

# MASTER AGREEMENT

Between

The Secretary of Veterans Affairs  
(Hereinafter Referred to as "The Secretary")

And

The Manufacturer Identified in Section VIII of this Agreement  
(Hereinafter Referred to as "The Manufacturer")

The Secretary, on behalf of the United States Department of Veterans Affairs, the Department of Defense, the Public Health Service, the Indian Health Service (collectively "the Federal Agencies" as identified in Section 8126(b) of Title 38, U.S.C.) and State homes receiving funds under Section 1741 of Title 38 U.S.C., and The Manufacturer, on its own behalf, for purposes of Sections 601 and 603 of the Veterans Health Care Act of 1992, Public Law No. 102-585, (hereinafter referred to as the "Act"), and Section 1927 of the Social Security Act, hereby agree to the following:

## I. DEFINITIONS

The terms defined in this section will, for the purpose of this Agreement, have the meanings specified in Section 603 of the Act (which creates a new Section 8126 in Chapter 81 of 38 U.S.C.) and Section 1927(k) of the Social Security Act, as interpreted and applied herein.

- A. "*Consumer Price Index for all urban consumer* (U.S. city average)" (hereinafter CPI-U) means the index of consumer prices developed and updates by the U.S. Department of Labor for all urban consumers.
- B. "*Covered drug*" will have the meaning set forth in Section 8126(h)(2) and with respect to the Manufacturer includes all drug products meeting the definitions in Section 8126(h)(2). Said definitions include insulin certified under Section 506 of the Federal Food Drug and Cosmetic Act, any biological product identified in Section 600.3 of Title 21, CFR, any innovator multiple source drug and any single source drug as identified in Section 1927(k)(7)(A), of the Social Security Act. The limiting definitions in Section 1927(k)(3) of the Social Security Act do not apply. For purposes of coverage under any pharmaceutical pricing agreement entered into by the Manufacturer under this Agreement, all of those covered drugs are to be identified by the Manufacturer's eleven-digit NDC number with labeler code segment.
- C. "*Change in non-Federal price*" will have the meaning set forth in Section 8126(h)(1).
- D. "*New non-FAMP*" means the result of the computation set forth in Section 8126(h)(1)(A).

- E. “*Old non-FAMP*” means the result of the computation set forth in Section 8126(h)(1)(B).
- F. “*Depot*” will have the meaning set forth in Section 8126(h)(3), and this definition will be interpreted to include Prime Vendor contractors of the Federal Government and direct vendor distribution arrangements.
- G. “*Manufacturer*” will have the meaning set forth in Section 8126(h)(4), except, for purposes of this Agreement, it also shall mean the entity holding legal title to or possession of the NDC number for the covered drug.
- H. “*Marketed*” means when a Covered Drug was made available for sale by a manufacturer in the United States after FDA approval.
- I. “*National Drug Code (NDC)*” is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of any pharmaceutical pricing agreement made pursuant to this Agreement, the complete eleven-digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code.
- J. “*Non-Federal Average Manufacturer Price (non-FAMP)*” Shall have the meaning set forth in Section 8126(h)(5). “*Nominal prices*” excluded from the non-FAMP calculation means any price less than 10% of the non-FAMP in the previous quarter. For the first annual non-FAMP report, “nominal prices” will be determined based upon the non-FAMP for the fourth calendar quarter of 1991.
- K. “*Quarter*” means calendar quarter unless otherwise specified.
- L. “*Single form and dosage unit of the drug*” as used in the above definition of non-FAMP means a single package unit of the drug as identified by the eleven-digit NDC. The Manufacturer will specify each package unit utilized for each covered drug as part of the submission of its reporting data and will submit separate non-FAMP and ceiling data on each package unit of a covered drug.
- M. “*Secretary*” means the Secretary of Veterans Affairs, or any successor thereto, or any officer or employee of the Department of Veterans Affairs or successor agency to whom the authority to implement this Agreement has been delegated.
- N. “*Weighted average price*” with respect to the calculation of any non-FAMP will have the meaning set forth in Section 8126(h)(6).
- O. “*Wholesaler*” means merchant middleman, including a prime vendor or similar distribution system, who sells chiefly to retailers, other merchants, or industrial, institutional, and commercial users, mainly for resale or business use. For drugs

only sold directly to the retailer, other merchants, or industrial, institutional, or commercial users, the buyer will be considered to be the wholesaler.

- P. “*Federal Supply Schedule of the General Services Administration*” means the Federal Supply Schedule for drugs, biologicals and pharmaceuticals negotiated, awarded and administered by the Department of Veterans Affairs.

## **II. MANUFACTURER’S RESPONSIBILITIES**

In consideration for the Secretary entering into this Agreement and reporting to the Secretary of Health and Human Services the Manufacturer’s execution of this Master Agreement (requirements for the Manufacturer to receive payment for the purchase of drugs or biologicals by the Federal Agencies and other entities described in Section 8126(a)(4)), the Manufacturer agrees to the following:

- A. Beginning January 1, 1993, the Manufacturer shall make available for procurement on the Federal Supply Schedule (“FSS”) of the General Services Administration each covered drug of the Manufacturer. To meet the requirement that it make available its covered drugs for procurement on the FSS, the Manufacturer must negotiate in good faith with VA to enter into a FSS contract or modification for any covered drug not already on FSS within the prescribed framework of the Federal Acquisition Regulation, the General Services Acquisition Regulation, the Veterans Affairs Acquisition Regulations and the GSA Handbook.
- B. 1. With respect to any covered drug of the Manufacturer procured by a Federal agency described in Section 8126(b) on or after January 1, 1993, that is purchased under Depot contracting systems or listed on the Federal Supply Schedule, the Manufacturer will have in effect a Pharmaceutical Pricing Agreement (“PPA”) with the Secretary under which the price charged during the one-year period beginning on the date on which the PPA takes effect may not exceed 76 percent of the non-Federal Average Manufacturer Price (“non-FAMP”) (less the amount of any additional discount required under Section 8126(c)) i.e., “the annual Federal ceiling price”, during the one-year periods as designated by the Secretary in this Agreement. The PPA will specify the annual Federal ceiling price for each covered drug of the manufacturer, calculated as  $.76$  of the non-FAMP for the appropriate one-year period minus any additional discount  $[(.76 \times \text{non-FAMP}) - \text{additional discount}]$ .
2. The annual Federal ceiling price (including any additional discount) will be computed once each calendar year (beginning in 1992 for existing covered drugs), and it will be inserted into the Manufacturer’s amended or new PPA for each covered drug on or before January 1 of the following year. The requirement that the Manufacturer enter into a PPA for each covered drug applies equally to new covered drugs not previously purchased by the Federal Government and covered drugs that are the subject of existing Government contracts.

3. All Multiyear contracts for covered drugs, including those entered into prior to January 1, 1993, are subject to the annual Federal ceiling price calculation under Section 8126(a)(2) and (c). For purposes of this agreement only, existing multiyear contracts, regardless of when entered into, will be deemed to be entered into on January 1, 1993. In the second and subsequent years of a multiyear Government contract for a covered drug, if the Manufacturer wishes to raise the contract price, the annual Federal price ceiling will be calculated by two methods. First, Section 8126(d)(1) calls for the actual FSS contract price charged during the preceding one-year period to be increased by the annual percentage increase in the CPI-U, and, second, Section 8126(d)(2) calls for the reported annual non-FAMP for the preceding year to be multiplied by .76, minus any additional discount. The method of calculation that yields the lowest price ceiling will determine the Federal ceiling price for the second year or a subsequent year of such a contract. If the Manufacturer chooses not to raise the contract price, the Federal ceiling price for the second and subsequent years will be calculated only under the second method above.

4. For purposes of calculating the 1992 annual non-FAMP in PPA's to be entered into as of January 1, 1993, the Manufacturer will utilize the Secretary's designated year-long period for computation: October 1, 1991 through September 30, 1992. The Manufacturer will utilize the Secretary's designated period for calculation of the New non-FAMP under Section 8126(h)(1)(A), July 1, 1992 through September 30, 1992 for PPA's to be entered into as of January 1, 1993. The Secretary has designated the period for calculation of the old non-FAMP as July 1, 1991 through September 30, 1991, and has designated the months for computing the percentage increase in the CPI-U under Section 8126 (c) as September 1991 and September 1992. For purposes of calculating the additional discount on covered drugs that are the subject of existing multiyear contracts with the Government, the Manufacturer will utilize for its New non-FAMP calculation the third quarter of 1992 and for its old non-FAMP the third quarter of 1991. For the purposes of calculating the increase in the CPI-U, the annual non-FAMP and the additional discount in 1993 and subsequent years, the same time periods identified in this paragraph, advanced by one year annually, will be used.

5. All non-FAMP's will be calculated based upon net prices paid by wholesalers as that term is defined above. In other words, all weighted average price computations will be net of all cash discounts and similar price reductions including rebates, charge backs and incentive use based reductions or credits (where a buyer realizes a net reduced price with increased utilization of a product). All such computations may exclude sales returns, but these must be supported by records of return and the value of those returns are realized by the customer. The Manufacturer's non-FAMP calculations will be based on the annual accrual method whenever that data is available, and they will reflect generally accepted accounting principles.

- C. Beginning on January 1, 1993, the Manufacturer's price charged for each of its covered drugs sold to a State home receiving funds under Section 1741 of Title 38, U.S.C., will not exceed the price charged by the Manufacturer under the FSS at the time said covered drugs are procured.
- D. In compliance with Section 8126(e), the Manufacturer will report to the Secretary for each covered drug the price of which is determined in accordance with a PPA the following information at the times specified.
- 1) not later than December 7, 1992, the non-FAMP for each such covered drug during the one-year period that ends on September 30, 1992, along with the non-FAMP information necessary to calculate the additional discount under Section 8126(c); and
  - 2) not later than 30 days after the last day of each quarter for which a PPA is in effect, the non-FAMP for each such covered drug during such quarter; and
  - 3) not later than November 15, 1993, and November 15 of each succeeding year during which a PPA is in effect, the non-FAMP for each such covered drug during the one-year period that ends on the last day of the quarter previous to November 15, i.e., the one-year period that ends on September 30, 1993, and on September 30 of each succeeding year during which a PPA is in effect.

The Manufacturer will retain all records relevant to generation of the above reports and the calculations of annual Federal price ceilings for not less than five years from the date of their creation. Pursuant to Section 8126(e)(3), the Secretary or his designee will be afforded unrestricted access to said records of the Manufacturer as necessary to audit the records to determine the accuracy of the Manufacturer's non-FAMP data and ceiling price calculations.

- E. In a case in which a new FSS contract or a modification to an existing contract that adds the Manufacturer's covered drugs to FSS and is signed subsequent to January 1, 1993, the three-month period used to calculate the New non-FAMP for purposes of calculating the change in the non-Federal price under Section 8126(h)(1)(A), will be the calendar quarter preceding the month when the new FSS contract or modification adding covered drugs is signed.
- F. The weighted average price computation for each covered drug of the Manufacturer in any period is to be done in accordance with Section 8126(h)(6). This Section requires that the Manufacturer determine all of the prices at which a package unit, as identified by the eleven-digit NDC of a covered drug, was sold to wholesalers, that each of these prices be multiplied by the quantity of package units sold at each price during the period and that the products of these multiplications for each class of trade be added together and then divided by the total quantity of package units sold during the period.

- G. The Manufacturer will submit all reports under this Agreement to the Secretary or his designee in the electronic format described in Appendix A, which is attached to this Agreement and incorporated herein. If during a particular reporting period a Manufacturer is unable to generate and transmit the required reporting in said electronic form, the Manufacturer will so inform the Secretary prior to the deadline for submitting its report and the Secretary will determine a reporting format.
- H. If during the life of this Agreement the Manufacturer adds to its PPA's a new covered drug or a new package unit (new NDC number item) for which there exists no data or data insufficient to calculate any non-FAMP or additional discount, the Manufacturer will so inform the Secretary and the Secretary will determine a method for calculating the annual non-FAMP used to determine the Federal price ceiling for the new drug or new item during the first year that it is marketed. For new covered drugs marketed for less than one year, all data available will be used.

### III. THE SECRETARY'S RESPONSIBILITIES

- A. Pursuant to Section 8126(e)(4), any proprietary information contained in a report submitted to the Secretary under paragraph (1) of Section 8126(e) or obtained by the Secretary through any audit conducted under paragraph (3) of said Section which has been disclosed by the Manufacturer in connection with this Agreement shall remain confidential, except as the Secretary determines necessary to carry out the provisions of Section 8126 and to permit the Comptroller General and the Director of the Congressional Budget Office to review the information provided.
- B. Pursuant to Section 8126 (f), the Secretary will supply to the Secretary of Health and Human Services, upon the execution or termination of this Master Agreement, the name of the Manufacturer and the fact that it has entered into or terminated this Agreement.
- C. The Secretary will supply to the Federal agencies named in the preamble to this Agreement which purchase the Manufacturer's covered drugs, upon execution or termination of this Master Agreement, the name of the Manufacturer and the fact that it has executed or terminated this Agreement. The Secretary will also supply said Federal agencies with the annual Federal ceiling price for each covered drug purchased by them from the Manufacturer. The Secretary will adopt measures designed to prevent the unauthorized dissemination by any Federal employee of the Manufacturer's confidential information to the Manufacturer's competitors, members of the public or Government officials not involved in Federal procurement of the Manufacturer's covered drugs.
- D. Notwithstanding the non-renewal or termination of this Agreement for any reason, the above confidentiality provisions will remain in full force and effect.

#### IV. PENALTY PROVISIONS

- A. As set forth in Section 1927(b)(3)(B) of the Social Security Act, the Secretary may survey wholesalers and manufacturers that directly distribute covered drugs, when necessary, to verify the Manufacturer's non-FAMP and ceiling prices reported under Section 8126(e)(1). The Secretary may impose a civil monetary penalty in an amount not to exceed \$100,000.00 on a wholesaler, Manufacturer, or direct seller, if the wholesaler, Manufacturer, or direct seller of a covered drug refuses a request for information about charges or prices by the Secretary in connection with doing such a survey or knowingly provides false information.
- B. Pursuant to Section 1927(b)(3)(C) of the Social Security Act, if the Manufacturer fails to provide information required under Section 8126(e)(1) of Title 38, U.S.C., on a timely basis, the amount of the penalty shall be \$10,000.00 per day for which such information has not been provided and such amount shall be paid to the Treasury, and if such information is not reported within 90 days of the deadline imposed, this Agreement shall be suspended after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).
- C. Pursuant to Section 1927(b)(3)(C) of the Social Security Act, if the Manufacturer knowingly provides false information in discharging its obligations under this Agreement, it will be subject to a civil money penalty in an amount not to exceed \$100,000.00 for each item of false information. Such civil money penalty(s) is (are) in addition to any other penalties that may be prescribed by law.
- D. Notice and hearing procedures, if any, required by the Social Security Act for imposition of the above penalties will be afforded by the Secretary of Veterans Affairs.

#### V. DISPUTE RESOLUTION

- A. If a dispute arises between the Manufacturer and the Secretary concerning the amount to be specified in a PPA as the annual Federal ceiling price of any covered drug and the Manufacturer in good faith believes that the amount specified by the Secretary is erroneous under the terms, the Manufacturer will so notify the Secretary in writing within five working days after discovering the alleged error.
- B. The Secretary and the Manufacturer will devote their best efforts in order to resolve any dispute concerning the correct annual Federal price ceiling for a covered drug within 30 days of the Secretary's receipt of the Manufacturer's notification of the alleged error. In the event that the Secretary and the Manufacturer are not able to resolve the dispute concerning the Federal ceiling price, the Secretary will make available to the Manufacturer the hearing

mechanism set forth in the Contract Dispute Act or, if VA Board of Contract Appeals declines jurisdiction, a similar hearing mechanism established by the Secretary for rendering a decision on the correct annual Federal price ceiling to be used in the Manufacturer's PPA.

- C. During the time in which the Secretary and the Manufacturer are attempting to resolve a good faith dispute concerning the correct annual Federal price ceiling under the above provisions, if the Manufacturer is in compliance with all other provisions of the Veterans Health Care Act of 1992, entities listed in Section 8126(a)(4) may continue to purchase a covered drug which is the subject of a dispute. Payments for said purchases will be limited to the price determined by the VA. Disputed amounts will be suspended until 15 working days after the dispute is resolved by the parties or by the VA Board of Contract Appeals or other administrative entity hearing the dispute.

#### VI. NON-RENEWAL AND TERMINATION

- A. Unless terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an initial period of one year beginning on January 1, 1993 and shall be automatically renewed for additional successive terms of one year unless the Manufacturer gives written notice of intent not to renew the Agreement at least 90 days before the end of the then current period.
- B. The Manufacturer may terminate this Agreement for any reason, and such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, or the ending date of the then-current term of this Agreement if notice has been given in accordance with Paragraph A, above.
- C. The Secretary may terminate this Agreement for a violation of the Agreement, violation of a PPA entered into pursuant to this Agreement, or for other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide the Manufacturer, upon its written request, with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.
- D. If this Agreement is not renewed or is terminated, the Manufacturer will be prohibited from entering into another such Agreement until a period of at least one calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for early reinstatement.
- E. Any non-renewal or termination of this Agreement will not affect payments to the Manufacturer for covered drugs purchased or ordered before the effective date of the termination.

## VII. GENERAL PROVISIONS

- A. Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing via certified mail. Notice to the Secretary will be sent to:

*Deputy Assistant Secretary for Acquisition and Material Management (049)*  
Department of Veterans Affairs  
810 Vermont Avenue N W  
Washington, DC 20420

Notice to the Secretary concerning data transfer and information systems issues are to be sent to:

*Chief, Drugs and Pharmaceuticals Products Management Section*  
P.O. Box 126  
Hines, IL 60141

Addresses listed above may be updated upon written notice to the Manufacturer. Notice to the Manufacturer will be sent to the address specified by it in the authorized contact portions of its annual non-FAMP report submitted to the Secretary, as updated by any Manufacturer's written notification to the Secretary at the first address specified above.

- B. In the event of transfer of ownership of the Manufacturer, this Agreement is automatically assigned to the new owner, subject to the new owner meeting the requirements and this Agreement.
- C. Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.
- D. This Agreement shall be construed in accordance with the Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.
- E. Except for changes in the notification addresses specified in paragraph VII(A) above, this Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.
- F. In the event that a due date falls on a weekend or Federal holiday, the report or other item required by this Agreement will be due on the first business day following that weekend or Federal holiday.

- G. The Manufacturer agrees that all reports submitted to the Secretary as required under this Agreement will be considered certified as accurate to the best knowledge and belief of the Manufacturer, regardless of which of the Manufacturer's employees has approved and authorized the report.
- H. Appendix A attached hereto is a part of this Agreement.
- I. Except as otherwise indicated, all references herein to a section will be deemed to be references to a section of Title 38, U.S.C.

**VIII. SIGNATURES**

FOR THE SECRETARY OF VETERANS AFFAIRS

SIGNATURE: \_\_\_\_\_ DATE: \_\_\_\_\_

TITLE: Assistant Director – FSS

ACCEPTED FOR THE MANUFACTURER: I certify that I have made no alterations, amendments or other changes to this Master Agreement.

NAME OF MANUFACTURER: \_\_\_\_\_

SIGNATURE: \_\_\_\_\_ DATE: \_\_\_\_\_

TITLE: \_\_\_\_\_

MANUFACTURER'S ADDRESS: \_\_\_\_\_

MANUFACTURER'S LABELER CODE(s): \_\_\_\_\_

