain beneficial practices or meet certain standards of efficiency?

A: No. VA's P.L. 102-585, Sec. 603, Policy Group views percent-of-sales incentive fees offered to wholesalers, in order to achieve business goals of the manufacturer, as not being IMA fees that are excludable from non-FAMP. Specific fee situations that may not clearly fit into the IMA or incentive fee categories should be discussed with auditors from VA's Office of Inspector General. (55).

Dear Manufacturer of Covered Drugs

If you have questions concerning the above interpretations of manufacturers' obligations under 38 U.S.C. 8126, please telephone the undersigned at (708) 786-5167.

Sincerely,

Melbourne A. Noel, Jr.
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Office of General Counsel