Department of Veterans Affairs
Veterans Health Administration
Pharmacy Benefits Management
PO Box 126
Hines, IL 60141

For FCP's effective 1/99

October 16, 1998

578/119D

Dear Manufacturer:

The following information is provided to assist your company in reporting the annual data mandated by Section 603 of Public Law 102-585 (Veterans Health Care Act of 1992; 38 U.S.C. 8126). Annual Non-Federal Average Manufacturers Price (NFAMP) calculations with 1999 Federal Ceiling Prices (FCP) for covered drugs are to be reported to Associate Chief Consultant, Pharmacy Benefits Management (PBM) (formerly Chief, Drug & Pharmaceutical Product Management (DPPM)), **on or before November 16, 1998.** (Any anticipated changes in your company's method of accounting for chargebacks, etc., must be implemented in accordance with Generally Accepted Accounting Principles (G.A.A.P.) and explained to the above office prior to submission of annual data.)

Each covered drug's mandated FCP for 1999 (the second 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 (CPIU) will be utilized in performing both calculations. This change in CPIU is identified as the percent change from September 1997 to September 1998. **The Bureau Of Labor Statistics data shows the percent change to be 1.49%, which will be used as the CPIU for the Federal Ceiling Price calculations due on November 16, 1998.**

The one-half percent 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 selling price. Please see instructions from your contracting officer.

The Section 8126 (d)(1) calculation will begin with the **Federal Supply Schedule (FSS) contract price of a covered drug in effect on September 30, 1998.** For those manufacturers that elected dual FSS pricing, the **FSS contract price is the September 30, 1998 price charged to other government agencies** and other authorized Schedule users, **not** the price paid by the Department of Veterans Affairs, Department of Defense (DoD), or Public Health Service (PHS)/Indian Health Service & Coast Guard. The appropriate FSS price will then be increased by the above percent change in CPIU to arrive at the 1999 FSS price cap. This cap applies to all "other user" FSS prices in 1999.

The Section 8126 (a)(2) & (c) calculation will begin with the 1998 annual non-FAMP computation; it will continue by multiplying that number by .76 and then subtracting any additional discount calculated based on a difference between "old" and "new" non-FAMPs. **The lower of the above calculation and the 1999 FSS price cap will become the 1999 FCP.** If there are "no sales" in a benchmark third quarter of a year that is used to derive the new NFAMP or old NFAMP, there can be no additional discount calculation for that particular item. In those cases, the additional discount will be entered as zero (0). If a covered drug had no reportable sales in 1998, its calculated 1999 FCP will be the 1999 FSS price cap.

If they meet the other VA criteria, nominal prices for exclusion from non-FAMP's for 1999 calculations must be prices that do not exceed 10 percent of that particular item's non-FAMP during the third quarter of 1998 (7/1/98 through 9/30/98). 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 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 these entities at prices determined by PHS under Sect. 602. However, sales to these entities at prices lower than Sect. 602 prices must be included in NFAMP calculations.

As an added service to streamline efficiency for the 1999 report, PBM is enclosing a diskette with all your company's covered line items in database form. The diskette contains a file that will display your company's covered items. All that you need to run the diskette is access to a personal computer that has Microsoft Windows (versions 3.x, 95, 98 or NT), and then follow the enclosed diskette instructions for use. The database contains certain pre-filled fields based on the Public Law data supplied last year by your company. For example: we have provided the 1998 NFAMP Old (1997 NFAMP New which is the time period of 7/1/97 through 9/30/97). Therefore, all that is required of your company is that you furnish the 1998 Annual NFAMP and NFAMP New in the appropriate fields. After you return the completed diskettes to Pharmacy Benefits Management, we will calculate Change in NFAMP, Additional Discount, and 1999 Federal Ceiling Price. Pharmacy Benefits Management will send you a printout of your company's calculated 1999 Federal Ceiling Prices via facsimile or e-mail file within seven days after our receipt of your data. If we do not hear from your company within five workdays after we send the printout, we will assume that you agree with VA's calculations of the federal ceiling prices.

If there are changes to the data which PBM has provided in the pre-filled fields (e.g. Office of Inspector General audit recommendations), you have the option of changing the information on a separate electronic or hard copy submission. If your company elects to do so, you **must** submit a letter of explanation regarding all changes.

It is highly recommended and preferred that you submit your data in electronic format, using either the enclosed diskette, our electronic bulletin board service, or Pharmacy Benefits Management e-mail. You may submit the data as you have in the past on the form provided using the instructional packet as a guide to Public Law 102-585 compliance if you do not have access to a personal computer system.

All correspondence related to NFAMP calculations, FCP calculations, quarterly NFAMP reports, annual FCP reports, FCP reports for new products, FCP recalculations for new products, corrections to quarterly NFAMP reports and correction to annual FCP reports should be forwarded to:

George J. Hill, R.Ph., M.B.A.
Public Law Database Manager
Pharmacy Benefits Management (119D)
P.O. Box 126
Hines, Illinois 60141

Express Mail: 5th Ave. & Roosevelt Rd.
Building 1, Room A148

E-Mail: NonFamp@med.va.gov

The quarterly non-FAMP report for the third quarter of 1998 consists of the same data as the "new NFAMP" (7/1/98-9/30/98) reported on the annual calculation form for 1999 FCP's which is due by **November 16, 1998**. Consequently, it will not be necessary to submit the NFAMP Third Quarter 1998 Report separately. However, manufacturers that do not meet the November 16, 1998 annual reporting deadline will be subject to penalties for late

data reporting as described in the Master Agreement, 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 Master Agreement) 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 package.**

Section 8126(e) of the Law states that quarterly NFAMP 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 Inspector General (IG) audits. Nevertheless, to assist manufacturers in providing the most accurate quarterly NFAMP calculations possible, the Pharmacy Benefits Management Section (PBM) will not seek imposition of late penalties for unreported data until 45 days after the end of each quarter. Again, please note that each year the NFAMP third quarter data may be submitted as part of the Annual Report (which is due 45 days after the end of the third quarter).

After your company reports its annual 1998 NFAMP data in the format on the enclosed diskette or sheets, the authorized official who signed your company's PPA addendum in 1998 (or an authorized successor) must prepare and sign a new PPA addendum, listing each covered drug and its 1999 FCP. This addendum should then be forwarded before December 1, 1998 to the VA National Acquisition Center (90N-P), Building 37, First Avenue, 1 block North of Cermak Rd., P.O. Box 76, Hines, Illinois 60141.

It is strongly suggested and recommended at this time that you review your company's computer hardware and Public Law data software capabilities for complying with Year 2000 (Y2K) requirements, and perform corrective measures where necessary. If you have any questions about any of the above information, please call George Hill or John Weisman at (708) 216-2079, extension 4939 or 4930, respectively.

Sincerely,

George D. Hill

for Michael Valentino, R.Ph.
Associate Chief Consultant
Pharmacy Benefits Management Strategic Healthcare Group
VACO Pharmacy Service

Enclosures: 4
Instructions for VHA's 1998 Non-FAMP Report
Data Sheet
Data Diskette
Diskette Instructions

Instructions for VHA's 1998 Non-FAMP Report for Public Law 102-585 due November 16, 1998.

<1> Preparation Date: [_][_]-[_][_]-[_][_]

Explanation - The date the report is prepared. Format is intended to be month-day-year. Example 11/01/98. [PREP_DATE]

Note Page [_][_][_] of [_][_][_]

Explanation - If hard copy report is provided, pages should be numbered to assure complete document is received. (Not part of electronic database submission, only used in hard copy paper submission.)

<2> FDA Assigned Labeler Code: [_][_][_][_][_]

Explanation - First segment of National Drug Code that identifies the manufacturer, labeler, relabeler, packager, repackager or distributor of the drug. Field is right justified and leading zeros are added to provide 5-digit code. [NDC_1]

<3> Product Code: [_][_][_][_]

Explanation - Second segment of the National Drug Code. Field is right justified and leading zeros are added to provide 4-digit code. [NDC_2]

<4> Pkg. Code: [_][_]

Explanation - Third segment of the National Drug Code. Field is right justified and leading zero is added if necessary to provide 2-digit code. [NDC_3]

<5> Units per Pkg: [_][_][_][_][_][_][_][_]

Explanation - Number of units per package. Example - bottles of 1000 tablets would be "1000"; Liquid bottles of 473 ML would be "473ML"; Aerosol containers of 17.5 GM would be "17.5GM". Maximum of 8 characters, free text. [UNT_PKG].

<6> Date Entered Market: [_][_]-[_][_]-[_][_]

Explanation - Date the specific product and package size (NDC) was first commercially made available for sale. **This field is not mandatory for line items that entered the market before October 1992.** The Format is intended to be month-day-year. Example 12-02-95. [DATE_ENTER]

<7> Dosage Form: [_][_][_][_][_][_][_][_][_][_][_][_]

Explanation - Dosage form of the product. Example- Capsules or CAP, Aerosol, Solution. Field identification may be obtained from United States Pharmacopoeia Dispensing Information, Volume III or you may provide the same 3-digit code used to identify "UNIT TYPE" provided to the Healthcare Finance Administration (HCFA). Maximum 12 characters, free text. [DOSE_FORM]

<8> Strength: [_][_][_][_][_][_][_][_][_][_][_][_]

Explanation - Product strength. Example- 250MG; 325MG/5ML; etc. Field identification may be obtained from United States Pharmacopoeia Dispensing Information, Volume III. Maximum 12 characters, free text. [STRENGTH]

<9> Product Name Listed on FDA Application (limit 63 characters):

Explanation - This 63-character field is intended for entry of the product name as it appears on FDA registration form. The field is free text, left justified and limited to a maximum of 63 characters. [FDA_NAME]

<10> Trade Name (limit 35 characters):

Explanation - This 35-character field is intended for entry of the product's patented trade name or brand name. The field is free text, left justified and limited to a maximum of 35 characters. [TRADE_NAME]

<11> Generic Name (limit 35 characters):

Explanation - This 35-character field is intended for entry of the product's generic name. The field is free text, left justified and limited to a maximum of 35 characters. [GENERIC]

<12> % Increase in CPIU (Sept 97 - Sept 98): [_][1].[4][9]

Explanation - The September 1997 and September 1998 Consumer Price Index - Urban (CPI-U) can be obtained from the Bureau of Labor Statistics or from the Pharmacy Benefits Management Section, telephone numbers indicated on page 3 of the cover letter. The Percent Increase in the CPI-U is calculated by multiplying the difference between the two index numbers by 100 and that product divided by the older (1997) of the two CPI-U's. This calculation is rounded to two decimal places. This field is numeric, 5 (This includes the decimal point and two decimal places). [PCT_CPIU] Rounding rules: After specified number of decimal spaces, if number is equal to or greater than 5, round up. If number is less than 5, round down.

<13> [_][_][_][_][_][_][_].[_][_]
1998 Federal Supply Schedule price

Explanation- The 1998 Federal Supply Schedule Price is the permanent contract price in effect or awarded on September 30, 1998 for single price companies. For manufacturers that selected dual FSS pricing, the 1998 Federal Supply Schedule Price is the September 30, 1998 awarded permanent contract price charged to other government agencies and authorized Schedule users not the price paid by the Department Veterans Affairs (VA), Department of Defense (DoD), or Public Health Service (PHS). This field is numeric, 10 (This includes the decimal point with two decimal places). [FSS98]

<14> [_][_][_][_][_][_][_].[_][_]
1999 Maximum FSS Price per 38 U.S.C. 8126 (d)(1)
(1998 FSS + Allowable CPIU Increase)

Explanation - This price is determined by increasing the 1998 Federal Supply Schedule price by the allowable percent increase in CPIU. This price is defined in Section 38 U.S.C. 8126 (d)(1). This field is numeric, 10 (This includes the decimal point with two decimal places). [FSS99MAX]

<15> [_][_][_][_][_][_][_].[_][_]
1998 Annual NFAMP (10/1/97-9/30/98):

Explanation - The 1998 Annual NonFederal Average Manufacturer's Price (NFAMP) is the weighted average manufacturer's sales price for that NDC line item. This is total non-Federal dollar sales (described by paragraph's I.J.,N.,O and II.B.5 of the Master Agreement) for the period indicated (Oct 1, 1997 through Sep 30, 1998) divided by the total unit volume of sales for that NDC line item, 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. This number is expressed in dollars and cents and should be rounded off using the rules in Example <12>. The field is numeric, 10 (This includes the decimal point with two decimal places). [NFAMP_98]

<16> □□□□□□□.□□
Old NFAMP (7/1/97-9/30/97):

Explanation - The Old Non-Federal Average Manufacturer's Price is a weighted average manufacturer's sales price for that NDC line item. This is total non-Federal dollar sales for the period indicated (Jul 1, 1997 through Sep 30, 1997) divided by the total unit volume of sales for that NDC line item, excluding nominally priced sales and returned goods if records are available for verification. Dollar sales must reflect rebates, cash discounts, and charge backs. This number is expressed in dollars and cents and should be rounded off using the rules for field <12>. This field is numeric, 10 (This includes the decimal point with two decimal places). [NFAMP_OLD]

<17> □□□□□□□.□□
New NFAMP (7/1/98-9/30/98):

Explanation - The New Non-Federal Average Manufacturer's Price is a weighted-average manufacturer's sales price for that NDC line item. This is total non-Federal dollar sales for the period indicated (Jul 1, 1998 through Sep 30, 1998) divided by the total unit volume of sales for that NDC line item, excluding nominally 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. This number is expressed in dollars and cents and should be rounded off using the rules for field <12>. This figure also constitutes the Quarterly NFAMP report for the third quarter of 1998. (The third quarter's NFAMP Report submission date has been extended until November 16, 1998 to correspond with the Annual NFAMP reports.) This field is numeric, 10 (This includes the decimal point with two decimal places). [NFAMP_NEW]

<18> □□□□□□□.□□
Change in NFAMP:

Explanation - The Change in NFAMP is the difference between the New NFAMP (7/1/98-9/30/98) and the Old NFAMP (7/1/97-9/30/97). This number can be a negative number and is expressed in dollars and cents. This field is numeric, 10 (This includes the decimal point with two decimal places). [NFAMP_CHG]

<19> □□□□□□□.□□
Additional Discount:

Explanation - Additional Discount is the difference between the actual Change in NFAMP (Entry 16 on this form) and the legislative allowable increase. The allowable increase is the product of the Old NFAMP (Entry 14 on this form) and percent increase in CPI-U (Entry 12 on this form). The Additional Discount is expressed in dollars and cents and is always a positive number. If the Change in NFAMP (Entry 16 on this form) is negative, then a 0.00 should be entered as the Additional Discount. This field is numeric, 10 (This includes the decimal point with two decimal places). [ADD_DISC]

Example: If Old NFAMP (Entry 16) = $115.00
New NFAMP (Entry 17) = $121.00
1998 Annual NFAMP (Entry 15) = $118.00
Percent Increase in CPI-U (Entry 12) = "1.49"
Then Change in NFAMP (Entry 18)= $121.00 - $115.00 = $ 6.00

Allowable increase is the product of Old NFAMP (Entry 16) and the percent increase in CPI-U. Allowable increase = $115.00 x 0.0149 = $1.71

Additional Discount (Entry 19) = Change in NFAMP (Entry 18) minus Allowable Increase (Entry 12 X Entry 16). In this example case Additional Discount = $6.00 - $1.71 = $4.29

<20> [_][_][_][_][_][_][_].[_][_]
1999 Calculated Ceiling
per 38 U.S.C. 8126 (d)(2) and (a)(2)

Explanation - The calculation based on 38 U.S.C. 8126 (d)(2) and (a)(2) and (c) is the product of the 1998 Annual NFAMP (Entry 15) and .76 (as defined in legislation), less any Additional Discount (Entry 19). This number is expressed in dollars and cents and should be rounded off using the rules for field <12>. This field is numeric, 10 (This includes the decimal point with two decimal places). [CALCMAX99]

In the case described above, the Calculated Federal Ceiling Price is:

(Entry 15) $118.00 x .76	=	$89.68
Less Additional Discount		- 4.29
1999 Calc. Federal Ceiling Price	=	$85.39

<21> [_][_][_][_][_][_][_].[_][_]
1999 Federal Ceiling Price
(Lowest of 38 U.S.C. 8126 (d)(1) or
38 U.S.C. 8126 (d)(2) & (a)(2))

Explanation- This figure is determined by taking the lower of fields 14 or 20. This field is numeric, 10 (This includes the decimal point with two decimal places). [FCP_99].

<22> [V][7][9][7][P]-[5][_][_][_][_]
1998 FSS Contract Number

Explanation - This is the FSS contract number assigned by the National Acquisition Center (NAC) during 1998. The number normally consists of 1 alpha character, 3 numerics, 1 alpha character, 1 dash, four numerics and 1 alpha character. Typically, the 1998 FSS Contract Number begins with "V797P-" and the last 5 characters are unique for each company. [CNT_NO]

<23> Company Official's Name.

Explanation - The name of the company official authorizing and certifying that the data provided in this report is correct. This field is left justified and maximum of 40 characters.
[COMPANY_OF]

FORMAT OF 1998 NON-FAMP DATA RELATED TO PUBLIC LAW 102-585

The following data elements must be provided to the Pharmacy Benefits Management Section (PBM) of the Veterans Health Administration:

Structure for database: NFAMP99.DBF

Field	Field Name	Type	Width	Dec
1	PREP_DATE	Date	8	
2	NDC_1	Character	5	
3	NDC_2	Character	4	
4	NDC_3	Character	2	
5	UNT_PKG	Character	8	
6	DATE_ENTER	Date	8	
7	DOSE_FORM	Character	12	
8	STRENGTH	Character	12	
9	FDA_NAME	Character	63	
10	TRADE_NAME	Character	35	
11	GENERIC	Character	35	
12	PCT_CPIU	Numeric	5	2
13	FSS98	Numeric	10	2
14	FSS99MAX	Numeric	10	2
15	NFAMP_98	Numeric	10	2
16	NFAMP_OLD	Numeric	10	2
17	NFAMP_NEW	Numeric	10	2
18	NFAMP_CHG	Numeric	10	2
19	ADD_DISC	Numeric	10	2
20	CALCMAX99	Numeric	10	2
21	FCP_99	Numeric	10	2
22	CNT_NO	Character	11	
23	COMPANY_OF	Character	40	
Total **			339	

PLEASE NOTE: Page Numbers are not required in the electronic submission structure.

The database format is compatible with DBASE III Plus, FoxPro, Visual FoxPro, Quick Silver, DBXL or equivalent (*.DBF)and should be placed on a 3.5 inch high density disk or provided through direct electronic communications. To expedite the electronic transmissions, the data may be compressed using PKZIP. PKZIP may also be used to reduce size of file provided on a 3.5-inch high-density disk.

An ASCII format is an alternate method of providing data in the above sequence, using a **comma** delimiter file.

If previous data was submitted in the ASCII format in the above sequence, using a (2) caret (^) as the delimiter between fields and limiting the maximum field length in the above manner, reports may continue to be submitted as such. If the caret delimiter is used, each line item entry should end with the tilde (~) and a hard return. If a field is null, the carets dividing fields should appear, indicating a null entry (example - ^^). An electronic bulletin board has been established for the purpose of submitting the NFAMP data electronically. The bulletin board telephone number is 708-531-7947. Electronic submission may also be accomplished via e-mail to NonFamp@med.va.gov. If electronic submission is not possible, data may be submitted on diskette or manually (Form OMB NO. 2900-0393 rev 9/98) enclosed to:

George J. Hill, R.Ph., M.B.A.
Public Law Database Manager
Pharmacy Benefits Management (119D)
Building 1, Room A148
P.O. Box 126
5th Ave. and Roosevelt Road
Hines, IL 60141

For contract questions, you may contact Carole O'Brien or your contracting officer, at the National Acquisition Center, Pharmaceutical Products Division, (708)-786-4956.

Preparation Date: 1 [_][_]-[_][_]-[_][_]

Page: [_][_] of: [_][_]

Veterans Health Administration
NFAMP 1998 Report for Public Law 102-585
(For Pharmaceutical Pricing Agreements - 1999)
FDA Assigned Labeler Code: 2 [_][_][_][_][_]

3 [_][_][_][_]
Product Code

4 [_][_]
Pkg. Code

5 [_][_][_][_][_][_][_][_]
Units Per Pkg

6 [_][_]-[_][_]-[_][_]
Date Entered Market

7 [_][_][_][_][_][_][_][_][_][_][_][_]
Dosage Form (limit 12 characters)

8 [_][_][_][_][_][_][_][_][_][_][_][_]
Strength (limit 12 characters)

9 [_]
Product Name Listed on FDA Application (limit 63 characters)

10 [_]
Trade Name (limit 35 characters)

11 [_]
Generic Name (limit 35 characters)

12 [_][1].[4][9]
% Increase in CPIU
(Sep 97-Sep 98)

13 [_][_][_][_][_][_][_].[_][_]
1998 Federal Supply
Schedule Price

14 [_][_][_][_][_][_][_].[_][_]
1999 Maximum FSS Price
per 38 USC 8126 (d)(1)
(1998 FSS + Allowable CPIU Increase)

15 [_][_][_][_][_][_][_].[_][_]
1998 Annual NFAMP
(10/1/97-9/30/98)

16 [_][_][_][_][_][_][_].[_][_]
Old NFAMP
(7/1/97-9/30/97)

17 [_][_][_][_][_][_][_].[_][_]
New NFAMP
(7/1/98-9/30/98)

18 [_][_][_][_][_][_][_].[_][_]
Change in NFAMP

19 [_][_][_][_][_][_][_].[_][_]
Additional Discount

20 [_][_][_][_][_][_][_].[_][_]
1999 Calculated Ceiling
per 38 USC 8126 (d)(2)&(a)(2)

21 [_][_][_][_][_][_][_].[_][_]
1999 Federal Ceiling Price
(Lower of Field 14 or Field 20)

22 [V][7][9][7][P][-][5][_][_][_][_]
FSS Contract Number

23 [_]
Company Official's Name Authorizing and Certifying the accuracy of this report (limit 40 Characters)

OMB No. 2900-0393 (Rev. 9/98)