DEPARTMENT OF VETERANS AFFAIRS
Office of General Counsel
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October 18, 2006

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 guidance on issues that relate to the calculation of Non-Federal Average Manufacturer Prices (non-FAMPs). On the assumption that VA's responses to these inquiries would be useful to other manufacturers as they begin preparing their 2006 annual reports, we have summarized some of them below in a Q. & A. format.

1. Are IMA Fees Paid To Wholesalers Excludable From non-FAMP?

Since October 2004, VA's P.L. 102-585, Section 603, Policy Group (the Policy Group) has said that wholesaler fees associated with inventory management agreements, fees charged by general wholesalers (pharmaceutical prime vendors) to manufacturers that have chargeback agreements with them, are excludable from non-FAMP, as long as they are defined service charges imposed on manufacturers generally. Product discounts or rebates granted by manufacturers to wholesalers in order to make their drugs more attractive in the market place cannot be excludable fees.

2. Are Sales To Medicare Part D Plans Excludable From non-FAMP?

The Policy Group has decided that manufacturers' sales of covered drugs to Medicare Part D plans are commercial sales, which (assuming that the drugs are delivered through wholesalers in the United States) are to be included in non-FAMPs.

3. Are Sales To Foreign Entities Made Through U.S. Wholesalers Excludable From non-FAMPs?

In response to a question of whether covered drug units sold to U.S. wholesalers but ultimately delivered to customers outside of the U.S. are includable in non-FAMP, the Policy Group decided that they are to be included in non-FAMP because they are sales to wholesalers in the United States under the definition of

non-FAMP contained in the statute (38 U.S.C. 8126(h)). Congress created no exception based on the ultimate purchaser being located outside of the U.S.

4. When Must Temporary non-FAMP Reports Be Filed?

Apparently there has been some uncertainty expressed by industry representatives concerning the allowable time for filing the temporary non-FAMP and FCP reports for new covered drugs, which reports are based on the first 30 days of wholesale sales history. The Policy Group's position is that the deadline for filing a temporary non-FAMP report establishing a Temporary Federal Ceiling Price is 45 days after the end of the first 30 days of sales of the new drug.

5. When Are Sales Of Custom Packages Sold Direct To End Users Not To Be Added To The Standard Commercial Package's Wholesale Sales?

The Policy Group wishes to slightly revise its previous guidance regarding treatment of custom packages of a covered drug. The Dear Manufacturer Letter of October 15, 1997 (at section 4.), states that manufacturers may avoid listing on the FSS and making separate non-FAMP reports for custom packages of a covered drug whose identical contents are contained in a standard commercial package, if wholesale sales of the custom package are added into the non-FAMP of the standard commercial package. However, under current VA guidance, where the custom package with its special labeling is sold only direct to an end user and where the standard commercial package is sold in significant quantities through wholesalers, the custom package direct sales should not be added to the commercial package sales for non-FAMP reporting because direct sales are never to be added to wholesale sales for non-FAMP purposes.

6. What Is The Impact On 2006 Annual Reports Of The Decision In *Coalition v. Secretary Of VA*?

The Coalition for Common Sense in Government Procurement brought an action in the U.S. Court of Appeals for the Federal Circuit a year and a half ago to challenge on many grounds the validity of VA's October 14, 2004, Dear Manufacturer Letter. That letter communicated a decision of the Secretary regarding application of Federal Ceiling Prices (FCPs) to purchases by the Department of Defense through its TRICARE Retail Pharmacy Network (TRRx). On September 11, 2006, the Court of Appeals issued its opinion in this matter. While not reaching the merits of VA's statutory interpretation, the Court held that the Dear Manufacturer Letter imposed a new requirement that manufacturers provide FCP discounts through a refund system and that VA could accomplish

this only through legislative rule making. The Court, therefore, set aside the Dear Manufacturer Letter as procedurally defective and remanded it to VA for compliance with the Administrative Procedures Act.

As a consequence of the decision, DoD has suspended collections of FCP refunds for TRRx purchases of covered drugs and has decided to reimburse all manufacturers who voluntarily paid such refunds. As stated in VA Pharmacy Benefits Management's 2006 Instruction Letter, sales of covered drugs through wholesalers that were used by TRICARE network pharmacies to fill prescriptions for TRICARE beneficiaries will be considered commercial sales not excludable from 2006 non-FAMP reports, unless a manufacturer actually paid refunds to DoD in FY 2006 under the TRRx FCP refund system and does not accept DoD's return of the FCP-based refunds.

If you have any questions concerning the above policies, please telephone the undersigned at (708) 786-5167.

Sincerely,

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