



# Pharmacia & Upjohn

11/3/97

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Mr. Melbourne A. Noel, Jr.  
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Dear Mr. Noel:

I have received your October 15, 1997 letter and understand Points 1, 2, and 3. Point 4 has caused me some concern. I am writing some examples and my conclusions to those examples for your review. Would you please return your comments and opinions to me as soon as possible.

## EXAMPLE 1

Company A holds the NDA for product XYZ. (XYZ is round, white, the size of a dime and has XYZ imprinted.)

Company A sells product XYZ direct and indirect under its own labeler code and NDC# 0001.

Company A "custom" manufactures a product for Company B, under a supplement to the NDA for XYZ, that has the same active chemical compound, but has a different label identifier, NDC# (0002), size, shape, coloring and markings. (NDC# 0002 is oblong, red, the size of a nickel, and has BBB imprinted.)

Company A sells the "custom" product direct only to Company B and Company B then sells to wholesalers and direct to commercial customers.

### Conclusion:

Company A does NOT include the sale of this product in the non-FAMP calculations. Company A does not have access to wholesaler sales figures to do calculations.

P.L. 102-585 specifically addresses different labelor codes and how to handle.

### Question:

Does Company A have to include the sale of this "custom" product in its' non-FAMP calculations?  
Should Company B have this product on a Master Agreement and PPA of its own?

## EXAMPLE 2

Company A holds the NDA for product XYZ. (XYZ is round, white, the size of a dime and has XYZ imprinted.)

Company A sells product XYZ direct and indirect under its own labeler code and NDC# 0001.

Company A manufactures product XYZ and packages that product in a “private” label for a HMO. The “private” label has the HMO name on it and a specific NDC#(0008). The “private” label package is for a specified number of tablets per bottle that Company A does not manufacture for itself or any other company. The label identifier is Company A’s.

Company A sells the “private” label product only to the HMO directly and does not distribute to the final end user. The HMO has their own distribution system. The final end user is hospital and clinics owned and operated by the HMO. This product never enters the wholesaler system.

**Conclusion:**

Company A should supply this information to the FSS Contracting Officer but does NOT include this sale in the non-FAMP calculations as this is a Direct Sale of a specifically requested size. Company A manufactures many different package sizes larger and smaller than this “private” label size, so this is not really a “Bulk Package”.

**Question:**

Does Company A have to include the sale of this “private label” product in its’ non-FAMP calculations?

**EXAMPLE 3**

Company A holds the NDA for product XYZ. (XYZ is round, white, the size of a dime and has XYZ imprinted.)

Company A sells product XYZ direct and indirect under its own labeler code and NDC# 0001.

Company A manufactures product XYZ and packages that product in a “private” label for a wholesaler. The “private” label has a different label code and received NDC#(0008).

Company A sells the “private” label product only to the wholesaler direct and does not distribute to the final end user. The final end user is the normal wholesaler customers.

The product manufactured for the wholesaler is different in size, shape and has WH1 printed on it.

**Conclusion:**

Company A does NOT include these sales in their non-FAMP calculations as Company A has no way of knowing the true wholesaler sales price. The price charged the wholesaler does not include normal and customary sales and distribution markup in the contract price.

**Question:**

Does Company A have to include the sale of this “private” labeled product in their non-FAMP calculations?

Should Company A notify the wholesaler that the wholesaler needs to have a MA and PPA?

**EXAMPLE 4**

Company A holds the NDA for product XYZ. (XYZ is round, white, the size of a dime and has XYZ imprinted.)

Company A sells product XYZ direct and indirect under its own labeler code and NDC# 0001.

Company A manufactures product XYZ and packages that product in a “ custom” label for a HMO which purchases half the product direct and half of the product through one or more contracted wholesalers at the contract price. The HMO is the only customer the wholesaler has for this specific “custom” label. The “custom” label package is for a specified number of tablets per

bottle that Company A does not manufacture for itself or any other company. The label identifier is Company A's.

Conclusion:

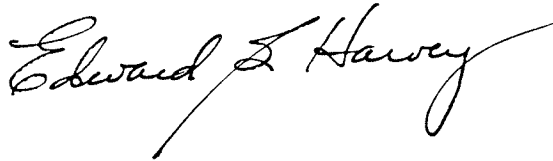
Company A should include the wholesaler sales only and that data should be combined with the "closest commercially available package size" in non-FAMP calculations for the commercial package.

Question:

Does Company A include "only" wholesaler sales in the non-FAMP calculations?

One last request, would you please supply me with a copy of the "Bulk-package" policy that you refer to in the last sentence of Point 4.

Thank you for your assistance

A handwritten signature in cursive script that reads "Edward J. Harvey". The signature is written in black ink and is positioned below the typed text "Thank you for your assistance".