November 1, 2006

RE: Public Law Price Updates and PPA Submission

Dear Federal Supply Schedule Manufacturer:

The following information is provided in order to assist your firm in updating its Pharmaceutical Pricing Agreement (PPA) – Addendum A and the Federal Supply Schedule (FSS) contract pricing for covered drugs. These revisions are mandated by Section 603 of Public Law 102-585, Veterans Health Care Act of 1992 (the Act).

You recently received instructions from Pharmacy Benefits Management Strategic Health Group (PBM) to assist in calculating the 2007 Federal Ceiling Price (FCP) for each covered drug awarded under your FSS contract. This is the first step in the process, and your annual report must be completed by November 15, 2006 and prior to updating your current FSS contract.

Request of Modification Submission: A request to update the Department of Veterans Affairs, Department of Defense, Public Health Service (including Indian Health Service) and the Coast Guard pricing must be submitted to your Contracting Officer for consideration in the form of a request for modification on or before Monday, December 4, 2006. Requests for changes must be submitted by this date in order to allow time for approval and submission of changes to the agencies' authorized Prime Vendors for a January 1, 2007 effective date. Your firm will be required to honor the updated 2007 FCP calculations effective January 1, 2007, if these recalculations result in a lower price than currently awarded under the FSS contract. Please note: This cut-off date applies to all modifications during this period and not just the Public Law changes, e.g. temporary price reductions, product additions, product deletions, etc.

To help your efforts and ours in ensuring timely approval and submission of changes to our Prime Vendor, attached please find a copy of the Request for Modification Form. It is requested that you provide any spreadsheet information on a diskette or e-mail the file to your Contracting Officer. Please be sure to use a font size of no smaller than 12 when submitting your information, as well as providing information in numeric order of your NDC numbers. Note: Changes received after December 4, 2006 or modifications that have been submitted with missing and/or inaccurate information will most likely have an adjusted effective date of January 15, 2007 or later. These changes must be based on the calculations submitted to PBM and the established FCP. If your current FSS prices are below the calculated 2007 FCPs, no contract modification action is required.

Addendum A: Enclosed please find a copy of the Addendum A form for 2007 to be completed and returned to your Contracting Officer as soon as possible, but not later than December 4, 2006 to coincide with your submitted modification request. The Addendum A should reflect only the established 2007 FCP for each covered drug line item, without the Industrial Funding Fee (IFF). The authorized official who signed your company's PPA (or an authorized successor) must complete and sign the new Addendum A to the PPA for 2007. Please note: Our office must receive an original hard copy with signature. (If additional space is needed, please provide an attachment using the same format as the Addendum A Form.)

If you have any questions or need additional information, please contact your Contracting Officer at (708) 786-5180. You may fax the documents and follow-up with hard copy originals. The office fax numbers are is (708) 786-4974 or (708) 786-4975. Thank you for your cooperation in providing your request(s) to modify your current FSS contracts and your updated Addendum A for the year 2007

Sincerely,

Cheryl Ward-Roberts Assistant Director Federal Supply Schedule Service – Pharmaceutical Team (049A1F1)

Enclosures: PPA 2007 Addendum Form, Request for Modification Form

#### PHARMACEUTICAL PRICING AGREEMENT ADDENDUM A 2007 ANNUAL

| PRODUCT BRAND NAME                   | NDC NUMB        | <u>ER</u>                                | FEDERAL CEILING PRICE PER PACKAGE       |           |
|--------------------------------------|-----------------|--|---|-----------|
|                                      |                 |  | UNIT (NDC)                              |           |
| 1.                                   |                 |  |   |           |
| 2.                                   |                 |  |   |           |
| 3.                                   |                 |  |   |           |
| 4.<br>5.                             |                 |  |   |           |
| 6.                                   |                 |  |   |           |
| 7.                                   |                 |  |   |           |
| 8.                                   |                 |  |   |           |
| 9.<br>10.                            |                 |  |   |           |
| 11.                                  |                 |  |   |           |
| 12.                                  |                 |  |   |           |
| 13.                                  |                 |  |   |           |
| 14.<br>15.                           |                 |  |   |           |
| 15.                                  |                 |  |   |           |
|                                      |                 |  |   |           |
| stetion 1 1 1 TEEP                   |                 | TO 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | 1 |           |
| **Please do not include IFF in the j | price provided. | This should repr                         | esent your calculated FCP pr            | ice only. |
|                                      |                 |  |   |           |
|                                      |                 |  |   |           |
|                                      |                 |  |   |           |
| Manufacturer and Contract Num        | nher:           |  |   |           |
| manuacturer and Contract Mun         | ibei.           |  |   |           |
|                                      |                 |  | V797P-                                  |           |
| Name and Title of signator:          |                 |  |   |           |

**Signature and Date:** 

DEPARTMENT OF VETERANS AFFAIRS

NATIONAL ACQUISITION CENTER

FEDERAL SUPPLY SERVICE (049A1F1)

PHARMACEUTICAL TEAM

P.O. BOX 76, BLDG. 37 (1ST. AVE., 1 BLOCK NORTH OF 22ND ST.)

HINES, ILLINOIS 60141

#### FEDERAL SUPPLY SCHEDULE

#### REQUEST FOR MODIFICATION FORM

For Federal Supply Schedules:
FSC 65, Part I, Section B – Pharmaceuticals
FSC 65, Part VII – InVitro Diagnostics, Reagents, Test Kits, and Test Sets

### THIS COPY IS FOR YOUR CONTRACT FILE AND SHOULD BE USED AS YOUR MASTER COPY.

**CONTRACTOR**: Please use this form in conjunction with the Modification Clause, 552.243-72 and Generic Item Modifications, AS212, of your contract. This form should be used to submit <u>ALL</u> changes to your FSS contract. Pages 3 and 6 include a suggested format of the required information needed to be submitted with your request. You may replace our form with your own format as long as it contains all the required information and any attachments if necessary.

### Submit only the pages that pertain to the change(s) being requested and please do not submit this cover page.

This request for modification form(s) may be faxed to (708) 786-4975 or 4974 and <u>MUST</u> be followed by an original copy.

**Note**: Please review the required information needed for each type of change and submit all required information pertaining to that specific change in your package. If all required material is not received, your Contracting Officer may return your package with no additional action.

644 of your contract)

#### REQUEST FOR MODIFICATION FORM

| Contractor Name:  | Date submitted to VANAC:   |
|---|--|
| Contract No.: V797P   |  |
| FSS Schedule: Please check the  | correct schedule:  ( ) 65 Part I, Section B - Pharmaceuticals ( ) 65 Part VII, InVitro Diagnostics/Reagents  |
|   | ecial Item Number (SIN) Category:<br>2-5, 555-1, 555-2, 555-3, 555-4, 555-5, 555-6, 555-7, 555-8, 555-9,   |
| Pharmaceuticals, Public Law 10  | est is for items covered under 65 Part I, Section B,<br>02-585, Veterans Health Care Act of 1992, please be sure to provide<br>(Pharmacy Benefits Management) before submitting to the<br>IAC. |
|   | livery time and manufacturing location(s) for the offered items. (This ard, but must be restated for the proposed items.) <i>The manufacturer's</i> d in the United States.                    |
| DELIVERY TIMEdays A   | RO (after receipt of order)  |
| MANUFACTURING NAME AND COMPLETE ADDRESS: (DO NOT list distributors or P. O. Box Number) |  |
| MANUFACTURER'S CONTACT  | PERSON:  |
| TELEPHONE NO.:  |  |
|   | ations been provided to PBM? YES NO<br>our calculations, please contact George Hill at 708-786-4387.   |
| available, provide dated, internal p  | MERCIAL PRICE LIST for the proposed items. If one is not pricing document(s) that clearly identify the commercial list price of the nat pricing provided and date is true and correct.         |
| D) Provide a listing of the following   | g information for each item(s) offered:  |
| Proposed item - Generic name,<br>description, including strength, size                  | Trade/Brand Name, National Drug Code (NDC) or item number and e, etc.  |
| 2) Proposed FSS price without Inc   | lustrial Funding Fee (IFF) and proposed FSS price with IFF.  |
| 3) Proposed discount off the comm   | percial price list.  |
| 4) Either Actual or Estimated Com   | mercial Annual sales for <u>each</u> item offered.   |
| 5) <u>Either</u> Actual <u>or</u> Estimated Anni  | ual Government sales for <u>each</u> item offered.   |
|   | nit letter of commitment from the manufacturer which assures the offeror a fy the Government's requirements for the contract period (see Clause I-FSS-   |

#### REQUEST FOR MODIFICATION FORM

#### PRODUCT ADDITIONS (CONTINUED)

- E) Identify your lowest commercial price for each item offered, as described below:
- 1) If the lowest price is being proposed to the Government, identify your Most Favored Customer Commercial (MFC), the price this customer receives and whether this customer is the agreed upon tracking customer or within the category of customers awarded under your contract.
- 2) If the lowest price <u>is not</u> being offered to the Government, then provide all of your firm's <u>commercial prices that are lower which represent significant and frequent discounting practices excluding true ad hoc discounts. Include the following information for all items: generic name, trade/brand name, NDC number, commercial price, name of the commercial customer receiving this price, justification why the Government was not offered this lower price.</u>
- 3) Because these are product additions and no tracking customer has been agreed upon for these items, please provide a proposed tracking customer or category of customers for these items. This will not affect the previously awarded items and the previously agreed upon tracking customer or category of customers.

| F) Is/Are the item(s) being offered for distribution under<br>This will include all current eligible users of the progra<br>Indian Health Service facilities, etc.)                            |                | •                             |
|--|----------------|-------------------------------|
| YES NO   |                |                               |
| G) Complete the following certification:   |                |                               |
| I,certify that i deleted items with a lower cost.  |                |                               |
| <b>NOTE</b> : The effective date of the modification will be of the Contracting Officer. <u>Effective dates will be assigned</u> Approval of the modification is contingent upon your <u>p</u> | gned as either | the 1st or 15th of the month. |
| PLEASE PROVIDE AUTHORIZED SIGNATURE AND  | D DATE BELO    | W:                            |
| Signature and title of authorized person (Contractor)  |                |                               |
| ApprovedApproved as  | Amended        | Disapproved                   |
| Signature of Contracting Officer   | Date           | Effective Date                |
| Prepared by:   |                |                               |
| Signature of NAC Contract Specialist (if applicable)   | Date           | NAC CO Review                 |

#### SUGGESTED FORMAT (Excel compatible)

#### **REQUEST FOR MODIFICATION FORM**

| Contracto  | ntractor Name: Date submitted to VANAC:   |                     |  |                          |   |                |               |                                      |  |                    |   |  |
|------------|---|---------------------|--|--------------------------|---|----------------|---------------|--------------------------------------|--|--------------------|---|--|
| Contract   | Contract No.: V797P-  |                     |  |                          |   |                |               |                                      |  |                    |   |  |
| FSS Sche   | S Schedule: Please check the correct schedule:  ( ) 65 Part I, Section B - Pharmaceuticals  ( ) 65 Part VII – InVitro Diagnostics/Reagents                                    |                     |  |                          |   |                |               |                                      |  |                    |   |  |
| Industrial | ndustrial Funding Fee (IFF): ( ) Embedded ( ) Absorbed  |                     |  |                          |   |                |               |                                      |  |                    |   |  |
| Prime Ve   | ndor Partic   | ipation:            | ( ) Yes (                                | ) No                     |   |                |               |                                      |  |                    |   |  |
| Proposed   | Tracking (  | Customer(s)         | for item(s) being a                      | added for purpo          | ses of the Price Rec                      | luction Claus  | se:           |                                      |  |                    |   |  |
| Is the MF  | C the previ   | ously agreed        | l upon tracking cu                       | stomer or within         | n the tracking custon                     | ner category   | under thi     | s FSS cont                           | ract? YES  | NO                 |   |  |
|            |   |                     |  |                          | PRODUCT ADD                               | <u>DITIONS</u> |               |                                      |  |                    |   |  |
| Provide th | ne following  | information         | for each item to b                       | e added to you           | r contract. Please s                      | ubmit this inf | ormation      | in a minimu                          | um <b>FONT SIZE OF</b>                             | <u>12</u> (Arial). |   |  |
| Commerc    | cial Informa  | tion (See Co        | mmercial Sales F                         | ractices section         | n of your contract for                    | instructions   | )             |                                      |  |                    |   |  |
| NDC#1      | NDC#2   | NDC #3<br>or Item # | Generic Name<br><u>and</u> Trade<br>Name | Commercial<br>List Price | Estimated/Actual<br>Annual Comm.<br>Sales | *MFC<br>Name   | *MFC<br>Price | MFC<br>Discount<br>off List<br>Price | Quantity/Volume (include quantity or volume tiers) | FOB<br>Terms       | Additional<br>Discounts or<br>Concessions<br>(i.e. PPT) |  |
|            |   |                     |  |                          |   |                |               |                                      |  |                    |   |  |
|            | Most Favored Commercial Customer - See page 2, paragraph E, (1) & (2). Also, if paragraph E, (2) applies, please include a separate spreadsheet with all equired information. |                     |  |                          |   |                |               |                                      |  |                    |   |  |

#### **FSS Information**

| NDC # or<br>Item # | Generic Name<br>And Trade<br>Name | Unit | Strength | Size | Estimated/Actual<br>Annual Gov't.<br>Sales | Percent (%) Discount<br>off commercial list<br>price | Proposed FSS<br>Price without IFF | Proposed FSS<br>Price with IFF |
|--------------------|-----------------------------------|------|----------|------|--|--|-----------------------------------|--------------------------------|
|                    |                                   |      |          |      |  |  |                                   |                                |

If there are multiple line items, please submit all items on one spreadsheet.

#### REQUEST FOR MODIFICATION FORM

| Contractor Name:  | Date submitted to VANAC:  |
|---|---|
| Contract No.: V797P-  |   |
| FSS Schedule: Please check the correct schedule   | e: ( ) 65 Part I, Section B – Pharmaceuticals<br>( ) 65 Part VII – InVitro Diagnostics/Reagents   |
| PRICE CHANGES:  |   |
| PRICE INCREASES: (See Economic Price Adjust contract.)  | stment and Generic Item Modifications clauses in your   |
| Special Item Number (SIN)   |   |
| A) The following information should be provided for support the reasonableness of the price change:   | or each item being proposed for an increased price to (See attached spreadsheet, page 6)  |
| <ol> <li>Item (include generic and brand name, N</li> <li>Current FSS pricing</li> <li>Proposed FSS pricing (with and without In</li> <li>Percentage change from current FSS to p</li> <li>Previous tracking customer price</li> <li>Current tracking customer price</li> <li>Percentage change from previous trackin</li> <li>Previous commercial pricing</li> <li>Current commercial pricing</li> <li>Percentage change from previous commercial</li> </ol> | ndustrial Funding Fee) proposed FSS pricing g customer price to current tracking customer price   |
| Please Note: The awarded tracking customer your ability to receive an increase.   | and the established ratio at time of award will affect  |
| B) Provide a dated copy of previous and current of  | commercial price lists.   |
| C) Complete the following certification:  |   |
| I, certify that no adverse FSS price and the tracking customer price since t  | change has occurred in the ratio between the awarded the award of the item.   |
| PRICE REDUCTIONS: (See Price Reduction Cl   | ause in your contract.)   |
| Special Item Number (SIN)   |   |
| A) The requested price reduction is made for the  | following reason(s) (mark all that apply):  |
| predicated, to reduce prices.  3) Granted more favorable discounts or t commercial catalog, price list, or other documer  | t, or other document upon which the contract award was terms and conditions than those contained in the nts upon which the contract award was predicated. ing customer that was the basis of award, and the 5 for "covered drugs" only. |

\*If 2, 3 or 4 is marked, please submit a copy of the applicable catalog, price list, contractor bulletin, letter or customer agreement which details the effective date, duration, terms and conditions of the price reduction.

#### **REQUEST FOR MODIFICATION FORM**

#### PRICE REDUCTIONS (CONTINUED)

|                        |   | elow if the<br>ne frame.  | e price redu  | ction being   | g offered is   | temporar  | y or perma                                       | anent. If temporar  | y, indicate the                            |  |
|------------------------|---|---|---|---|--|---|--|---|--|--|
|                        | ( )   | Permane   | nt (  | ) Tempo   | orary (Tin   | ne Frame:   | Begin  | End _   | )  |  |
| C) I                   | ndicate b   | elow if the   | e reduced p   | ricing is lin                                       | nited to spe   | ecific eligib                                       | ole users o                                      | of the FSS prograr  | n.   |  |
|                        | ( ) No  |   |   |   |  |   |  |   |  |  |
|                        | VA  | SVH2  | CMOPs   | DoD   | ВОР  | IHS   | Big 4  | Oth   | er   |  |
|                        |   |   |   |   |  |   |  |   |  |  |
| SVH<br>Bure<br>D) F    | Legend:  SVH2 = Option 2 State Veterans Homes; CMOP = Consolidated Mail Outpatient Pharmacy; DoD = Department of Defense; BOP = Bureau of Prisons; IHS = Indian Health Service; Big 4=VA, DoD, HHS (including IHS) & US Coast Guard  D) Provide on an attachment, the item(s) to be reduced, NDC #, current FSS pricing, proposed reduced pricing, current Tracking Customer Price and if temporary, please provide the time frame. |   |   |   |  |   |  |   |  |  |
|                        |   |   | 5 PRICING   |   | ·  |   | •  | ine iine name.  |  |  |
|                        |   |   |   |   |  |   | • ,  |   |  |  |
|                        |   |   | all"covered ermitted by F                                 |   |  | and propo   | sed price  | changes (decreas  | es or                                      |  |
| B) (                   | Complete  | the follow  | ing certifica   | ition:  |  |   |  |   |  |  |
| to the price Class the | ne Goverr<br>e/discoun<br>use with r  | ice for and ment to forther to for | NDC and t<br>fall below th<br>ship applica<br>the mainten | hat the Pri<br>e FCP. 11<br>ble to my<br>ance of th | ice Reducti<br>nave reviev<br>awarded tra<br>e establish | on Clause<br>ved (a) my<br>acking cus<br>ed price/d | e may cause<br>commercestomer, and<br>iscount re | ederal Ceiling Pric<br>se the actual FSS<br>cial pricing and the<br>id (b) the Price Re<br>lationship, and (c)<br>ationship establish | selling price<br>duction<br>I certify that |  |
| the                    | Contracti   | ng Officei  | . Effective   | dates wi  | ll be assig  | ned as ei   | ther the 1                                       | e of approval of th<br>st or 15th of the<br>olement to the FS   | month.                                     |  |
| PLE                    | ASE PR  | OVIDE A   | UTHORIZE  | D SIGNAT  | URE AND  | DATE BE   | LOW:   |   |  |  |
| Sign                   | nature and  | d title of a  | uthorized p   | erson (Co   | ntractor)  |   | Date   |   |  |  |
| ( )                    | Approve   | d (   | ) Approve   | d as Amer   | nded (   | ) Disap   | proved   |   |  |  |
| Sign                   | nature of   | Contractir  | ng Officer  |   | Date   |   | Effective  | Date  |  |  |
| Pre                    | pared by  | :   |   |   |  |   |  |   |  |  |
| Sign                   | nature of   | NAC Con   | tract Specia  | alist (if app                                       | licable)   | Date  | <u>_</u>   | NAC CO Review   |  |  |

#### SUGGESTED FORMAT (Excel compatible)

#### **REQUEST FOR MODIFICATION FORM**

| Contractor Name: Contract No.: V797P |   |                       |                        |                  | Da       | Date submitted to VANAC:             |                               |                           |                            |                 |   |  |                                  |
|--------------------------------------|---|-----------------------|------------------------|------------------|----------|--------------------------------------|-------------------------------|---------------------------|----------------------------|-----------------|---|--|----------------------------------|
| FSS Sche                             | edule: Ple  | ase che               | ck the correct scl     | nedule:          |          |                                      | I, Section B<br>VII – InVitro |                           |                            |                 |   |  |                                  |
| Prime Ve                             | ndor Parti  | cipation:             | ( ) Yes                | ( )              | No       |                                      |                               |                           |                            | SIN             | <b>1</b> :                                |  |                                  |
| Please ch<br>(<br>(                  | PRICE INCREASE AND/OR DECREASE  Please check appropriate modification type:  ( ) Price Increase pursuant to Modification Clause or Generic Modification Clause (Complete columns A thru R)  ( ) Price Increase/Decrease in accordance with update to PL 102-585 pricing (SIN 42-2A items only) (Complete columns A thru E, G & H, J&K)  ( ) Price Reduction: (Complete columns A thru H, J & K, M & N, P-R) ( ) Permanent ( ) Temporary (Time Frame  Please submit this information in a minimum FONT SIZE OF 12. |                       |                        |                  |          |                                      |                               |                           |                            |                 |   |  |                                  |
| A A A B C                            |   |                       |                        | D D              | E        | F                                    | G                             | H                         |                            | <u> </u>        | K   | L  |                                  |
|                                      |   |                       |                        |                  |          |                                      |                               |                           |                            |                 |   |  |                                  |
| NDC#1                                | NDC#2   | NDC#3<br>or Item<br># |                        | Unit             | Strength | trength Size Current<br>FSS<br>Price |                               | Prop<br>FSS<br>w/o<br>IFF | Prop<br>FSS<br>with<br>IFF | % FSS<br>Change | Previous<br>Tracking<br>Customer<br>Price | Current<br>Tracking<br>Customer<br>Price | % Tracking<br>Customer<br>Change |
|                                      |   |                       |                        |                  |          |                                      |                               |                           |                            |                 |   |  |                                  |
|                                      | М   |                       | N                      | 0                |          |                                      | Р                             |                           |                            | Q               |   |  | R                                |
| NDC # or<br>Item #                   | Previou<br>Comm.  | -                     | Current<br>Comm. Price | % Comn<br>Change |          | S Contra<br>t added p                | ct Modification               |                           |                            |                 |   | Awarded FS customer ra                   |                                  |
| i                                    |   |                       |                        |                  |          |                                      |                               |                           |                            |                 |   |  |                                  |

If there are multiple line items, please submit all items on one spreadsheet.

#### **REQUEST FOR MODIFICATION FORM**

| Contractor Name:   |  | ate submitted                                  | to VANAC:                               |              |                              |      |
|--|--|--|---|--------------|------------------------------|------|
| Contract No.: V797P-   |  |  |   |              |                              |      |
| FSS Schedule: Please ch  | eck the correct schedule   |  | Part I, Section B<br>Part VII – InVitro |              |                              |      |
| PRODUCT DELETIO  | NS:  | ( ) 03   | art vii – iiiviiio                      | Diagnostics  | onteagents                   |      |
| Special Item Number (SIN   | N)   |  |   |              |                              |      |
| Provide a listing of the iter<br>number, description of the<br>(See suggested format be  | e product and reason for   |  |   |              |                              |      |
| **Note – Please submit<br>wholesalers/ distributor<br>window. If the depletion<br>will be returned with no   | s and Government Pha<br>n date of stock does no<br>action taken.                                       | rmaceutical F                                  | Prime Vendor fal<br>e 15-day windo      | lls within a | 15 - day                     |      |
| PI   | ease submit this informat  |  | <del></del>                             | OF 12.       |                              |      |
| Reason for deletion  | NDC Number or Item<br>Number   | Generic and                                    | Brand Name                              | Unit         | Strength                     | Size |
|  |  |  |   |              |                              |      |
| <ol> <li>Has product been sold address, and point of con</li> <li>Is stock of old NDC still much and what is estimated</li> <li>Is the deleted product the item been submitted to the item been submit</li></ol> | tact for the company that I available in distribution of the depletion date? being replaced by another | the product which ain and/or in the comparable | ventory? Yesitem? Yes                   | No<br>No     | . If YES, how —— If YES, has |      |
| NOTE: The effective date the Contracting Officer. EAPProval of the modification PLEASE PROVIDE AUTION 1.   | Effective dates will be as<br>on is contingent upon you  | ssigned as eit<br>ur <u>publication</u>        | her the 1st or 1<br>of a supplemen      | 5th of the r | nonth.                       |      |
| Signature and title of auth  | orized person (Contracto   | or)  | Date                                    |              |                              |      |
| ( ) Approved ( )   | Approved as Amended  | ( ) Disap                                      | oroved                                  |              |                              |      |
| Signature of Contracting (   | Officer D  | Date   | Effective Date                          |              |                              |      |
| Prepared by:   |  |  |   |              |                              |      |
| Signature of NAC Contract  | ct Specialist (if applicable   | ) Date   | NAC CO                                  | O Review     |                              |      |

#### **REQUEST FOR MODIFICATION FORM**

| Page 8         |   |                    |                                     |   |                 |  |       |   |                             |   |                             |   |                                      |
|----------------|---|--------------------|-------------------------------------|---|-----------------|--|-------|---|-----------------------------|---|-----------------------------|---|--------------------------------------|
| Contrac        | ctor Name                               |                    |                                     |   |                 | Date                                     | sub   | omitted to VA                               | NA                          | O:  |                             |   |                                      |
| Contrac        | ct No.: <u>V79</u>                      | 97P                |                                     |   | 8               | SIN:                                     |       |   |                             |   |                             |   |                                      |
| FSS Sc         | hedule: Pl                              | ease cl            | heck the co                         | orrect sch                                | nedule          |  |       | 55 Part I, Sec<br>55 Part VII –             |                             |   |                             |   | 6                                    |
| <u>ADMII</u>   | NISTRA                                  | TIVE/C             | OTHER C                             | HANG                                      | <u>ES:</u>      |  |       |   |                             |   |                             |   |                                      |
| <u>Trackir</u> | ng Custon                               | ner:               |                                     |   |                 |  |       |   |                             |   |                             |   |                                      |
| State th       | ie reason f                             | for char           | nge below (                         | or on an                                  | attach          | ment:                                    |       |   |                             |   |                             |   |                                      |
|                |   |                    |                                     |   |                 |  |       |   |                             |   |                             |   |                                      |
|                |   |                    |                                     | Sale Prac                                 | tice (C         | CSP) dat                                 | a foi | r the affected                              | H NE                        | )C:                                       |                             |   |                                      |
|                |   | Commer<br>Price (E |                                     |   | C Name MF       |  |       |   | MFC Discount off List Price |   | Additional Discount Concess | s or  |                                      |
|                |   |                    |                                     |   |                 |  |       |   |                             |   |                             |   |                                      |
|                | ormation                                |                    | Ctua a ath                          | Davasant                                  | . (0/ )         | Drana                                    | امما  | Droposed                                    | FS                          | <u> </u>                                  | <b>E</b> #                  | ective  | Awarded                              |
| NDC#           | Generic<br>Name<br>and<br>Trade<br>Name | Unit               | Strength<br>and<br>Size             | Percent<br>Discour<br>comme<br>list price | nt off<br>rcial | Propos<br>FSS<br>price<br>without<br>IFF |       | Proposed<br>FSS<br>price with<br>IFF        | Co<br>Mo<br># th            | ntract<br>dification<br>nat added<br>duct | dat<br>cor<br>mo<br>tha     | te of FSS<br>ntract<br>odification<br>at added<br>oduct | FSS<br>tracking<br>customer<br>ratio |
| Trackin        | na Custon                               | ner (TC            | c) Informat                         | ion:                                      |                 |  |       |   |                             |   |                             |   |                                      |
| Propos         | ed Trackir<br>istomer                   | ng Pe              | ercent (%) [<br>off commer<br>price | Discount<br>cial list                     | TC              | Net Pri                                  | се    | TC Sales (<br>months)                       |                             |   | С                           | omments   |                                      |
| custom         | er (TC) is                              | an app             | ropriate cu                         | stomer in                                 | terms           | s of ensu                                | ıring | in detail wh<br>the Govern<br>n positive pr | men                         | t price/disc                              |                             |   | _                                    |

#### REQUEST FOR MODIFICATION FORM

#### **ADMINISTRATIVE/OTHER CHANGES (Continued):**

#### NDC Number Change:

To ensure our customers experience a smooth transition from the current NDC number to the new NDC number, we may want to establish a transition period for incorporation of the new NDC number on your FSS contract. We need to ensure product under the new NDC number has been shipped to our Prime Vendor and ordering activities are aware of the NDC number change. As part of the transition, we may ask you to maintain both NDC numbers on the contract and honor chargebacks for a brief period of time. The transition period will depend on the commercial availability of the old NDC.

| Part I - Product Status | S |
|-------------------------|---|
|-------------------------|---|

| Please address the ques  | stions below:  |  |  |                |  |  |  |
|--|--|--|--|----------------|--|--|--|
| the date product<br>2. Is stock of old<br>YES, how much<br>3. Do you agree<br>If yes, until what | shipped to the PV: NDC still available in t and what is estimated to maintain both NDC date: | to the Prime Vendor(s): Yethe supply chain and/or invedepletion date? on the FSS contract for a permanent of the property of the prime ventors of the prin | ntory? <b>Yes</b> eriod of time: <b>Ye</b> | _ <b>No</b> If |  |  |  |
| Old NDC  | New NDC  | Product Description  | Description Strength                       |                |  |  |  |
|  |  |  |  | <u>Size</u>    |  |  |  |
|  |  |  |  |                |  |  |  |
|  | hanges being proposed  | d on an attachment which de<br>change, BPA and/or Incentiv   |  |                |  |  |  |
| Reason for Change:   |  |  |  |                |  |  |  |
|  |  | vill be determined at the time   |  |                |  |  |  |

the Contracting Officer. <u>Effective dates will be assigned as either the 1st or 15th of the month.</u>

Approval of the modification is contingent upon your <u>publication of a supplement</u> to the FSS price list.

#### **ADMINISTRATIVE/OTHER CHANGES (Continued)**

## PLEASE PROVIDE AUTHORIZED SIGNATURE AND DATE BELOW:

| Signature and title of authoriz  | ed person (Contrac          | tor) | <del></del>   | Date          |  |
|----------------------------------|-----------------------------|------|---------------|---------------|--|
| ( ) Approved ( ) App             | roved as Amended            | (    | ) Disapproved |               |  |
| Signature of Contracting Officer |                             | Date | Effectiv      | ctive Date    |  |
| Prepared by:                     |                             |      |               |               |  |
| Signature of NAC Contract Sp     | <br>pecialist (if applicabl | e)   | Date          | NAC CO Review |  |

# DEPARTMENT OF VETERANS AFFAIRS NATIONAL ACQUISITION CENTER FEDERAL SUPPLY SCHEDULE SERVICE (049A1F1) P.O. BOX 76 HINES, IL 60141

RE: Implementation of Public Law 102-585, Section 603 (Veterans Healthcare Act of 1992)

Dear Manufacturer:

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

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 FSS users or to adopt a dual price list (one for "the Federal agencies" and one for other FSS users and State Veteran Homes) whenever the FCPs of products are below what the FSS contract's most favored customer (MFC) 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 multi-year contract and requires two computations; the lower of the two computed prices becomes the second or subsequent year's multi-year contract ceiling price.

Where the FCP and FSS-MFC 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.

At this time, the beginning of the solicitation for the new contract period of the schedule, your company must elect either a single or dual price list granting the benefits of FCPs to all FSS users where 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-FSS 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.

We ask that an authorized representative of your company make the required election using the enclosed form and include it with your solicitation offer. If your company elects separate FSS price lists, it will have the responsibility of providing the correct price list to the "Federal Agencies" and all other FSS users.

We thank you for your cooperation. If you have any questions regarding this letter, you may call the undersigned at (708) 786-5167 or Carole O'Brien at (708) 786-4957.

Sincerely,

MELBOURNE A. NOEL, JR. Government Trial Attorney

ATTACHMENT TO SOLICITATION M5-Q50A-05

### MANUFACTURER'S FSS PRICE LIST ELECTION FORM UNDER PUBLIC LAW 102-585

(Please fill in and execute the <u>single</u> paragraph below that reflects the Manufacturer's choice. Return the executed form with your offer being submitted under solicitation M5-Q50A-03.)

| 1. [Manufacturer Name]undersigned, its officer or agent authorized to mal "Dear Manufacturer" letter concerning election of hereby elects to publish a single annual FSS price. Federal ceiling price (FCP) figure(s) for any covecustomer (MFC) price. This election will be effect will remain in effect through the termination of the  | f an FSS price list policy. Said manufacturer ce list that adopts for all FSS users the current red drug whose FCP is below the most favored ctive immediately upon award of a contract and  |
|--|--|
| SIGNATURE  | DATE   |
| TITLE  |  |
| (OR)************************************   | ************************************   |
| 2. [Manufacturer Name]undersigned, its officer or agent authorized to mal "Dear Manufacturer" letter concerning election of hereby elects <u>NOT</u> to publish a single FSS price I all FSS users, but rather, where a covered drug's F publish <u>separate price lists</u> , one containing FSS of users and one containing those FCP capped prices to the covered Big 4 (VA, DoD, PHS/HIS, and Cobe effective immediately upon award of a contractermination of the FSS contract. | f an FSS price list policy. Said manufacturer list extending Federal ceiling price benefits to FCP is lower that the company's MFC price, to contract prices to non-covered Federal-agency s which the Manufacturer wishes to extend only past Guard) Federal agencies. This election will |
| SIGNATURE  | DATE   |
| TITLE  |  |

| AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT  |  | 1. CONTRACT ID CODE PAGE OF PA |   |   |        |                        |            |                                   |
|---|--|--------------------------------|---|---|--------|------------------------|------------|-----------------------------------|
| 2. AN   | MENDMENT/MODIFICATION NO. 07-01                          | 3. EFFECTIVE D. January 1, 20  |   | 4. REQUISITION/PURCHASE REQ. NO. 5. PRO |        |                        | 5. PROJ    | 1   1<br>JECT NO. (If applicable) |
| 6. ISSUED BY Dept of Veterans Affairs National Acquisition Center (049A1F1) FSS Division - Pharmaceuticals P.O. Box 76, 1st Avenue north of Cermak Road, Building 37 Hines, IL 60141 Attn:  |  |                                | 7. ADMINISTERED BY (If other than Item 6) Dept of Veterans Affairs National Acquisition Center (049A1F1) FSS Division - Pharmaceuticals P.O. Box 76, 1st Avenue north of Cermak Road, Building 37 Hines, IL 60141 |   |        |                        |            |                                   |
|   | IE AND ADDRESS OF CONTRACTOR (No., str                   | reet, county, State, and       | ZIP Cod   | le)                                     | (√)    | 9A. AMENDI             | MENT OF SO | DLICITATION NO.                   |
| 12345   | maceutical Company<br>5 N. Main Street<br>here, IL 60007 |                                |   |   |        | 9B. DATED (            | SEE ITEM 1 | 1)                                |
|   |  |                                |   |   |        | NO.<br><b>V797P-55</b> | 55X        | CONTRACT/ORDER                    |
| CODE  |  | FACILITY CODE                  |   |   |        | 10B. DATED November    |            | ·                                 |
| 11. THIS ITEM APPLIES TO AMENDMENTS OF SOLICITATIONS    The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers   is extended,   is not extended.  Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:  (a) by completing Items 8 and 15, and returning copies of the amendment; (b) by acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF OUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified. |  |                                |   |   |        |                        |            |                                   |
|   | CCOUNTING AND APPROPRIATION DATA (IJ                     |                                | •   | 1                                       |        |                        |            |                                   |
| 13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS,  |  |                                |   |   |        |                        |            |                                   |
| IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.  (1)  A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify dithority), NE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.  |  |                                |   |   |        |                        |            |                                   |
| B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIE. TO DEFECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).  |  |                                |   |   |        |                        |            |                                   |
| X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: MODIFICATION CLAUSE 552.243-72.4731 1996)  |  |                                |   |   |        |                        |            |                                   |
| D. OTHER (Specify type of modification and authority)   |  |                                |   |   |        |                        |            |                                   |
| E. IMPORTANT: Contractor   is not,   X   is required to sign this document and return 1 copies to the issuing office.   |  |                                |   |   |        |                        |            |                                   |
| 14. DESCRIPTION OF AMENDMENT/McDIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)  This bilateral modification is issued to incorporate the attached price changes pursuant to Public Law 102-585   |  |                                |   |   |        |                        |            |                                   |
| This modification is contingent upon the vendor publishing a FSS pricelist supplement. All other terms and conditions remain unchanged  Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.  |  |                                |   |   |        |                        |            |                                   |
|   | AME AND TITLE OF SIGNER (Type or print)                  |                                |   | AME AND TITLE OF CON                    |        |                        |            | nt)                               |
| AUTH  | ORIZED CONTRACTOR NAME                                   | ,                              | W. R  | . Satterfield, III -                    | Con    | tracting Of            | fficer     |                                   |
| 15B. CO   | ONTRACTOR/OFFEROR  | 15C. DATE<br>SIGNED            | 16B. UI   | NITED STATES OF AMER                    | RICA   |                        |            | 16C. DATE SIGNED                  |
| AUTH  | ORIZED CONTRACTOR SIGNATURE                              |                                | BY  | (Signature of Cont                      | ractin | a Officer)             |            |                                   |

| AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT  |   |  | 1. CONTRACT ID CODE PAGE OF PAGE 1 1 1  |  |                                    |   |   |  |
|---|---|--|---|--|------------------------------------|---|---|--|
| 2. AME  | NDMENT/MODIFICATION NO.<br>07-01  | 3. EFFECTIVE 1 January 1, 2  |   | 4. REQUISITION/PURCHASE REQ. NO. 5. PR   |                                    |   | 5. PRO  | DJECT NO. (If applicable)                                      |
| 6. ISSUED BY Dept of Veterans Affairs National Acquisition Center (049A1F1) FSS Division - Pharmaceuticals P.O. Box 76, 1st Avenue north of Cermak Road, Building 37 Hines, IL 60141  |   | 7. ADMINISTERED BY (If other than Item 6) CODE Dept of Veterans Affairs National Acquisition Center (049A1F1) FSS Division - Pharmaceuticals P.O. Box 76, 1 <sup>st</sup> Avenue north of Cermak Road, Building 37 Hines, IL 60141   |   |  |                                    |   |   |  |
| 8. NAME   | AND ADDRESS OF CONTRACTOR (No., str   | eet, county, State, and  | d ZIP Cod   | le)  | (√)                                | 9A. AMENDI  | MENT OF S   | SOLICITATION NO.   |
| 12345 N   | aceutical Company<br>N. Main Street<br>ere, IL 60007  |  |   |  |                                    | 9B. DATED (   | SEE ITEM .  | 11)  |
|   |   |  |   | 10A. MODIFICATION OF CONTRACT/ORDER NO.  V797P-5555X  10B. DATED (SEE ITEM 13)   |                                    |   |   |  |
| CODE  |   | FACILITY CODE  |   |  |                                    | Novembe   |   |  |
| Offers must<br>(a) by con<br>By separate<br>THE PLAC<br>virtue of thi<br>solicitation   | bove numbered solicitation is amended as set for the acknowledge receipt of this amendment prior impleting Items 8 and 15, and returning or eletter or telegram which includes a reference to DESIGNATED FOR THE RECEIPT OF OF is amendment you desire to change an offer alread this amendment, and is received prior to the | orth in Item 14. The It to the hour and date stoppies of the amendment of the solicitation and a strength PRIOR TO THE addy submitted, such the opening hour and date of the submitted of the sub | hour and of<br>pecified in<br>ent; (b) by<br>amendmen<br>IE HOUR<br>change ma | n the solicitation or as amen<br>acknowledging reacipt of the<br>nt numbers. FAILUKE<br>AND DATE SPECIFIED May be made by telegram or lead | Offers deal, by less am YOUR LAY R | is extended, one of the followendment on each ACKNOWLEDGESULT IN REJE | wing metho<br>copy of the<br>GEMENT T<br>CTION OF | ds: offer submitted; or (c) O BE RECEIVED AT YOUR OFFER. If by |
| 12. ACCO  | OUNTING AND APPROPRIATION DATA (If  | required)  |   |  |                                    |   |   |  |
| 13. THIS ITEM APPLIES ONLY TO MOD. CATIONS OF CONTRACTS/ORDERS,   |   |  |   |  |                                    |   |   |  |
| IT MODIFIES THE CONTRACT /ORDER NO. AS DESCRIBED IN ITEM 14.  (1/2) A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify at hority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.  |   |  |   |  |                                    |   |   |  |
| B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).   |   |  |   |  |                                    |   |   |  |
| C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED IN 12 PURSUANT TO AUTHORITY OF:   |   |  |   |  |                                    |   |   |  |
| X D. OTHER (Specify type of modification and authority)  MODIFICATION CLAUSE 552 243 73 February 160  |   |  |   |  |                                    |   |   |  |
| E. IMPOI  | MODIFICATION CLAUSE 552 43-72 Feb 1 96)  E. IMPORTANT: Contractor \[ \( \times \) \] is not \[ \( \times \) a required to sign this document and return \[ \times \) copies to the issuing office.  |  |   |  |                                    |   |   |  |
| 14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)   |   |  |   |  |                                    |   |   |  |
| This unil   | ateral modification is issued to inco   | orporate the atta  | ached p   | rice changes pursua  | int to                             | Public Law 1  | 102-585   |  |
|   |   |  |   |  |                                    |   |   |  |
| This modification is contingent upon the vendor publishing a FSS pricelist supplement All other terms and conditions remain unchanged  Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect. |   |  |   |  |                                    |   |   |  |
|   | TE AND TITLE OF SIGNER (Type or print)  | referenced in Relii 5A 01  |   | AME AND TITLE OF CON   |                                    |   |   | rint)  |
|   |   |  | W. R  | . Satterfield, III -   | Con                                | tracting Of   | fficer  |  |
| 15B. CON  | TRACTOR/OFFEROR   | 15C. DATE<br>SIGNED  |   | NITED STATES OF AMER   |                                    |   |   | 16C. DATE SIGNED   |
| (Si <sub>ξ</sub>  | gnature of person authorized to sign)   |  | <i>D1</i>   | (Signature of Cont   | tracting                           | g Officer)  |   |  |

EXCEPTION TO SF 30 APPROVED BY OIRM 11-84 STANDARD FORM 30 (REV. 10-83) Prescribed by GSA FAR (48 CFR) 53.243





## **Agenda Outline**

ı. Background

vi. Implementation of Dual Prices

**II. Contracting Process** 

VII. NFAMP Calculation

Methodology Change

III. PV Issues

**VIII. FCP Appeal Process** 

Industrial Funding Fee Changes

ix. End of the Year Update

v. Modification Process



## Public Law Background

Presented by: Mel Noel



## Introduction

- ◆ Public Law 102-585 § 603: Veterans Health Care Act (VHCA) of 1992.
  - **■** Effective January 1, 1993.
  - **■** Imposed pricing calculations.



## Introduction

- ◆ Public Law 102-585 § 603: Veterans Health Care Act (VHCA) of 1992.
  - Requirements for affected vendors
    - Master Agreement.
    - Pharmaceutical Pricing Agreement (PPA).
    - Interim Agreement, if applicable.
    - FSS Contract.



## Who is eligible?

- ◆ The big 4 (VA, DoD, Public Health Service (PHS) (including Indian Health Service) and the Coast Guard.
- ◆ State Veteran Homes who have a sharing agreement with the VA and have elected options 2, 3 or 4 (VHA IL 10-99-001).
- ◆ Division of Immigration Health Services purchases of drugs for use in their clinics (10/19/01).



## What Drugs are Covered

- ◆ Sole source and multi-source innovator drugs for which a prescription is required, marketed under an original New Drug Application (NDA) approved by FDA.
- Biologics marketed under a FDA license
- ◆ This definition includes drugs marketed as "generics" which are marketed under an NDA.



# Obligations of Covered Drug Manufacturers

- ◆ Signify adherence to statutory requirements by signing a Master Agreement (MA) (Evergreen) and Pharmaceutical Pricing Agreement (PPA) (Addendum A to PPA revised each year).
- Make available on FSS each of its covered drugs.



# Penalties for non-participation

A manufacturer of a covered drug that fails to enter into a MA and does not offer the product on the FSS suffers a significant economic penalty. Such manufacturer may not be paid by "Big Four", Medicaid or PHS grantees for any drug or biological.



## Transferred covered drugs

- ◆ Dear Manufacturer letter dated October 15, 1997.
- Drugs transferred with exclusivity from one Manufacturer to another maintain their originally computed FCP throughout the year.
- ◆ The new manufacturer may enter a zero in the old-Non FAMP field when calculating the FCP applicable to their first full year of ownership.



## Introduction of New Drugs

- Provisional FCP (A means of pricing a new covered drug at introduction prior to accumulating 30 days of sales).
- ◆ Temporary FCP (based on 30 days of sales).
- Permanent FCP (based on one full quarter of sales).



## **Provisional FCP**

- ◆ Provisional FCPs may be placed on the FSS upon launch but the price must be agreed upon by the CO and may not exceed the wholesale price less prompt pay discount less 24 percent.
- ◆ Beginning October 1, 2001, manufacturers employing provisional FCPs need not tender to "Big Four" ordering activities the difference between the provisional FCP and the temporary FCP when the latter is lower than the former.



## **Temporary FCP**

◆ The temporary non-FAMP and FCP will be reported based upon the first 30 days of wholesale sales.



## **Permanent FCP**

◆ After one full quarter of experience, calculate and report a permanent non-FAMP and FCP effective for the remainder of the year.



- ◆ If a new covered drug is introduced in the first quarter: (January to March).
  - The Temporary FCP is determined by taking .76 of the non-FAMP based on the 1<sup>st</sup> 30 days of sales. The non-FAMP price should include any cash discounts if they pertain.
  - The Non-FAMP must be recalculated and a <u>final FCP</u> reported based on sales from day of product introduction through June 30. Data is due and effective on August 1.



- If a new drug is introduced in the 2nd or 3rd quarters: April through September:
  - The Temporary FCP is determined by taking .76 of the non-FAMP based on the 1st 30 days of sales. The non-FAMP price should include any cash discounts if they pertain.



- If a new drug is introduced in the 2nd or 3rd quarters: April through September:
  - The Non-FAMP will be recalculated using the data submitted for the following year's FCP and will be multiplied by .76 to produce the final FCP. This data is part of the annual report and is due on November 15. The final FCP will be effective from November 16 through December 31.



- ◆ If a new drug is introduced in the fourth quarter October to December:
  - The Temporary FCP is determined by taking .76 of the non-FAMP based on the 1st 30 days of sales. The non-FAMP price should include any cash discounts if they pertain.



## New drug calculation based on quarter of introduction

- ◆ If a new drug is introduced in the fourth quarter October to December:
  - The Non-FAMP must be recalculated and a final FCP reported based on sales from day 1 of product introduction through March 31. Data is due and effective on May 1.



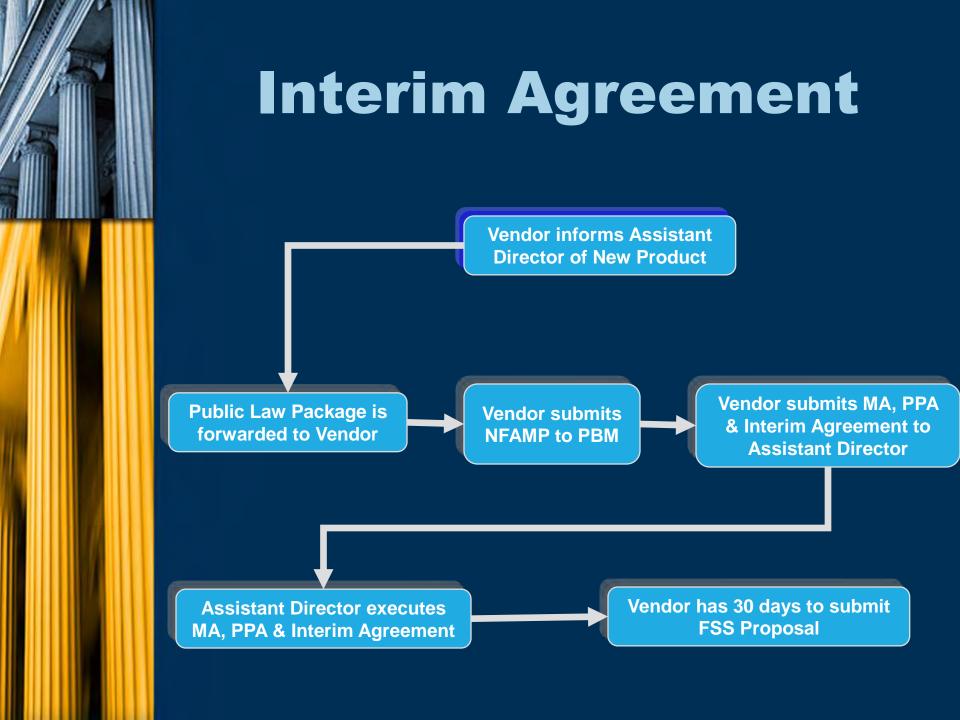
## **Contracting Process**

Presented by: Cheryl Ward-Roberts



## Interim Agreement

- Letter contract that is an interim agreement
  - Authority provided by FAR 16.603-2
  - Pursuant to Sect. 603 of Public Law 102-585
- Establishes a "binding commitment" when immediate performance is required
- Created to allow sufficient time to negotiate and award a new FSS contract





#### **FSS Solicitation**

◆ Federal Business Opportunities – All solicitations are announced and posted. Solicitation M5-Q50A-03-R1 can be viewed at the following website:

http://www.fedbizopps.gov

- ◆ Request for solicitation copy Can submit written request or download solicitation from the Federal Business Opportunities website.
- ◆ Open & Continuous solicitation Since there's no solicitation due date, proposals are submitted at vendor's convenience.



#### **FSS Solicitation Content**

- 1. Cover Page Notices
- 2. Checklist
- 3. Table of Contents
- 4. Standard Form 1449 Solicitation/Contract/Order for Commercial Items
- 5. Schedule of Items
- 6. Clauses
- 7. Commercial Sales Practices Format
- 8. Small Business Subcontracting Plan
- 9. Other Related Attachments



#### **FSS Four Phase Process**

(From offer submission to contract award)



Phase 1 – Review



Phase 2 – Evaluation



**Phase 3** – Negotiation



**Phase 4 – Contract Award** 



#### Phase 1 - Review

- Proposal is reviewed for missing information and clarifications.
- Missing information letter is generated by the contracting officer and sent to the offeror.
- ◆ Offeror is provided an opportunity to submit additional information.



#### Phase 2 - Evaluation

- Each proposal is evaluated based on the offeror's commercial sales practices (CSP) and not their competitors.
- Most Favored Customer pricing is identified based upon CSP disclosures. MFC is the customer or class of customer which receives the best discount and/or price arrangement on a given item from a supplier.
- Contracting officer identifies comparable commercial terms and conditions as they relate to Federal customer needs.
- Negotiation targets are established based on offeror's discounting policy, terms and conditions for all customers (federal and non-federal).



## Phase 3 - Negotiation

- Negotiation discussions are usually conducted via telephone conferences.
- ◆ Agreement is reached regarding the tracking customer, prices, and related terms and condition for the contract.
- ◆ Final Proposal Revisions (FPR) are submitted in writing at close of negotiations.



#### What are the negotiated terms?

- **♦** Tracking Customer
- Basic Discount
- Quantity Discount
- BPA Incentive Programs
- Delivery Terms
- Expedited Delivery

- Prompt Payment
- **♦ FOB Terms**
- ◆ Minimum Order
- Warranty Terms
- ♦ Return Goods Policy
- ◆ Annual Rebates
- Distribution Programs (PPV)



#### Phase 4 – Contract Award

- Determining Factors for contract award:
  - Did the Government achieve a fair and reasonable price?
  - Did offeror complete all certifications and regulatory requirements in their entirety?
  - Is past performance history satisfactory?
  - Is the offeror financially responsible or capable?
  - Is it in the overall best interest of the Government?



#### **Contract Award Actions**

- Award package is issued to schedule contractor identifying discounts, terms, and conditions of award.
- ◆ Vendor must prepare and maintain an "Authorized Federal Supply Schedule Pricelist" in accordance with the Contract Price List Clause.
- ◆ VANAC submits award information to PBM and to GSA for posting on the Schedules E-Library.



# PPV Issues IFF Changes

Presented by: Cheryl Ward-Roberts



#### **Prime Vendor Issues**

- ◆ Participation in PV
  - Obligation
  - Non-participants
    - Sell Direct

**♦ NDC Lock-outs** 

◆ NDC Changes



## **Industrial Funding Fee**

- ◆ IFF Changes
  - Reduced from 0.5% to 0.25%
  - **■** Effective January 1, 2007
- ◆ Reason for Change
  - OA&MM NAC is Supply-fund based and is required to charge fees to recover cost
  - Reduction in fee determined sufficient to cover operating cost



## **Industrial Funding Fee**

- ◆ Implementation
  - Updated clause 552.238-74 "IFF & Sales Reporting"
  - Instruction Letter Generics
  - Instruction Letter Covered Drugs
    - Information provided in Nov 1<sup>st</sup> NAC letter
    - Update IFF with End-of-the-Year PL Update



## **Industrial Funding Fee**

- ◆ The formula used to back out the 0.5% fee and add in the 0.25%:
  - Step 1: Current FSS contract price x (1-0.005) = XX Figure (Contract price without .5% IFF).
  - Step 2: XX Figure / (1-0.0025) = New adjusted FSS contract price (with .25% IFF).



## **Modification Process**

Presented by: Bob Satterfield



#### **Modification Process**

- New Request for Mod Form
  - Oct 2006
  - Oct 2006 v 2.0
- Electronic Submission of CSP Data is encouraged (Excel format)
- Product Addition
  - Single Price
  - Dual Price
  - Drug Transfers
  - Price Changes



#### **Modification Process**

◆ Price Changes

#### Reductions

- Voluntary
- Revised Price List
- Grant More Favorable Terms than in Price List
- Tracking Customer Violation
- Public Law
- Price Changes



#### **Modification Process**

- ◆ Price Changes
  - Increases
    - EPA
    - Public Law
  - Public Law
  - Deletions
  - Administrative Changes



## Implementation of Dual Prices

Presented by: Bob Satterfield



#### **Dual Prices**

- ◆ Use Mod Form → Product Addition
  - **■** Complete pages 1-3
  - Confirm Mfg, Proposed TC, CSP Disclosure
- ◆ Single/Dual Price Election Form
- Goal is same; receive pricing equal to/better than MFC
- Negotiated Pricing
- Tracking Customer Ratio is Math based



#### **Dual Prices**

- Dual Price will not be awarded unless Govt can determine price is fair & reasonable
- ◆ Dual Price typically not negotiated if FCP is Provisional or Temporary since CSP data is not available.
- ◆ Dual Price is not established under Interim Agreements.





## Methodology Changes

Presented by:

Mark Myers, CPA
Office of Inspector General
Office of Contract Review



## **Methodology Changes**

- Any methodology changes should be filed by Nov 1.
- Methodology changes must be approved in advance and the old non-FAMP period must be recalculated to reflect the change in methodology.
  - Decision to exclude returns
  - Decision to smooth/not smooth chargebacks



### FCP Appeals

- ◆ Do immediately.
- Appeals fall into to 2 basic categories:
  - Requests for relief
  - Requests for relief generally occur because of some anomalies in the calculation.
  - Formal FCP appeal
  - FCP appeals generally occur because the calculated FCP is proper but would cause the manufacturer to sell at a loss.



## FCP Appeals

- **◆** Communicate anomaly to 025NAC.
- ◆ FCP Committee will consider what relief, if any, can be granted.
- ◆ FCP formal appeals must follow the guidance in the Dear Manufacturer letter dated February 24, 1993 and be accompanied by the required certification.



#### **Communication of Errors**

- ◆ Any errors that were detected during the calculation of your annual non-FAMPs, especially those that require restating the old non-FAMP period, need to be communicated to VA.
- ◆ The following slides detail the process to correct any errors detected.



#### **Communication of Errors**

- ◆ Communication between the parties is key.
- ◆ Barriers to effective communication include not having access to the parties who are conducting the analysis.
- ◆ VAOIG will insure that the key VA parties are apprised of the status of the disclosure.



#### **Basic Process**

- ◆ Once a manufacturer determines that an error has occurred affecting the Federal Ceiling Price (FCP), the following initial steps should be taken:
  - Determine the cause of the error.
  - Make necessary changes to the reporting system to rectify the error.
  - Determine the scope of the error.
  - Disclose the error.



#### **Disclose the Error**

- Inform your contracting officer with copies to General Counsel, PBM and OIG.
- ◆ Include in your notification a description of the error and the expected time line for completion of internal analysis and submission to VA for review.



## Steps in the Process

◆ The methodology used to recompute your non-FAMPs must be approved by VA in order to prevent unnecessary work by the manufacturer in the event that the methodology is not approved.



## Steps in the Process

- Data required include:
  - a full explanation of the error(s).
  - steps taken to ensure that the error(s) has been corrected.
  - measures taken to ensure that the error does not occur in the future.
  - All data supporting the recalculated non-FAMPs along with the data supporting the originally filed non-FAMPs.



### Steps in the Process

- ◆ Once the methodology is approved, recalculation of non-FAMPs and FCPs can commence.
- ◆ If the error spanned more than one year and affects the current year pricing, the focus should be on first correcting the current year on a provisional basis.
- Any recalculation must go back to the old non-FAMP period in order to calculate the FCP using a consistent methodology across the periods.



#### Recalculations

◆ VAOIG will review the new calculations to include the underlying data as compared to the originally filed non-FAMPs and their underlying data.



#### Steps in the Process

Corrected non-FAMPs and FCPs for the current year need to be submitted to both Pharmacy Benefits Management (PBM) and your contracting officer. These FCPs should reflect a good estimation of what the final calculated prices will be. This submission will be considered provisional pending full recalculation.



#### Recalculations

- ◆ All years affected by the error must be recalculated.
- ◆ Remember the first years (of a multi-year contract) are 1993, 1996, 1998 and 2004.



#### Recalculations

◆ If the manufacturer is a single pricer, each year of recalculation affects the second and subsequent year of a multi-year contract. This means that an error that affects more than one year will be dependent upon the prior year.



- ◆ Determine amounts due for periods prior to the disclosure by figuring all actual charges in excess of the recalculated FCPs (no offsets).
- ◆ Calculation of overcharges should be performed after the modification to the FSS contract implements the corrected FCPs so that the overcharge calculation can take into account all of the relevant sales transactions.



- Overcharges are only calculated on sales to the Big 4 agencies, regardless of whether you are a single or dual-pricer.
- Manufacturers should identify purchases by DoD separately from the other Big 4 agencies.



- ♦ When calculating final amounts due, the period that the current "provisional" prices were in effect (a period less than one calendar year) is handled differently than the period prior to disclosure.
- ◆ If the final recalculations result in slightly different FCPs, offsets are allowed against the provisionally corrected prices.



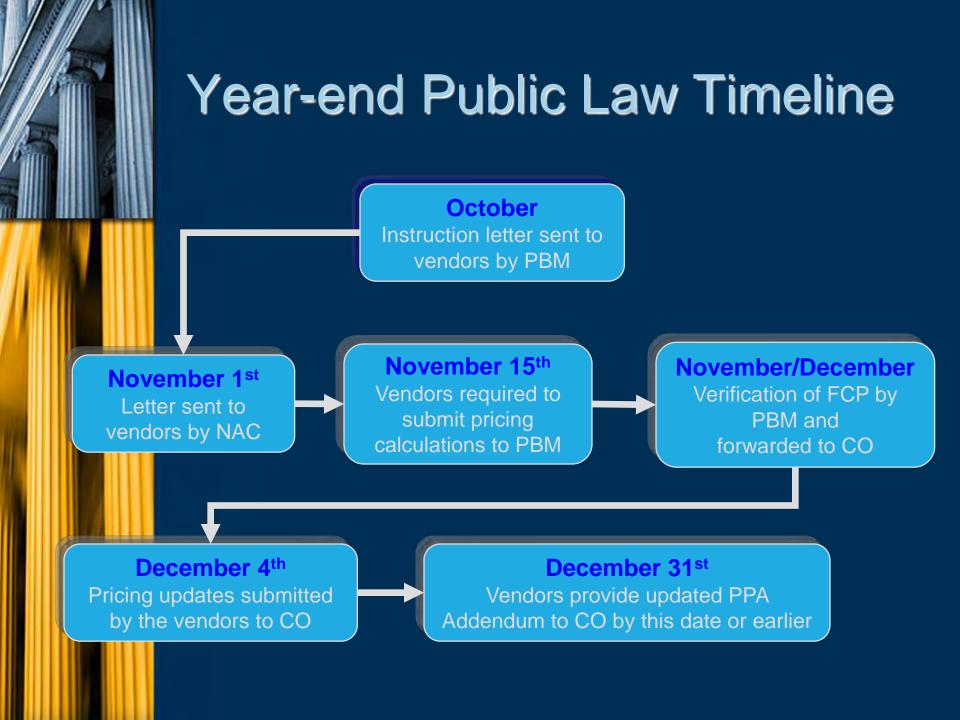
This means that if the final recalculated FCPs are both higher and lower than the provisional prices filed when the error initially was disclosed and corrected on a provisional basis, differences can be netted to determine amounts due, if any.

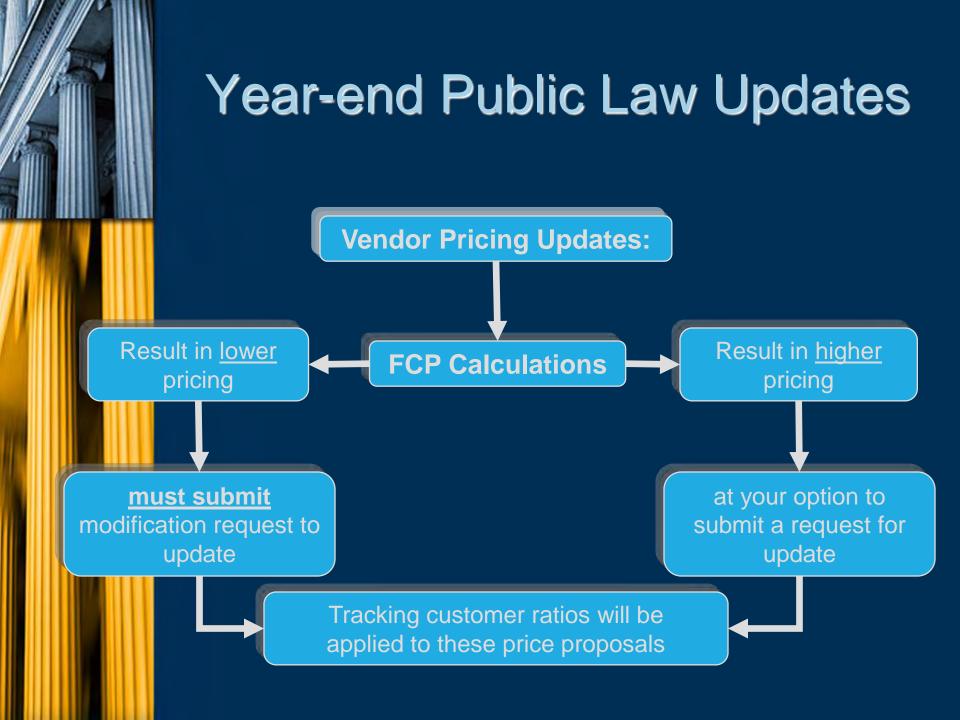


# **End of the Year Update**

Presented by: Cheryl Ward-Roberts

**Bob Satterfield** 







#### Year-end Public Law Updates

- ♦ Need to meet established deadlines to ensure January 1<sup>st</sup> effective date
  - Due dates outlined in October letter
  - Reiterated in November 1<sup>st</sup> letter
- Update FSS pricelist to incorporate pricing updates



#### **Workload Analysis**

- ◆ Taking a look at the numbers
  - Average Modifications Actions Processed: 250 per month
  - Modifications Actions Processed during PL: 730
  - PL line items reviewed: 8,510 in December 2005



#### **Dissemination of Data**

**CO sends updated FSS pricing to PBM** 

PBM updates their database and provides updates to PV electronically

PV updates their database



#### **Disclaimer:**

Please note the pricing scenarios are meant to provide an illustration of the review process used by the contracting officer in determining if the price offered is compliant with Public Law and Price Reduction Clause. The numbers used are based on actual proposals reviewed by VA. The numbers have been changed to protect the innocent. The CPI-U (Consumer Price Index-Urban) used is 2.06% from 2007.



#### **◆ CO Reviews:**

- FCP Compliance
  - (Ensure the Proposed price does not exceed FCP)
- Max "K" FSS (TC x TC Ratio)
  - (Ensure the Proposed price is compliant the with tracking customer ratio (TC) pursuant to the Price Reduction (PRP) clause of the FSS Contract. Proposed price cannot exceed PRP)
- Max CPI-U Cap (Current FSS x CPI-U)
  - (Ensure the Dual price proposed does not exceed the Maximum allowable price which is capped by the change in the Consumer Price Index Urban (CPI-U)



- ◆ The MATH
  - Max "K" FSS = TC Price X TC Ratio
    - (This is the maximum allowable price pursuant to the Price Reduction Clause of the FSS contract)
  - TC Ratio = Govt Price/TC Prices (Round to 2 decimals)
  - Max CPI-U = Current FSS Price X CPI-U

#### Legend:

"K" = Contract; TC = Tracking Customer; CPI-U = Consumer Price Index – Urban PRC = Price Reduction Clause



**◆FCP Increases**Single Price



## FCP Price Increase – Single Price

◆ Current FSS Price: \$93.41

◆ Proposed FSS Price: \$106.00

◆ Tracking Customer Price: \$106.00

**♦** TC Ratio: 1.00

◆ FCP: \$110.97

♦ What is the Max K FSS? (TC Price X TC Ratio)

**\$106.00**, based on PRC

♦ Is the proposed price acceptable?

Yes, proposed price is less than FCP and compliant with PRC



## FCP Price Increase – Single Price

◆ Current FSS Price: \$11.66

◆ Proposed FSS Price: \$17.27

**◆** Tracking Customer Price: \$22.75

**♦** TC Ratio: 1.00

**♦** FCP: \$17.27

◆ What is the Max K FSS? (TC Price X TC Ratio)

**\$22.75**, based on PRC

Is the proposed price acceptable?

Yes, proposed price is equal to FCP and compliant with PRC



FCP Decreases
Single Price



# FCP Price Decrease – Single Price

◆ Current FSS Price: \$29.76

◆ Proposed FSS Price: \$28.33

◆ Tracking Customer Price: \$39.12

**♦** TC Ratio: 1.00

**♦** FCP: \$28.33

♦ What is the Max K FSS? (TC Price X TC Ratio)

**\$39.12**, based on PRC

♦ Is the proposed price acceptable?

Yes, proposed price equals FCP and is compliant with PRC



## FCP Price Decrease – Single Price

◆ Current FSS Price: \$205.65

◆ Proposed FSS Price: \$196.57

**◆ Tracking Customer Price:** \$329.32

**♦** TC Ratio: 1.00

◆ FCP: \$196.57

♦ What is the Max K FSS? (TC Price X TC Ratio)

**\$329.32**, based on PRC

◆ Is the proposed price acceptable?

Yes, price equals FCP and is compliant with PRC



Dual Price



## Big 4 Price Changes (Company A)

♦ Current Big 4 Price: \$269.34

◆ Proposed Big 4 Price: \$289.34

♦ Tracking Customer Price: \$315.84

**◆ TC Ratio:** 1.00

◆ CPI-U 2.06%

**♦** FCP: \$289.34

- ♦ What is the Max K FSS? (TC Price X TC Ratio)
  \$315.84, based on PRC
- ◆ Is the proposed price acceptable?
  Offer is compliant with FCP; need to review the Dual price before accepting



## Dual Price Changes (Company A)

**♦** Current Dual Price: \$275.93

◆ Proposed Dual Price: \$289.34

**♦** Tracking Customer Price: \$315.84

♦ TC Ratio: .99

◆ CPI-U 2.06%

**♦** FCP: \$289.34

- ♦ What is the Max K FSS? (TC Price X TC Ratio) \$312.68
- ♦ What is the Max CPI-U? (Current FSS Price X CPI-U) \$281.61
- Is the proposed price acceptable?
  No, proposed price exceeds Max CPI-U
- ♦ Is Big 4 > Dual?
  Yes, therefore single price to all = \$281.61



## Big 4 Price Changes (Company B)

◆ Current Big 4 Price: \$60.64

◆ Proposed Big 4 Price: \$68.68

**♦** Tracking Customer Price: \$69.73

**◆ TC Ratio:** 1.00

◆ CPI-U 2.06%

**♦ FCP:** \$56.39

- ♦ What is the Max K FSS? (TC Price X TC Ratio) \$69.73, based on PRC
- ♦ Is the proposed price acceptable?
  No, proposed price exceeds exceeds FCP;
  price needs to be lowered to FCP



## Dual Price Changes (Company B)

**♦** Current Dual Price: \$84.73

◆ Proposed Dual Price: \$72.68

**♦** Tracking Customer Price: \$69.73

**◆ TC Ratio:** 1.00

◆ CPI-U 2.06%

**♦** FCP: \$56.39

♦ What is the Max K FSS? (TC Price X TC Ratio)

\$69.73

♦ What is the Max CPI-U? (Current FSS Price X CPI-U) \$86.48

♦ Is the proposed price acceptable? No, proposed price exceeds Max K FSS pursuant to PRC; price needs to be lowered to \$69.73

♦ Is Big 4 > Dual?
No



## Big 4 Price Changes (Company C)

♦ Current Big 4 Price: \$97.71

Proposed Big 4 Price: \$95.06

**♦ Tracking Customer Price:** \$100.56

◆ TC Ratio: .95

◆ CPI-U 2.06%

◆ FCP: \$95.06

- ♦ What is the Max K FSS? (TC Price X TC Ratio)
  \$95.53, based on PRC
- ◆ Is the proposed price acceptable? Yes, proposed price is equal to FCP and less than Max K FSS pursuant to PRC



## Dual Price Changes (Company C)

◆ Current Dual Price: \$97.71

◆ Proposed Dual Price: \$99.50

**♦** Tracking Customer Price: \$100.56

♦ TC Ratio: .95

◆ CPI-U 2.06%

♦ FCP: \$95.06

♦ What is the Max K FSS? (TC Price X TC Ratio) \$95.53

- ♦ What is the Max CPI-U? (Current FSS Price X CPI-U) \$99.72
- ♦ Is the proposed price acceptable? No, proposed price exceeds Max K FSS pursuant to PRC; price needs to be lowered to \$95.53
- Is Big 4 > Dual?
  No



## Big 4 Price Changes (Company D)

◆ Current Big 4 Price: \$521.78

◆ Proposed Big 4 Price: \$550.68

♦ Tracking Customer Price: \$550.68

**◆** TC Ratio: 1.00

◆ CPI-U 2.06%

♦ FCP: \$557.38

- ♦ What is the Max K FSS? (TC Price X TC Ratio) \$550.68, based on PRC
- ◆ Is the proposed price acceptable? Proposed price is compliant with Max K FSS and FCP, appears acceptable. Check Dual



## Dual Price Changes (Company D)

**♦** Current Dual Price: \$567.77

◆ Proposed Dual Price: \$568.09

**♦** Tracking Customer Price: \$550.68

♦ TC Ratio: .98

◆ CPI-U 2.06%

◆ FCP: \$557.38

♦ What is the Max K FSS? (TC Price X TC Ratio) \$539.67

♦ What is the Max CPI-U? (Current FSS Price X CPI-U) \$579.47

♦ Is the proposed price acceptable?
No, proposed price exceeds Max K FSS pursuant to PRC

♦ Is Big 4 > Dual?Yes, therefore single price to all = \$539.67



## Big 4 Price Changes (Company E)

◆ Current Big 4 Price: \$147.21

◆ Proposed Big 4 Price: \$134.03

◆ Tracking Customer Price: \$167.01

**◆ TC Ratio:** 1.00

◆ CPI-U 2.06%

◆ FCP: \$134.03

- ♦ What is the Max K FSS? (TC Price X TC Ratio) \$167.01, based on PRC
- ◆ Is the proposed price acceptable? Yes, proposed price equals FCP and is less that Max K FSS pursuant to PRC



## Dual Price Changes (Company E)

◆ Current Dual Price: \$160.72

◆ Proposed Dual Price: \$153.65

◆ Tracking Customer Price: \$167.01

♦ TC Ratio: .90

◆ CPI-U 2.06%

♦ FCP: \$134.03

♦ What is the Max K FSS? (TC Price X TC Ratio)

\$150.31

♦ What is the Max CPI-U? (Current FSS Price X CPI-U) \$164.03

♦ Is the proposed price acceptable? No, proposed price exceeds Max K FSS; price needs to be lowered to \$150.31

Is Big 4 > Dual?
No



#### **Points of Contact**

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## QUESTIONS & ANSWERS



#### THANK YOU!