

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

May 4, 1993

in Reply Refer To:

025NAC

RE: Implementation of P.L. 102-585 (Veterans Health Care Act of 1992; the Law)

Dear Manufacturer:

With the cooperation of manufacturers of covered drugs, the Department of Veterans Affairs (VA) has completed the process of obtaining 1992 non-Federal Average Manufacturer Price (non-FAMP) data and Master and Pharmaceutical Pricing Agreements specifying the 1993 Federal ceiling prices (FCPs) for all covered drugs. VA has also nearly completed the process of adding covered drugs to the Federal Supply Schedule (FSS). With VA's participation, Congress recently passed and the President signed a technical amendments bill, P.L. 103-18, which corrects some technical deficiencies in P.L. 102-585. (See copy of enrolled bill enclosed with this letter.)

As part of the next stage of our implementation efforts, we are checking published price lists and invoices issued to Federal agencies for covered drug purchases. In connection with this effort, we wish to bring to your attention some refinements of the Law and an election which your company will need to make.

38 U.S.C. 8126(a) requires that at least a 24% discount be given to "a Federal agency" that procures a covered drug under a depot contracting system or through the FSS. Section 8126(b) describes the relevant "Federal agencies" as VA, DOD and PHS (including the Indian Health Service). As you probably know, although these three Federal agencies place the overwhelming majority of all pharmaceutical orders made on the PSS, there are many other governmental or not-for-profit organizations which are authorised by Congress or the General Services Administration to use the FSS. Non-Federal-agency users of PSS are not entitled to FCPs established under the Law, unless manufacturers elect to give them the benufit of the FCPs. By publishing a single FSS price list in January 1993 and subsequent months, manufacturers have been offering to sell their products to all FSS users at the same price, regardless of whether that price reflects the FCP.

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At this time, we would like to point out some of the ramifications of such a decision and ask each covered-drug manufacturer to formally elect to offer a single price to all YSS users or to adopt a dual price list (one for "the Federal agencies" and one for other FSS users and State Veterans Homes) whenever the FCPs of products are below what the FSS contract most favored customer (NFC) price would be.

In deciding whether to elect a single or dual price list approach, each manufacturer should consider, in addition to the sections of the Law mentioned above, the requirements of Section 8126(d). That provision deals with establishing FCPs in the second and subsequent years of a multiyear contract and requires two computations; the lower of the two computed prices becomes the second or subsequent year's multiyear contract ceiling price. As amended by P.L. 103-18, subsection (d)(1) confirms the Master Agreement's statement that the first computation begins with the current contract year's TSS contract price and increases it by the percentage increase in the CPI-U for a twelve-month period in order to arrive at a new inflation-adjusted figure. Subsection (d)(2) requires that the second computation be done as in the first contract \ year under subsection (a)(2). Thus, next November when these calculations are performed for all covered drugs on a multiyear contract to determine whether subsection (d)(1) or (d)(2) will set their 1994 multiyear FCPs, the actual 1993 FSS contract price will be the beginning point. If a company has a product for which the 1993 FCP is lower than what the FSS negotiated MFC price would be and the company allows the FCP figure to become the single FSS contract price for all users, that same FCP figure will be the starting point for the calculations to determine the product's 1994 multiyear FCP.

Where the 1993 FCP and FSS-MPC price are approximately the same or where the FSS negotiated price is lower than the FCP, it may not seem necessary to make an election because there would be no current economic impact from the choice of a single or dual price list policy. (There would already be a single FSS price with no alternative to choose from.) However, even in these situations, VA has decided that each manufacturer must elect to establish a single FSS contract price for all users or dual price lists (where applicable) for the remainder of the contract period.

To ensure that every covered pharmaceutical and biological item on the 1993 PSS has a contract price established under the normal FSS-MPC discount negotiation procedures, contracting officers from the National Acquisition Center will be contacting your representative. Once this has been done, your company must elect either a single FSS price list granting the benefits of FCPs to all FSS users where

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appropriate or a dual FSS price list, one version being applicable only to "the Federal agencies". The latter election may be implemented on an item-by-item basis so that, where the FCP is lower than an MFC price, a manufacturer may elect to allow the ceiling price figure to stand as the all-PSS selling price for some items but not for others.

Also, it should be remembered that the FSS contract price (and not the FCP, unless the Manufacturer specifies otherwise) will be subject to the FSS Price Reduction clause with its comparable customer discount tracking mechanism. (A manufacturer's desire not to subject any FCP to the discount tracking mechanism would be one reason why every covered drug should have an PSS contract price, regardless of whether or not it is the published selling price.)

We ask that an authorized representative of your company make the required election using the enclosed form and forward it to the appropriate contracting officer, no later than June 1 1991. If your company elects separate FSS price lists, it will have the responsibility of providing the correct price list to the "Pederal Agencies" and all other FSS users.

We again thank you for your cooperation with our efforts to implement P.L. 102-585. If you have any questions regarding this letter, you may call the undersigned or Maura Brown at (708) 216-2505 or your contracting officer at the National Acquisition Center.

Sincerely yours,

Melbourne A. Noel,

Government Trial Attorney

Assistant General Counsel (025)

Chief, Pharmaceutical Products Division (904E)

Chief, Pharmacy Service/D&PPK (119)

Director, Acquisition Analysis & Lizison Staff (96)

Chief, Adquisition Review Division (950)

MANUFACTURERS' FSS PRICE LIST ELECTION UNDER P.L. 102-585

[Please fill in and execute the <u>single</u> paragraph below that reflects the Manufacturer's choice. Return the executed form to the appropriate contracting officer at the VA National Acquisition Center, Hines, Illinois 60141.]

through the undersigned, its officer or agent authorized to make this election, has read and understood VA's 5/4/93 "Dear Manufacturer" letter concerning election of an FSS price list policy. Said manufacturer hereby elects to publish a single annual FSS price list that adopts for all FSS users the current Federal ceiling price (FCP) figure(s) for any covered drug whose FCP is below the most favored customer (MFC) negotiated FSS price. This election will be effective immediately after VA receives this executed form and will remain in effect through the termination of FSS Contract No.

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Signature	Date
Title	
[or]	
2. [Manufacturer Name] the undersigned, its officer	or agent authorised to make this
election, has read and unders	tood VA'S 5/4/93 "pear ng election of an FSS price list
single FBS price list extendi to all FBS users, but rather,	ng Pederal ceiling price Denaille where a covered drug's FCP is
lower than its FSS-MPC price, one containing FSS contract p	to publish <u>separate price lists</u> , rices to non-Federal-agency users
and one containing those FCP Manufacturer wishes to extend	only to Federal agencies. This
election will be effective im- executed form and the resulti-	mediately after VA receives this
approved by the appropriate c	ontracting officer; the election the termination of FSS Contract
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Bignature	Data

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