DEPARTMENT OF VETERANS AFFAIRS
Office of General Counsel
PO Box 76
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November 21, 1997

In Reply Refer To: 025NAC

Edward B. Harvey
Federal Contract Sales Manager
Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, Michigan 49001-0199

Dear Ed,

Along with the VA Office of Inspector General (53C), I have studied your letter of October 27, 1997, in which you describe four hypothetical custom labeling scenarios and ask various questions regarding the manufacturer's obligations under Public Law (P.L.) 102-585, Section 603 (38 U.S.C. 8126). On November 14, 1997, I offered oral responses to the questions contained in your letter of October 27, and now I am able to put those answers in writing. (A copy of your letter is attached hereto for ease of reference to the various scenarios it describes.)

Under "Example 1", we agree with your conclusion. In that situation, "Company B" becomes a "manufacturer" under the Statute and should place the product on a Master Agreement (MA) and Pharmaceutical Pricing Agreement (PPA) of its own. "Company A" does not have to include the sales of the "custom" pack product in its own non-Federal Average Manufacturer Price (non-FAMP) calculations.

Under "Example 3", we are assuming you mean to describe a situation where a wholesaler decides to obtain a product and market it as its own, and there are no indicia of ordinary wholesale sales of this particular product, such as standard chargeback arrangements. Under these circumstances, "Company A" does not have to include the sale of the "private labeled" product in their non-FAMP calculations. However, as in "Example 1", the wholesaler becomes a "manufacturer" under the Statute and should have its own MA and PPA.

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Under "Example 4", the custom manufactured product for the HMO would, as you state, have its wholesale sales combined with the "closest commercially available package size" sales for a single non-FAMP calculation. "Company A" is to include only the wholesale sales in the non-FAMP calculation.

Finally, we are unable to agree with your conclusion in "Example 2". We disagree that the "private label" product sold directly to an HMO need not be included in "Company A's" non-FAMP calculations. We also disagree that the HMO is not the final end-user, but rather its wholly owned hospital and clinics are the end-users. For purposes of application of our Statute, both the HMO and its hospitals are end-users. The private label sales in this situation do not differ significantly from those described in "Example 4".

Under VA's policy, when a package has only direct sales, those sales are reportable as if they were made through a wholesaler. Under our so-called "bulk package" policy, the private label HMO sales should be combined with the "closest commercially available package size" sales in non-FAMP calculations for the commercial package. It is possible that VA would allow a manufacturer an option in this situation to calculate a non-FAMP and Federal ceiling price (FCP) for the private label bottle itself and place it as an individual item on the Federal Supply Schedule (FSS). It has always been our belief that the "bulk package" policy benefits industry by capturing the relevant sales in the non-FAMP of a commercially available package, while not requiring a manufacturer to put the private label item individually on its FSS contract.

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I hope that VA's response to your scenarios and questions will be of assistance in your good faith efforts to comply with P.L. 102-585.

Sincerely yours,

Melbourne A. Noel, Jr.

cc: Deputy Assistant General Counsel (025C)
Director, Contract Review & Evaluation (53C)
Associate Chief, Pharmacy Benefits Mgmt (119D)