



**Department of Veterans Affairs  
Veterans Health Administration  
Pharmacy Benefits Management Services  
1<sup>st</sup> Ave – 1 Blk N of Cermak Rd  
Bldg 37 Rm 139  
Hines, IL 60141**

October 16, 2012

578/119D

Dear Manufacturer:

**Introduction:**

The Office of Pharmacy Benefits Management Services (PBM) is responsible for maintaining calculated federal ceiling prices (FCPs) for covered drugs through the Public Law annual reporting process. All manufacturers of covered drugs are obligated to comply with the reporting requirements under Public Law 102-585.

**Background:**

Public Law 102-585 is the Veterans Healthcare Act of 1992, and it became law on November 4, 1992. Section 603 of Public Law 102-585 (38 U.S.C. 8126) (Public Law) and the provisions of each manufacturer's Master Agreement (MA) require manufacturers to report annual non-Federal Average Manufacturer's Price (non-FAMP) calculations for covered drugs. Information about Public Law is available on the Office of Acquisition and Logistics—Federal Supply Schedule Service (FSS) website at: <http://www.va.gov/oal/business/fss/publiclaw.asp>.

**Purpose:**

Provide manufacturers with an advance timeline and instructions on how to complete the 2012 annual non-FAMP reporting requirements mandated by Public Law.

**System Requirements:**

- Microsoft Excel (.xls)

**Timeline:**

- **By October 19, 2012**—Manufacturers' designated non-FAMP representative will receive an e-mail from the PBM Public Law Manager ([nonfamp@va.gov](mailto:nonfamp@va.gov)). This e-mail will have an Excel workbook (.xls) of covered items as an attachment. The Excel workbook (.xls) will be used by manufacturers to complete the 2012 annual non-FAMP reporting requirements. Attachment A is a data dictionary of the Excel workbook. Should there be an omitted item, manufacturers are to immediately notify PBM via e-mail and follow the guidance on Attachment B for submitting non-FAMP data for any omitted item(s). Manufacturers must report all covered drug items for the purpose of determining Federal Ceiling Price (FCP) calculations.
- **By October 22, 2012**—Manufacturers must report and describe modifications in existing methodology used to calculate non-FAMP to PBM, the VA Office of General Counsel (OGC), and the VA Office of Inspector General (OIG). Attachment C provides instructions on how manufacturers may report these modifications via e-mail.

- **By October 26, 2012**—Manufacturers must report any disputes of a covered drug's FSS price that was in effect or awarded on September 30, 2012, as well as any dispute of the calculated non-FAMP for July 1, 2011 to September 30, 2011 that was provided on the Excel workbook (.xls) by the PBM Public Law Manager. Attachments D & E provide instructions on how to submit disputes to the appropriate department office via e-mail.
- **By November 15, 2012**—Manufacturers must report the annual non-FAMP (10-1-2011 through 09-30-2012) and Quarter 3, Calendar Year 2012 non-FAMP (07-01-2012 through 09-30-2012) calculations to the PBM on the Excel workbook (.xls) for covered items provided by the PBM Public Law Manager. Attachment F has a list of compliance reminders.
- **By November 16, 2012**—The PBM Public Law Manager will start to calculate the covered items' changes in non-FAMP, additional discounts (if any), and the 2013 FCP for manufacturers. Once the calculations are completed, the Excel workbook (.xls) containing these values will be sent by e-mail to the manufacturers' designated non-FAMP representative. Manufacturers have **two business days** to dispute or resubmit calculations related to the 2013 FCPs to PBM, OGC, and OIG. Attachment G provides information on the calculations and instructions on how to submit disputes by e-mail.
- **By December 3, 2012**—The manufacturer's authorized official, who signed the company's PPA addendum for 2012 FCPs (or an authorized successor), must prepare and sign a new PPA addendum, listing each covered drug and its 2013 FCP. To incorporate updated pricing into your FSS contract, you must submit a properly prepared request for modification (RFM) to VA National Acquisition Center (NAC) FSS Service via e-mail to [VAFSSMODS@va.gov](mailto:VAFSSMODS@va.gov). The properly prepared RFM must be received by December 5, 2012 to guarantee an effective date of January 1, 2013. The PPA addendum should be submitted along with the RFM and a hardcopy may be mailed to: VA National Acquisition Center (003A4B), Building 37, First Avenue, 1 block North of Cermak Rd., PO Box 76, Hines, Illinois, 60141. NAC will be issuing additional guidance on submitting the RFM no later than November 4, 2012.

### **General Guidance:**

Each covered drug's mandated FCP for 2013 (the fifth year of FSS multiyear contracts for statutory purposes) will be determined by adopting the lower of two calculation results. These two calculations are described in (1) 38 U.S.C 8126 (d) (1) and (2) 38 U.S.C. 8126 (d) (2), (a) (2) & (c). The same percent change in Consumer Price Index-Urban (CPI-U) will be utilized in performing both calculations. This change in CPI-U is identified as the percent change from September 2011 to September 2012. **The U.S. Bureau of Labor Statistics shows the percent change to be 1.99%, which will be used as the CPI-U figure for the FCP calculations in November, 2012.**

The one-half of one percent (0.5%) industrial funding fee (IFF) being incorporated into FSS contracts will not be included in calculations of non-FAMP or reporting of FCP, but will be included in the FSS/Big 4 selling price, if warranted. Please see additional instructions from your respective contracting officer(s).

The Section 8126 (d) (1) calculation will begin with the **permanent FSS contract price of a covered drug in effect on September 30, 2012**. For those manufacturers that elected dual FSS pricing, **the FSS contract price is the September 30, 2012 price charged to other government agencies** and other authorized Schedule users; **not** the price paid by the Department of Veterans Affairs (VA), Department of Defense (DoD), Public Health Service (PHS)/Indian Health Service & Coast Guard. The appropriate FSS price will then be increased

by the above percent change in CPI-U to arrive at the 2013 FSS price cap. This cap applies to all “other users” FSS prices in 2013.

The Section 8126 (a) (2) & (c) calculation will begin with the 2012 annual non-FAMP computation; it will continue by multiplying that number by 0.76 and then subtracting any additional discount calculated based on any difference between “old” and “new” non-FAMPs. **The lower of the above calculation and the 2013 FSS price cap will become the 2013 FCP.** If there are “no sales” in a benchmark third quarter of a year that is used to derive the new non-FAMP or old non-FAMP, there can be no additional discount calculation for that particular item. In those cases, negative non-FAMPs should be reported and the additional discount will be entered as zero (0.00). If a covered drug had no reportable sales in fiscal year 2012, its calculated 2013 FCP will be the lower of: (A) the 2012 FCP increased by an amount equal to the 2012 FCP multiplied by the percent change to the CPI-U (as explained and provided above) OR (B) the FSS price in effect on September 30, 2012 increased by an amount equal to the September 30, 2012 FSS price multiplied by the percent change to the CPI-U.

If they meet the other VA criteria, nominal prices excludable from non-FAMP’s for 2012 calculations must be prices that are less than 10 percent of that particular items non-FAMP during the third quarter of 2011 (7/1/2011 through 9/30/2011). Where sales to end-users are required for calculation of non-FAMP due to the absence of wholesale sales, you need not include purchases by PHS grantees or disproportionate share hospitals (“covered entities”) if the prices for those transactions were determined by PHS pursuant to Sect. 602 of the Veterans Health Care Act of 1992. Also, in figuring wholesale sales, you need not include the chargebacks required to satisfy end-user purchases by the entities at prices determined by PHS under Sect. 602, or at prices set in negotiations with the PHS Section 602 pharmaceutical prime vendor (PPV) and any subcontractors. However, sales to these entities at prices not negotiated by the Sect. 602 PPV and lower than Sect. 602 statutorily calculated prices must be included in non-FAMP calculations. Finally, sales of specific inpatient covered drugs to disproportionate share hospitals at Sect. 602 prices may be excluded from non-FAMP if you have properly obtained a “hold harmless letter” from VA (see July 8, 2004 Dear Manufacturer Letter).

**VA must require that all wholesale sales (or direct sales where those are the proper beginning point) used for 2012 annual and 3<sup>rd</sup> quarter 2012 non-FAMP reports (to be filed this November) be reduced by amounts reflecting certain TRICARE Retail Network usage data posted or transmitted by DoD during the FY 2012 12-month reporting period, because the TRICARE usage constitutes sales to the Federal Government.**

**Manufacturers will use DoD’s payment-due dates to decide which TRRx usage may be ascribed to the relevant reporting periods (See further guidance in Attachment F). Covered drug scripts filled for TRICARE beneficiaries through the TRRx/T-Pharm Network should be treated by manufacturers as sales to the Federal Government, for non-FAMP reporting purpose, beginning on the payment-due date transmitted by DoD to the manufacturer in the File containing the manufacturer’s quarterly DoD usage data and refund invoice.**

After PBM receives your non-FAMP data, we will calculate your {Change in non-FAMP}, {Additional Discount}, and {2013 Federal Ceiling Price}. PBM will send you an Excel workbook (.xls) via e-mail of your company’s calculated 2013 FCPs after the non-FAMP data has been calculated. **If we do not hear from your company within two workdays after we send the e-mail, we will assume that you agree with VA’s calculations of the FCPs. If you submit any corrected annual non-FAMP reports, they will be accepted on a provisional basis but will be subject to review by the OIG.**

The quarterly non-FAMP report for the third quarter of 2012 consists of the same data as the “new non-FAMP” (7/1/2012 to 9/30/2012) reported on the 2012 annual calculation form, which is due by **November 15, 2012**. Consequently, it will not be necessary to submit the non-FAMP third quarter 2012 report separately. However, manufacturers that do not meet the November 15, 2012 annual reporting deadline will be subject to penalties for late data reporting as described in the MA, paragraph (IV) (B). **Please note that 38 U.S.C. 8126 (e) (2) and Sect. 1927 (b) (3) of the Social Security Act (reflected in the MA) impose a civil money penalty on late reporting manufacturers in the amount of \$10,000.00 for each day in which required information has not been provided. VA asks that you submit the required annual data as soon as possible after the CPI-U change is posted in October and you receive this e-mail.**

Section 8126 (e) of the Law states that quarterly non-FAMP reports are due 30 days after the end of the quarter. These figures should be as accurate as possible, since they serve as an indicator of pricing trends and will be used during OIG audits. Nevertheless, to assist manufacturers in providing the most accurate quarterly non-FAMP calculations possible, PBM will not seek imposition of late penalties for unreported data until 45 days after the end of each quarter. **The same 45 day forbearance applies to filing Temporary and Permanent New Drug non-FAMPs.** Again, please note that each year the non-FAMP third quarter data is submitted as part of the Annual Report (which is due 45 days after the end of the third quarter).

If you have any questions about any of the above information, please call Ted Karnezis or John Weisman, at (708) 786-4387 or (708) 786-7878, respectively.

Sincerely,

//s// Vincent S. Calabrese

Vincent S. Calabrese, Pharm.D.  
Associate Chief Consultant  
Pharmacy Benefits Management  
Services VACO Pharmacy Service

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## Attachment A

### Public Law Microsoft Excel Workbook Data Definitions

**NOTE: In the 2010 Dear Manufacturer Letter this was equivalent to the Structure for database (NFAMP2011.DBF)**

Field Name	Definition	Old Name	Edits Allowed
ID	Unique integer assigned to item in PBM non-FAMP database	N/A	No
YearID	Effective calendar year that FCPs are on file	N/A	No
Prep_date	Date the report is prepared by manufacturer. Format = "mm/dd/yyyy" NOTE: Date entered must be greater than 10/01/2012	SAME	Yes
Ndc_1	Labeler code	SAME	No
Ndc_2	Product code	SAME	No
Ndc_3	Package code	SAME	No
Unt_pkg	Number of units per package	SAME	No
Date_enter	Date the NDC was reported as first commercially available for sale	SAME	No
Dose_form	Dosage form of the NDC	SAME	No
Strength	NDC strength	SAME	No
FDA_name	NDC name reported by manufacturer as exists on FDA registration form	SAME	No
Trade_name	NDC brand name reported by manufacturer	SAME	No
Generic_name	NDC generic name	Generic	No
Pct_cpiu	Percent Increase in Consumer Price Index (CPI-U). Calculated by multiplying the difference between the two index numbers by 100 and that product divided by the older of the two CPI-U's. Calculation is rounded to two decimal places; rounding up if 2 <sup>nd</sup> decimal is >=5	SAME	No
Fss	2012 Federal Supply Schedule (FSS) price and is the permanent contract price in effect or awarded on September 30, 2012 for single price companies. For dual FSS pricing companies, the 2012 FSS price is September 30, 2012 awarded permanent contract price charged to other government agencies and authorized FSS users other than the Department of Veterans Affairs (VA), Department of Defense (DoD), or Public Health Service (PHS). NOTE: The FSS price in this field DOES NOT include the Industrial Funding Fee (IFF) for companies that embed this fee.	FSS(XX) where XX=2 digit year (eg FSS10 was 2010 FSS price)	No
Fssmax	2013 Maximum Price per = 2012 FSS + Allowable CPI-U increase	FSS (XX)MAX where XX=2 digit year	No

Field Name	Definition	Old Name	Edits Allowed
Nfamp	2011 Annual non-FAMP is the weighted average manufacturers' sales price for the NDC. Total non-Federal dollar sales as described by paragraphs I., J., N., O., and II.B.5. of the Master Agreement for the time frame 10/1/2011 thru 9/30/2012 divided by the total unit volume of sales for the NDC, excluding nominal priced sales and returned goods if records are available for verification. Dollar sales must reflect rebates, cash discounts, charge backs or other similar price reductions. <b>Calculation is rounded to two decimal places</b> ; rounding up if 2 <sup>nd</sup> decimal is >=5. If no reportable sales, enter "0.00". <b>Do not return spreadsheet with blank values.</b>	NFAMP_XX) where XX=2 digit year	Yes
Nfamp_old	Non-Federal Average Manufacturer's Price for 7/1/2011 thru 9/30/2011. See NFAMP field for calculation and reporting requirements.	SAME	No
Nfamp_new	Non-Federal Average Manufacturer's Price for 7/1/2012 thru 9/30/2012. See NFAMP field for calculation and reporting requirements. NOTE: Do not leave this field blank. If no reportable sales, enter "0.00"; This number can be negative.	SAME	Yes
Nfamp_chg	Difference between NFAMP_NEW and the NFAMP_OLD. This number can be negative. NOTE: This field is not included until the PBM sends workbook back to the manufacturers with the calculations.	SAME	No
Add_disc	Difference between NFAMP_CHG and the legislative allowable increase. The allowable increase is the product of the NFAMP_OLD and PCT_CPIU. This number must be >= \$0.00. If NFAMP_CHG is negative, then \$0.00 will be entered. NOTE: This field is not included until the PBM sends workbook back to the manufacturers with the calculations.	SAME	No
Calcmax	2013 Calculated Ceiling. Calculation based on 38 U.S.C.8126 (d)(2),(a)(2) and (c) is the product of the NFAMP and 0.76, less ADD_DISC. Calculation is rounded to two decimal places; rounding up if 2 <sup>nd</sup> decimal is >=5. NOTE: This field is not included until the PBM sends workbook back to the manufacturers with the calculations.	CALCMAX(XX) where XX=2 digit year	No
FCP	2013 Federal Ceiling Price. Lower of 38 U.S.C. 8126(d)(1) or 38 U.S.C. 8126 (d)(2) , (a)(2) & (c). This field is determined by using the lower number of FSSMax or CalcMax. NOTE: This field is not included until the PBM sends workbook back to the manufacturers with the calculations.	FCP_(XXXX) where XXXX=4 digit year	No
Disc_Date	This field represents a covered item's discontinuation date from the manufacturer's FSS. NOTE: This field is not included until the PBM sends workbook back to the manufacturers with the calculations.	N/A	No

<b>Field Name</b>	<b>Definition</b>	<b>Old Name</b>	<b>Edits Allowed</b>
non_TAA	This field indicates covered item(s) which have been removed from your FSS contract due to its non-U.S., non-designated-country source and the requirements of the Trade Agreements Act (TAA). As they are considered covered drugs as defined by the Veteran's Health Care Act of 1992, P.L. 102-585, Sect. 603., your company must continue to report non-FAMP to PBM for any covered drug and maintain a Federal Ceiling Price (FCP) for the drug annually with PBM. NOTE: This field is not included until the PBM sends workbook back to the manufacturers with the calculations.	N/A	No
Cnt_no	FSS contract number assigned by the national Acquisition Center (NAC) as of 9/30/2012	SAME	No
Company_of	Name of the manufacturer's official authorizing and certifying that the data provided in this workbook is correct	SAME	Yes
Dispute_fss	Enter a "Y" to dispute the FSS price. Follow the directions outlined in Attachment D.	N/A	Yes
Dispute_nfam p_old	Enter a "Y" to dispute the 3Q old non-FAMP data. Follow the directions outlined in Attachment E.	N/A	Yes



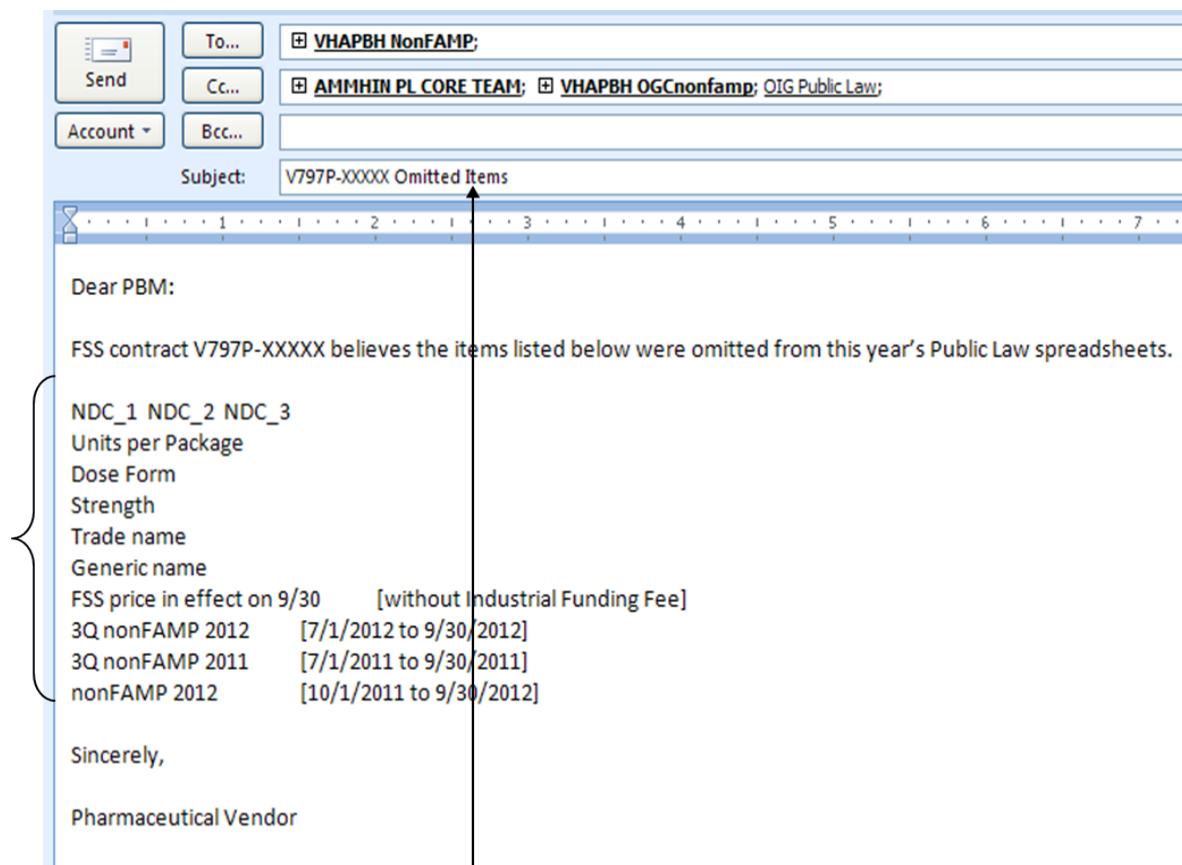
## Attachment B

### Instructions: How to Submit Calculated non-FAMP for Omitted Contract Items that were in a Permanent FCP status prior to September 30, 2012

**Purpose:** For the manufacturer to inform PBM of a covered item that was omitted from the Excel workbook provided by the Public Law Manager. Attachment B is intended for reporting items that have already achieved a permanent status. For new items that are still going through the various stages and not subject to the annual reporting process, (ie, provisional and temporary filings) or products that establish a permanent FCP after 9/30/2012 please submit the non-FAMP reports under separate e-mail.

1. Identify the number of covered items omitted from the Excel workbook.
2. In the body of the e-mail, provide the data for the following fields:
  - NDC
  - UNITS per PACKAGE, DOSE FORM, STRENGTH, TRADE,GENERIC NAME
  - FSS PRICE in effect on September 30<sup>th</sup>
  - 3Q Calendar Year 2012 non-FAMP sales (7/1/2012 to 9/30/2012)
  - 3Q Calendar Year 2011 non-FAMP sales (7/1/2011 to 9/30/2011),if applicable
  - 2012 non-FAMP sales (10/1/2011 to 9/30/2012)
3. Send e-mail to [nonfamp@va.gov](mailto:nonfamp@va.gov).
4. Carbon Copy (CC) [AMMHINPLCORETEAM@VA.GOV](mailto:AMMHINPLCORETEAM@VA.GOV) , [OGCNONFAMP@VA.GOV](mailto:OGCNONFAMP@VA.GOV) and [OIGPUBLICLAW@VA.GOV](mailto:OIGPUBLICLAW@VA.GOV) .
5. The omitted item(s) will be verified by the appropriate departments and be included on the final 2013 FCP calculation spreadsheets.

Example:



Note the subject matter and e-mail groups

## Attachment C

### Instructions: How to Report Modifications in Existing Methodology Used to Calculate non-FAMP

**Purpose:** For the manufacturer to notify OIG/OGC of a change in their methodology used to calculate non-FAMP data for the 2012 annual reporting year. **NOTE: This format is only for non-FAMP methodology changes that are reported in advance of the due date (October 22<sup>nd</sup>, 2012).**

1. Prepare a letter requesting approval for a change in calculation methodology.
2. Specify the reasons for the change in methodology and provide all supporting documentation.
3. Send e-mail to [OGCNONFAMP@VA.GOV](mailto:OGCNONFAMP@VA.GOV) and to [OIGPUBLICLAW@VA.GOV](mailto:OIGPUBLICLAW@VA.GOV)
4. CC the Public Law Manager at [nonfamp@va.gov](mailto:nonfamp@va.gov).
5. Subject should include the full FSS contract number, manufacturer's name, and the words: "METHODOLOGY CHANGE"

Example:

Send

To... [VHAPBH OGCnonfamp; OIG Public Law;](#)

Cc... [VHAPBH NonFAMP;](#)

Account ▾ Bcc...

Subject: V797P-XXXXX Methodology Change

Attached:

Dear OGC/OIG:

FSS contract V797P-XXXXX is requesting approval in the methodology used to calculate nonFAMP data for this year's Public law.

Attached are the supporting document(s) for the change in methodology.

Sincerely,

Pharmaceutical Vendor

Note the format for the subject line and the body of the e-mail

## Attachment D

**Instructions: How to Submit a Dispute in regards to Federal Supply Schedule (FSS) price that was in effect or awarded on September 30, 2012**

**Purpose:** Provides the manufacturer a way to dispute the reported FSS price in effect on September 30<sup>th</sup>, 2012 (Dispute\_FSS) on the Excel workbook received from the Public Law Manager).

1. Identify all covered items that potentially have a disputed FSS price.
2. Mark column W (Dispute\_FSS) with a "Y" in the Excel workbook received from the Public Law Manager. *NOTE: It is important to mark these fields as "Y" as the PBM Public Law Manager will mark the database to flag these records as under review*
3. In the body of the e-mail, provide the following information:
  - NDC
  - UNITS per PACKAGE,
  - TRADE and GENERIC NAME
  - The manufacturer's record of FSS PRICE in effect on September 30<sup>th</sup>:
    - Inclusive of the 0.5% IFF Fee
    - Exclusive of the 0.5% IFF Fee
4. Subject heading should include the full contract number and title "Dispute FSS"
5. Send e-mail to [AMMHINPLCORETEAM@VA.GOV](mailto:AMMHINPLCORETEAM@VA.GOV)
6. CC [nonfamp@va.gov](mailto:nonfamp@va.gov)
7. Attach copies of modifications to support manufacturer's price dispute
8. Include the original Excel workbook received from PBM

Example:

Send

To... AMMHIN PL CORE TEAM;

Cc... VHAPBH NonFAMP;

Account ▾ Bcc...

Subject: V797P-XXXXX FSS Dispute

Attached:

Dear FSS:

FSS contract V797P-XXXXX is disputing the following NDC's September 30<sup>th</sup>, 2012 price as reported in the PBM's spreadsheet.

NDC\_1 NDC\_2 NDC\_3  
Units per Package  
Trade name  
Generic name

Manufacturer's record of FSS price in effect on 9/30  
with IFF  
without IFF

Supporting documentation includes copies of modification(s) and effective date [attached], along with the Excel Workbook sent by the PBM Public Law Manager.

Sincerely,

Pharmaceutical Vendor

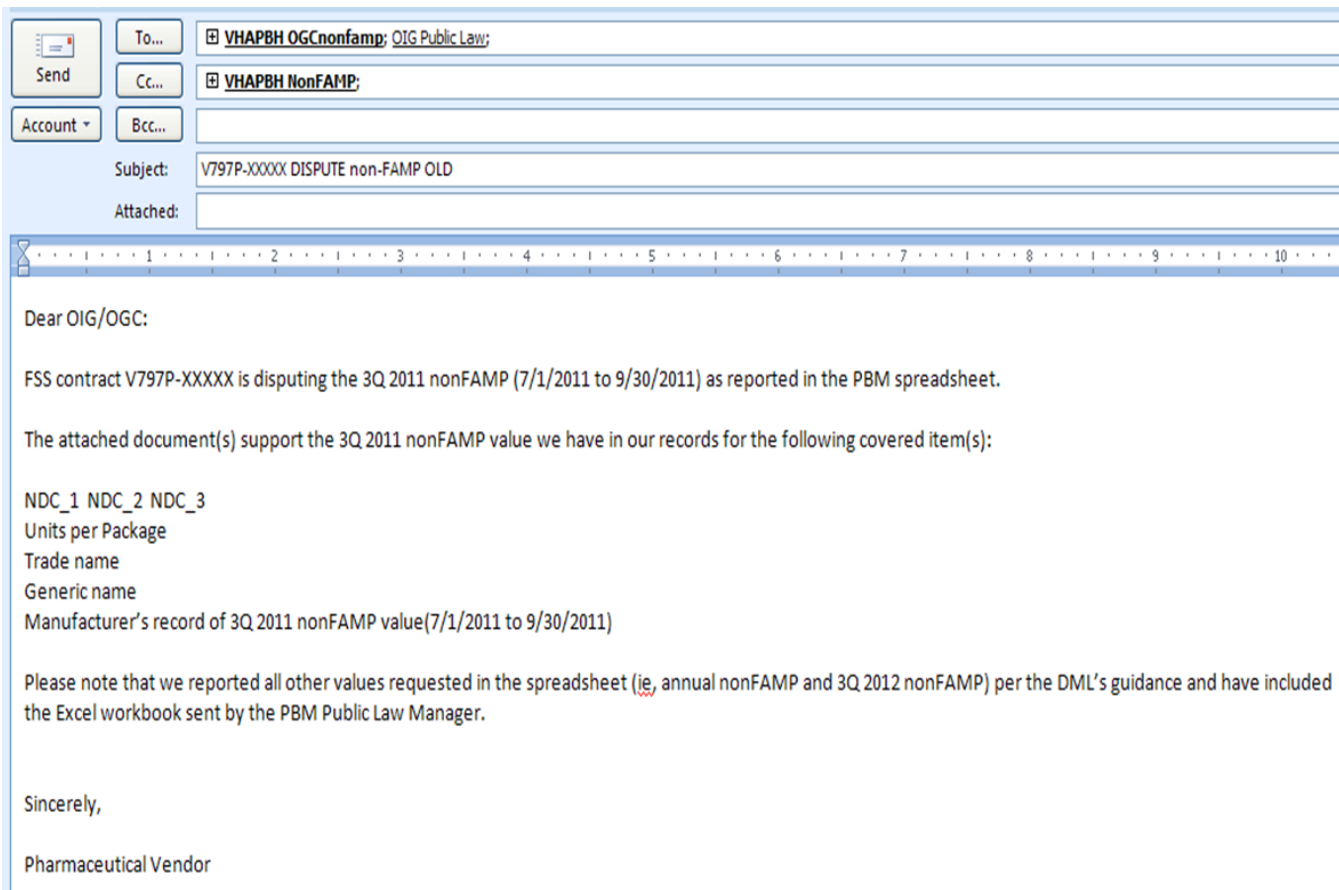
## Attachment E

**Instructions: How to Submit a Dispute in regards to calculated 3Q calendar non-FAMP for July 1, 2011 to September 30, 2011**

**Purpose:** Provides the manufacturer a way to dispute the reported 3Q calendar non-FAMP for July 1, 2011 to September 30, 2011 (Field Q on the Excel workbook received from the Public Law Manager).

1. Identify all covered items that potentially have a disputed non-FAMP\_old.
2. Mark column X (Dispute\_nfamp\_old) with a "Y" in the Excel workbook received from the Public Law Manager. **NOTE:** *It is important to mark these fields as "Y" as the PBM Public Law Manager will mark the database to flag these records as under review*
3. Send the e-mail to [OGCNONFAMP@VA.GOV](mailto:OGCNONFAMP@VA.GOV) and [OIGPUBLICLAW@VA.GOV](mailto:OIGPUBLICLAW@VA.GOV)
4. CC [nonfamp@va.gov](mailto:nonfamp@va.gov)
5. In the body of the e-mail, provide the values for the following fields:
  - NDC\_1, NDC\_2, NDC\_3
  - UNITS per PACKAGE
  - TRADE and GENERIC NAME
  - Manufacturer's 3Q Calendar Year 2011 non-FAMP sales (7/1/2011 to 9/30/2011) on record
6. Provide documents to support the disputed 3Q 2011 value(s) and include the Excel Workbook sent by PBM

Example:



Dear OIG/OGC:

FSS contract V797P-XXXXX is disputing the 3Q 2011 nonFAMP (7/1/2011 to 9/30/2011) as reported in the PBM spreadsheet.

The attached document(s) support the 3Q 2011 nonFAMP value we have in our records for the following covered item(s):

NDC\_1 NDC\_2 NDC\_3  
Units per Package  
Trade name  
Generic name  
Manufacturer's record of 3Q 2011 nonFAMP value(7/1/2011 to 9/30/2011)

Please note that we reported all other values requested in the spreadsheet (ie, annual nonFAMP and 3Q 2012 nonFAMP) per the DML's guidance and have included the Excel workbook sent by the PBM Public Law Manager.

Sincerely,

Pharmaceutical Vendor

**Note: Companies that have submitted a methodology change which affects the calculated non-FAMP for July 1, 2011 to September 30, 2011 value are still required to file an Attachment E in order for the 2013 FCP calculations to be properly calculated.**

## **Attachment F**

### Compliance Reminders:

- Annual non-FAMP data from 10/1/2011 to 09/30/2012 (nfamp column in spreadsheet) and 3Q New data from 7/1/2012 to 9/30/2012 (nfamp\_new column in spreadsheet)—these columns must contain data. **Calculation is rounded to two decimal places; rounding up if 2<sup>nd</sup> decimal is >=5.** If there are no reportable sales for the covered item(s), enter “0.00”. Do not leave the cells in the columns blank. Incomplete submissions will be returned to the manufacturer for verification and correction.
- Items that have been removed from your FSS contract due to its non-U.S., non-designated-country source and the requirements of the Trade Agreements Act (TAA), are still considered covered drugs as defined by the Veteran’s Health Care Act of 1992, P.L. 102-585, Sect. 603. Your firm is still obligated to comply with the other requirements outlined in the MA and PPA that your firm executed. Therefore, your company must continue to report non-FAMPs to PBM for any covered drug and maintain a FCP for the drug annually with PBM, as well as submit an updated PPA Addendum annually to Cheryl Ward-Roberts at the NAC.
- Annual non-FAMP data will not be required to be reported for a new drug that has not experienced at least one full calendar quarter of sales by September 30<sup>th</sup>, 2012.
- New Package Sizes (NPS): The following is a clarification of the guidance on NPS items that was issued in the 2010 OGC letter (see at: <http://www.va.gov/oal/docs/business/nac/fssPL102-585CorrespondenceArchive.zip>). A manufacturer must submit a modification to add a NPS item to its FSS contract, at a calculated FCP from an existing package FCP, to coincide with the NPS item’s launch (the first day the product is available in the commercial marketplace). However, any covered drug that has a calculated FCP from an existing package’s FCP will not be included on the spreadsheet for annual calculations. These NPS covered items will need a separate permanent report filed with PBM (in like manner of new products) after achieving a full calendar quarter of sales data. After the NPS item’s permanent FCP has been established on the FSS contract, it will be included in annual calculations.
- Permanent FCP establishment: All new covered drugs that reach Permanent FCP stage must be reported in a separate e-mail from the annual report. The permanent FCP established by November 15<sup>th</sup>, 2012 will have the FCP effective for the remainder of the 2012 calendar year and through the 2013 calendar year until the next annual filing due in November of 2013.
- Flu Vaccines: These items will not be included on the Excel Workbook (.xls) as specific rules and requirements exist for reporting the provisional and permanent FCP data. Instead, the FCPs will be determined according to the guidance provided in the March 31, 2004 New Flu Vaccine Policy.
- Dear Manufacturer Letters (DML): You will find a library of all DMLs by accessing the following website: <http://www.va.gov/oal/business/fss/publicLaw.asp>
- NDC Changes: If a manufacturer of a covered drug changes their NDC, the non-FAMP sales of both NDCs must be combined when reporting. If new covered drug NDC(s) are not included in the workbook received from the Public Law Manager, please follow the directions under attachment “I”. The new NDC(s) will be included in the final 2013 FCP workbook.
- Excel workbook: Several of the cells in the Excel workbook are locked and read-only. A copy of an unlocked Excel workbook will be supplied to manufacturers upon request if needed for data processing. However, the final Excel workbook submitted to the Public Law Manager by manufacturers must be the locked Excel workbook.

## **Attachment F**

### Compliance Reminders (cont'd):

- TRICARE (TRRx): VA has provided further guidance to manufacturers on how to treat sales which become the basis for TRICARE Retail Pharmacy Program (TRRx) rebates. This guidance can be found at: <http://www.va.gov/oal/docs/business/nac/TrrsSales-NfampFags.doc>. There were four TRRx rebate invoice utilization and payment due dates during this year's annual reporting period: 10 Oct. 2011, 9 Jan. 2012, 9 Apr. 2012, and 26 Jul. 2012. TRRx utilization data from all quarters of 2008 and calendar quarters 1 & 2 of 2009 that may have been submitted by TRICARE with retroactive rebate invoices due during this year's annual reporting period **need not be excluded** from 2012 non-FAMPs.
- Self-disclosures: If a manufacturer discovers that it is not in compliance with some aspect of the Public Law, or was not in compliance during a prior period, it should notify the VA. Attachment H provides instructions on how to submit a self disclosure.
- FSS Contract Number Changes: FSS contracts are awarded with a five-year duration. Your FSS contract may be awarded a new contract number during Public Law season after the locked spreadsheet has been received by your company. PBM will keep record of the newly awarded contract number and provide the correct contract number with the final 2013 FCP workbook.
- Trade Agreements Act (TAA): A covered drug that has been removed from its manufacturer's FSS contract for non-compliance with the TAA and, thus, is not available on a VA multi-year contract will no longer be subject to the dual calculation prescribed by 38 U.S.C. 8126(d)(1). Beginning with 2013 pricing, TAA-non-compliant covered drugs that cannot be sold through a VA multi-year contract (like FSS) will have FCPs determined in all years under the calculations found in 38 U.S.C. 8126(a)(2) & (c). If such drugs later are sourced in the U.S. or a TAA designated country, the dual calculation will again apply in the appropriate years.

## Attachment G

### Instructions: How to Submit a Dispute in the 2013 calculated FCPs for annual reporting year 2012

**Purpose:** Manufacturer is to use this format to dispute or resubmit data for 2012 FCP calculations.

1. Identify all covered items where the 2012 FCP is being disputed.
2. In the body of the e-mail, provide the values for the following fields:
  - NDC\_1, NDC\_2, NDC\_3
  - UNITS per PACKAGE,
  - TRADE and GENERIC NAME
  - Revised non-FAMP 2012 sales (10/1/2011 to 9/30/2012)
  - Revised 3Q Calendar Year 2012 sales (7/1/2012 to 9/30/2012)
3. State the reason for the dispute.
4. Include all documentation that would support the dispute or resubmission, as necessary.
5. Subject heading should include the full contract number and title "Dispute 2013 FCP"
6. Send the e-mail to [nonfamp@va.gov](mailto:nonfamp@va.gov)
7. CC [OGCNONFAMP@VA.GOV](mailto:OGCNONFAMP@VA.GOV) and [OIGPUBLICLAW@VA.GOV](mailto:OIGPUBLICLAW@VA.GOV)
8. Include the final Excel workbook (.xls) of 2013 FCPs as an attachment

Example:

The screenshot shows an email composition window with the following details:

- To:** VHAPBH NonFAMP;
- Cc:** OIG Public Law; VHAPBH OGCnonfamp;
- Subject:** V797P-XXXXX DISPUTE 2013 Calculated FCPs
- Attached:** (empty)

The email body contains the following text:

Dear PBM:

FSS contract V797P-XXXXX is disputing the 2013 calculated FCP data for the following NDCs:

NDC_1	NDC_2	NDC_3
Units per Package		
Trade name		
Generic name		

Revised nonFAMP 2012 data	(10/1/2011 to 9/30/2012)
Revised 3Q 202 nonFAMP data	(7/1/2012 to 9/30/2012)

Reason for dispute:

The attached document(s) support the disputed calculated FCPs.  
We have included the Excel workbook sent by the PBM Public Law Manager.

Sincerely,

Pharmaceutical Vendor

## Attachment H

### **Instructions: How to Submit a Self-disclosure for Federal Supply Schedule (FSS) Public Law Non-Compliance or Pricing Errors**

**Purpose:** Provides the manufacturer with a process for making a self disclosure of any Public Law non-compliance or pricing errors that occurred during any period the manufacturer was subject to the Public Law (manufacturing and selling covered drug products). Examples of non-compliance or pricing errors requiring disclosure include (but are not limited to):

- Failure to obtain an FSS contract and sign a Master Agreement in a timely manner
- Failure to submit non-FAMP data and add a new covered drug to an FSS contract in a timely manner
- Errors in calculating non-FAMPs
- Misclassifying covered drugs as non-covered drugs
- Deleting covered drugs from an FSS contract prematurely

To make a self-disclosure, a manufacturer should do the following:

1. Prepare a letter that states the non-compliance error, what caused the error, what covered drug item(s) were affected by the error, how long the error occurred, and what remedial action the manufacturer is proposing or has taken.
2. Provide supporting documentation for the disclosure.
3. Send e-mail notification to the assigned contract specialist at [AMMHINPLCORETEAM@VA.GOV](mailto:AMMHINPLCORETEAM@VA.GOV), [OGCNONFAMP@VA.GOV](mailto:OGCNONFAMP@VA.GOV) and to [OIGPUBLICLAW@VA.GOV](mailto:OIGPUBLICLAW@VA.GOV).
4. CC: the Public Law Manager at [NONFAMP@VA.GOV](mailto:NONFAMP@VA.GOV).
5. Subject should include the full FSS contract number, manufacturer's name, and the words: "Self Disclosure".

Example:

The screenshot shows an email composition window with the following fields:

- To:** AMMHINPLCORETEAM@VA.GOV OIGPUBLICLAW@VA.GOV OGCNONFAMP@VA.GOV
- Cc:** NONFAMP@VA.GOV
- Bcc:** (empty)
- Subject:** V797P-XXXXX Manufacturer Name - Self-disclosure
- Attached:** Provide all supporting documents

The email body contains the following text:

Dear OGC/OIG:

FSS contract V797P-XXXXX would like to report that during a self audit we have discovered the following issues over the course of X years.

Describe the issue

Provide all supporting documentation and contact phone numbers.

Sincerely,

Pharmaceutical Vendor



## Attachment I

**Instructions: How to submit new NDC's for covered drugs due to NDC changes which are not listed in the annual workbook**

**Purpose:** Provides the manufacturer a method of reporting non-FAMP data for new covered drug NDC(s) due to NDC changes. This should be submitted with the annual report to ensure all covered items have calculated FCPs.

1. Identify all covered items that experienced a change of NDC that are not listed in the annual workbook.
2. In the body of the e-mail, provide the information for the following fields:
  - Old 11 digit NDC of covered drug (including preceding zeros)
  - New 11 digit NDC of covered drug (including preceding zeros)
  - Trade name
  - Generic name
3. Submit this information when your final workbook is submitted to PBM to nonfamp@va.gov.
4. The new NDC(s) will be included in the final 2013 FCP workbook that is submitted back to the company.

Example:

Send

To... **VHAPBH NonFAMP:**

Cc...

Account ▾ Bcc...

Subject: V797P-XXXXX Covered Drug NDC Change

Attached:

Dear PBM:

Please note that the following item(s) are NDC changes and were not captured on the annual workbook under FSS contract V797P-XXXXX.

<u>OLD NDC</u>	<u>NEW NDC</u>	<u>TRADE NAME</u>	<u>GENERIC NAME</u>
00111-0252-03	00001-0002-03	DRUG NAME ONE	GENERIC NAME ONE
11111-2222-33	12345-54-73	DRUG NAME TWO	GENERIC NAME TWO

Also attached is the completed annual workbook to calculate the 2013 FCPs.  
Please ensure that the new NDCs are included in the final workbook.

Sincerely,

Pharmaceutical Vendor

**NOTES:** Both old and new NDC numbers have preceding zeros included (if necessary) to have 11 digits.