ADDENDUM TO CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE

I. PREAMBLE

Effective April 15, 2003, SmithKline Beecham Corporation d/b/a GlaxoSmithKline (GlaxoSmithKline) entered into a Corporate Integrity Agreement with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) (hereinafter referred to as the "CIA"). GlaxoSmithKline hereby enters into this Addendum to the CIA (hereinafter referred to as the "Addendum" or the "CIA Addendum"). Contemporaneously with this Addendum, GlaxoSmithKline is entering into a Settlement Agreement with the United States, and the CIA and this Addendum are incorporated by reference into that Settlement Agreement. GlaxoSmithKline is also prepared to enter into related settlement agreements with various States (the Related State Settlement Agreements), and GlaxoSmithKline's agreement to the CIA and to this Addendum is a condition precedent to those agreements.

II. TERM AND SCOPE OF THE CIA AND THE CIA ADDENDUM

A. Continuation of CIA and Term of the CIA Addendum.

All of the obligations assumed by GlaxoSmithKline under the CIA shall continue for the period set forth in the CIA. In addition, unless otherwise specifically revised by this Addendum or excepted, all of the provisions of the CIA shall be and hereby are incorporated into this Addendum and shall remain in full force and effect during the period covered by this Addendum, with the following exceptions: Section III.D of the CIA (entitled "Review Procedures"), the Annual Report requirements of Section V.B of the CIA which relate to the Medicaid Rebate System Review and Contract Pricing Review required by the CIA, Attachment A to the CIA (entitled "Medicaid Rebate and Contract Pricing Reviews") and Attachment B to the CIA (entitled "Certification"). These excepted provisions shall continue only for the period set forth in the CIA.

The period covered by this Addendum, during which the compliance obligations agreed to by GlaxoSmithKline under this Addendum (including the non-excepted provisions of the original CIA) shall be in effect, shall be five years from the Effective Date of this Addendum. The Effective Date of this Addendum shall be the date on which the final signatory to this Addendum executes the document.

B. Certain Definitions.

1. "Covered Persons," both as used in the CIA and in this Addendum, shall hereinafter refer to:

   a. all employees, contractors, and agents of the Managed Care Business Units within the U.S. Pharmaceuticals Division of GlaxoSmithKline (U.S. Pharma) who have job responsibilities relating to: a) marketing or selling products to managed care entities; b) reporting of pricing information for any products that are reimbursed by Federal health care programs (Government Reimbursed Products), including under the Medicaid Drug Rebate Program, codified at 42 U.S.C. § 1396r-8; or c) obligations related to government contracts, including the agreements entered with the Department of HHS under the Medicaid Drug Rebate Program and the Drug Pricing Program under the Public Health Service (PHS) Act, 42 U.S.C. § 256.

   b. Specifically excluded from this definition of "Covered Persons" are employees, contractors, and agents of the following groups within the Managed Care Business Units of US Pharma: Professional and State Government Affairs; Trade Sales and Operations; and the Neurohealth Specialty Division.

2. "Additional Covered Persons," as used in this Addendum, shall refer to:

   a. all employees, contractors, and agents of U.S. Pharma whose job responsibilities relate to marketing or selling Government Reimbursed Products, including all sales representatives who are involved in detailing health care professionals.

   b. Specifically included in the definition of "Additional Covered Persons" are employees, contractors and agents of the following Business Units and departments of U.S. Pharma: General Pharmaceuticals – RTP, General Pharmaceuticals – PHL, Vaccines, HIV, Oncology, Neurohealth, New Product Planning, Marketing Analysis & Commercial Support, Trade Sales and Operations, Professional & State Government Affairs, Brand Reputation and Communications.

   c. Specifically excluded from the definition of "Additional Covered Persons" are employees, contractors, and agents of the following Business Units and departments of U.S. Pharma: Human

Resources, Finance, and Federal Government Relations & Public Policy.

3. "Relevant Covered Persons," both as used in the CIA and in this Addendum, shall hereinafter refer to all Covered Persons in the Pricing, Contract Strategy and Operations Group of the Managed Care Business Units and the PBM Segment Business Analysis Manager.

4. Other Entities or Individuals Included or Excluded.

   a. GlaxoSmithKline has entered or may enter joint venture agreements and agreements to co-market its products with other entities. The personnel of the entities with whom GlaxoSmithKline has or may, in the future, have such agreements shall be collectively referred to as "Third Party Personnel." GlaxoSmithKline has represented that: 1) the Third Party Personnel are employed by other pharmaceutical manufacturers; 2) GlaxoSmithKline does not control the Third Party Personnel; and 3) it would be commercially impracticable to compel their compliance with the requirements set forth in this Addendum or the CIA.

However, GlaxoSmithKline agrees to use its best efforts to promote compliance by the Third Party Personnel with Federal health care program requirements. In order to fulfill this obligation, GlaxoSmithKline agrees to the following:

1. Within 90 days after the Effective Date of this Addendum, and annually thereafter by the anniversary of the Effective Date of this Addendum, GlaxoSmithKline shall send a letter to all entities with which it has entered joint venture and co-market agreements to market GlaxoSmithKline's products. The letter shall outline GlaxoSmithKline's obligations under the Addendum and the CIA and its commitment to full compliance with all Federal health care program requirements. The letter shall include a description of GlaxoSmithKline's compliance program. GlaxoSmithKline shall attach a copy of its Code of Conduct to the letter and shall ask that the other entity either: (a) make a copy of GlaxoSmithKline's Code of Conduct and the description of GlaxoSmithKline's compliance program available to all relevant personnel within its organization, or (b) represent to GlaxoSmithKline that it has and enforces a substantially comparable Code of Conduct and compliance program for relevant persons within its organization.

2. GlaxoSmithKline shall submit: i) a copy of each such letter (including all attachments); ii) a list of all GlaxoSmithKline's existing joint venture and co-marketing agreements, and iii) a description of the entities' response to GlaxoSmithKline's letter to the OIG with the Implementation Report and each Annual Report.

b. The terms "Covered Persons," "Additional Covered Persons," and "Relevant Covered Persons," specifically include all personnel, apart from those acting under joint venture or co-marketing agreements, who comprise U.S. Pharma's contract sales force, if any.

c. The terms "Covered Persons," "Additional Covered Persons," and "Relevant Covered Persons," do not include any contractors or agents retained to provide consulting or business advice to GlaxoSmithKline who are not engaged directly in any: a) marketing or selling products to managed care entities; b) reporting of pricing information for any Government Reimbursed Products, c) obligations related to government contracts and d) marketing or selling Government Reimbursed Products on behalf of GlaxoSmithKline.

d. The terms "Covered Persons", "Additional Covered Persons," and "Relevant Covered Persons," do not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more 160 hours per calendar year, except that any such individuals who would otherwise qualify shall become "Covered Persons," "Additional Covered Persons," and/or "Relevant Covered Persons" at the point when they work more than 160 hours during the calendar year.

5. "Addendum Reporting Period," as used in this Addendum, shall mean each one-year period, beginning with the one-year period following the Effective Date of this Addendum. The Addendum Reporting Periods shall remain in effect until the expiration of the term of this Addendum, and the Reporting Periods set forth in the CIA shall remain in effect only through the expiration of the term of the CIA.

III. CIA AND ADDENDUM OBLIGATIONS

GlaxoSmithKline shall maintain a Compliance Program for U.S. Pharma that includes all the elements specified in the CIA and the additional new obligations created by this Addendum:

A. **Compliance Officer and Committee.**

The terms of Section III.A of the CIA remain in effect and GlaxoSmithKline shall continue its obligations under Section III.A through the term of this Addendum.

B. **Written Standards.**

1. *Code of Conduct.* The terms of Section III.B.1 of the CIA remain in effect and GlaxoSmithKline shall continue its obligations under Section III.B.1 through the term of this Addendum. In addition, to the extent not already accomplished, the distribution and certification requirements for the Code of Conduct set forth in Section III.B.1 of the CIA shall apply to both Covered Persons and Additional Covered Persons through the term of this Addendum, except that GlaxoSmithKline is provided 150 days after the Effective Date of this Addendum to implement these requirements for Additional Covered Persons. GlaxoSmithKline may choose to accomplish the distribution and certification requirements for the Code of Conduct in conjunction with the general training requirements set forth in Section III.C.1 below.

2. *Policies and Procedures.* The terms of Section III.B.2 of the CIA remain in effect and GlaxoSmithKline shall continue its obligations under Section III.B.2 throughout the term of this Addendum. In addition, to the extent not already accomplished, within 60 days after the Effective Date of this Addendum, the Policies and Procedures shall be amended to address the methods for gathering, calculating, verifying, and reporting Average Sales Prices as required for purposes of Part B of the Medicare program under 42 U.S.C. § 1395w-3a.

C. **Training and Education.**

1. *General Training.* With respect to Covered Persons, the terms of Section III.C.1 of the CIA remain in effect and GlaxoSmithKline shall continue its obligations under Section III.C.1 through the original term of the CIA. In addition, to the extent not already accomplished, the general training requirements set forth in Section III.C.1 of the CIA shall apply to both Covered Persons and Additional Covered Persons[1] through the term of this Addendum, except that GlaxoSmithKline is provided 150 days after the

[1] Clerical, secretarial, and administrative employees who are non-exempt overtime-eligible hourly employees shall receive training on the topics set forth in Sections III.C.1.a-b of the CIA. GlaxoSmithKline has represented that such employees do not have job functions involving the topics covered by the training required under Section III.C.1.c, and that such employees report to and are supervised by Covered Persons who receive training on the topics listed in Section III.C.1.c.

Effective Date of this Addendum to implement these requirements for Additional Covered Persons.

2. *Specific Training.* The terms of Section III.C.2 of the CIA with respect to Relevant Covered Persons remain in effect and GlaxoSmithKline shall continue its obligations under Section III.C.2 through the term of this Addendum. In addition, each aspect of specific training for Relevant Covered Persons shall be expanded to include training concerning the Average Sales Price calculation and reporting requirements.

The terms of Sections III.C.3-4 of the CIA remain in effect and GlaxoSmithKline shall continue its obligations under Sections III.C.3-4 through the term of this Addendum.

D. Additional Review Procedures.

The Review Procedures set forth in Section III.D of the CIA shall remain in effect for the term of the CIA, except that GSK may conduct the second Medicaid Rebate Systems Review required under the CIA during the third CIA Reporting Period, instead of the fourth Reporting Period, to overlap with the first systems review required under this Addendum.

In addition, the following Additional Review Procedures shall be established and shall remain in effect through the term of this Addendum:

1. *General Description of Additional Review Procedures.*

a. Retention of Independent Review Organization for Additional Reviews. Within 90 days after the Effective Date of this Addendum, GlaxoSmithKline shall retain an entity (or entities) such as an accounting, auditing, or consulting firm (hereafter "Independent Review Organization" or "IRO") to perform two additional reviews, as specified below and more fully described in Attachment A to this Addendum. GlaxoSmithKline may select the same IRO for purposes of complying with this Addendum section as it previously selected under the CIA, or a different IRO, provided two conditions are met. First, each IRO retained by GlaxoSmithKline pursuant to this Addendum shall have expertise in auditing and the requirements of Medicaid and Medicare Programs (including the requirements of the Medicaid Drug Rebate Program and the requirements for reimbursement of prescription drugs under the Medicare Program) as they relate to the calculation and reporting of Average Manufacturer Price (AMP) and Average Sales Price (ASP). Second, each IRO shall assess, along with GlaxoSmithKline, whether it can perform the IRO reviews in a professionally independent and/or objective fashion, as

appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist, and must find that it can, in fact, perform the reviews in a professionally independent and/or objective fashion.

b. Types and Frequency of Additional Reviews. The IRO or IROs retained pursuant to this Addendum shall conduct two types of reviews (in addition to those set forth in the CIA). Both of these Additional Reviews shall be focused on: (a) the AMP for the AMP Covered Products, as defined in Appendix A to this Addendum, and (b) the ASP for the ASP Covered Products, as defined in Appendix A.

The two Additional Reviews are:

First, as set forth more fully in Attachment A to this Addendum, the IRO shall perform an AMP/ASP Systems Review that shall address GlaxoSmithKline's systems, processes, policies, and practices associated with tracking, gathering, and accounting for all relevant data for purposes of appropriately calculating AMPs and ASPs reported under the Medicaid Drug Rebate Program and the Medicare Programs, respectively. Second, as set forth more fully in Attachment A to this Addendum, the IRO shall conduct an AMP/ASP Transactions Review that shall address and analyze GlaxoSmithKline's systems, policies, and practices with regard to specific transactions affecting the calculation of AMPs and ASPs.

If there are no material changes in GlaxoSmithKline's AMP/ASP related systems, processes, policies, and practices during the term of this Addendum, the IRO shall perform the AMP/ASP Systems Review for the first and fourth Addendum Reporting Periods. If GlaxoSmithKline materially changes its systems, processes, policies, and practices, then the IRO shall perform an AMP/ASP Systems Review for the Addendum Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Addendum Reporting Periods. The AMP/ASP Transactions Review shall be performed annually. The IRO shall perform all components of each Review.

c. Retention of Records. The IRO and GlaxoSmithKline shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and GlaxoSmithKline) related to the Additional Reviews.

2. *Additional Reviews Report(s).* The IRO shall prepare a report (or reports) based upon the AMP/ASP Systems Review and the AMP/ASP Transactions Review performed (the "Additional Reviews Report"). Information to be included in the Additional Reviews Report is detailed in Attachment A to the CIA Addendum.

3. *Validation Review and Independence/Objectivity Certification.* The provisions of Sections III.D.5 and 6 of the CIA shall apply in the same manner specified therein to each of the Additional Reviews required by this Addendum.

E. Disclosure Program.

The terms of Section III.E of the CIA remain in effect and GlaxoSmithKline shall continue its obligations under Section III.E through the term of this Addendum.

F. Ineligible Persons.

Except as otherwise specified herein, the terms of Section III.F of the CIA remain in effect, and GlaxoSmithKline shall continue its obligations under Section III.F through the term of this Addendum.

The first sentence in Section III.F.3 shall be modified to read as follows: "Within 120 days after the Effective Date of this Addendum, GlaxoSmithKline shall review its list of Covered Persons and Additional Covered Persons (hereafter collectively "Ineligibility Relevant Covered Persons") against the Exclusion Lists." The remainder of Section III.F.3 shall remain unchanged and in effect through the term of this Addendum.

G. Notification of Government Investigations or Legal Proceedings.

Except as otherwise specified herein, the terms of Section III.G of the CIA remain in effect and GlaxoSmithKline shall continue its obligations under Section III.G through the term of this Addendum. The first sentence in Section III.G shall be modified to read as follows: "Within 30 days after discovery by senior management at GlaxoSmithKline's corporate headquarters, GlaxoSmithKline shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to GlaxoSmithKline conducted or brought by a governmental entity or its agents involving an allegation that GlaxoSmithKline has committed a crime or has engaged in fraudulent activities."

H. **Reporting of Reportable Events.**

The terms of Section III.H of the CIA remain in effect and GlaxoSmithKline shall continue its obligations under Section III.H through the term of this Addendum.

I. **Reporting Requirements.**

This new Section III.I shall remain in effect and GlaxoSmithKline shall comply with its obligations under this Section III.I through the term of this Addendum.

1. *General Statement of Purpose and Intent.* On a quarterly basis, GlaxoSmithKline shall report to the entities identified below in Section III.I.2.c certain pricing information, as specified below in Sections III.I.2.a and b (collectively referred to as the "Pricing Information"). In particular, GlaxoSmithKline will report an ASP, as defined in Section III.I.2.a below, for the "ASP Covered Products" described in Appendix A, and GlaxoSmithKline will also report an AMP, as defined in Section III.I.2.b below, for the "AMP Covered Products" described in Appendix A. Such Pricing Information shall be provided subject to the confidentiality provisions set forth in Section IX of the CIA and the other confidentiality provisions and conditions set forth herein, in the Related State Settlement Agreements, or otherwise required by law.

2. *Specific Reporting Requirements.*

a. Average Sales Price Defined. For purposes of this CIA, "Average Sales Price" or "ASP" is defined to have the meaning of, and will be calculated in accordance with, Average Sales Price as defined in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), as amended, including any refinement of that definition that may be made by the Secretary of the Department of Health and Human Services through the issuance of regulations, written directives, or guidance. GlaxoSmithKline shall report, under this Addendum, the same Average Sales Prices for the same formulations of the ASP Covered Drugs that it reports to CMS pursuant to the MMA (calculated in the way that GlaxoSmithKline calculates ASPs when reporting them to CMS), and shall report these ASPs in the same electronic format used by GlaxoSmithKline to report ASPs to CMS under the MMA.

b. Average Manufacturer Price Defined. For purposes of this CIA, "Average Manufacturer Price," or "AMP," is defined to have the meaning of, and will be calculated in accordance with, Average Manufacturer Price as defined by 42 U.S.C. § 1396r-8(k)(1) and the Medicaid National Drug

Rebate Agreement, as interpreted by GlaxoSmithKline in accordance with CMS Program Releases and guidance concerning the calculation of AMP (collectively the "Medicaid Drug Rebate Program"). In accordance with these authorities, GlaxoSmithKline's AMPs will reflect the average price paid to the manufacturer for particular dosage forms and strengths of a drug when the drug is distributed to the "retail pharmacy class of trade," and will account for discounts (not just prompt payment discounts), purchaser rebates and chargebacks, including those provided to wholesalers and distributors, as well as those provided to drug purchasers that have been determined to be part of the retail pharmacy class of trade. GlaxoSmithKline shall report, under this Addendum, the same Average Manufacturer Prices for the same formulations of the AMP Covered Products that GlaxoSmithKline calculates and reports to CMS on a quarterly basis for each AMP Covered Product, along with any retroactive AMP adjustments that GlaxoSmithKline reports to CMS. GlaxoSmithKline shall report these AMPs and adjustments in the same electronic format used to report this information to CMS under the Medicaid Drug Rebate Program.

c. Reporting Obligations for ASP Covered Products and AMP Covered Products. Except as otherwise noted below, within 35 days after the last day of each calendar quarter, GlaxoSmithKline shall report, in accordance with Sections III.I.2.a and b above, the ASPs for the ASP Covered Products that GlaxoSmithKline has reported for that calendar quarter to CMS pursuant to the MMA, and the AMPs (and prior-quarter AMP adjustments) for the AMP Covered Products that GlaxoSmithKline has reported for that calendar quarter to CMS pursuant to the Medicaid Drug Rebate Program. GlaxoSmithKline shall make these reports to: 1) the Medicaid programs of those States that have entered into a Related State Settlement Agreement with GlaxoSmithKline; and 2) to a commercial drug price reporting service (such as First Data Bank, Inc.) designated by any state that has entered into a Related State Settlement Agreement and has received GlaxoSmithKline's ASPs and AMPs thereunder. The Pricing Information shall be reported to the commercial drug price reporting service[2] solely for the purposes of reporting pricing information to the Medicaid programs of those States that entered Related State Settlement Agreements and subject to the confidentiality provisions referenced in Section III.I.2.e.

[2] If appropriate to reflect changes in the sources from which the State Medicaid programs receive their Pricing Information, GlaxoSmithKline agrees that, upon the receipt of a written request by any of the States that have entered into a Related State Settlement Agreement, it will report the required information to a drug price reporting source other than, and in addition to, the drug price reporting service originally designated by the State, subject to the confidentiality provisions referenced in Section III.I.2.e.

The first report of ASPs and AMPs hereunder shall be made to each State that has entered into a Related State Settlement Agreement, and to the commercial drug price reporting service (such as First DataBank, Inc.) designated by any such State, within 35 days after the end of the first full calendar quarter following the Effective Date of that State's Related State Settlement Agreement.

d. Certification Requirement. A high managerial agent of GlaxoSmithKline will certify that the ASPs and AMPs reported hereunder are calculated in accordance with requirements and definitions set forth in Sections III.I.2.a-c above. Said certifications shall be made in the form attached hereto as Attachment B, and shall include an acknowledgment that the ASPs reported are those that have been reported to CMS pursuant to the MMA, and that the AMPs (and prior-quarter AMP adjustments) reported are those that have been reported to CMS pursuant to the Medicaid Drug Rebate Program. GlaxoSmithKline agrees that this certification by an appropriate employee or agent of GlaxoSmithKline constitutes a certification by GlaxoSmithKline.

e. Confidentiality of Reported Pricing Information. GlaxoSmithKline considers the Pricing Information it will report under this Section III.I to be confidential commercial information and proprietary trade secrets that if disclosed may cause substantial injury to the competitive position of GlaxoSmithKline. The Related State Settlement Agreements will contain certain confidentiality provisions governing the treatment of the reported Pricing Information. GlaxoSmithKline will enter good faith negotiations with the commercial drug prices reporting service(s) to reach a mutually acceptable confidentiality agreement to govern the handling of Pricing Information reported by GlaxoSmithKline to the commercial drug price reporting service. Among other provisions, such confidentiality agreement shall: a) permit the commercial drug price reporting service to disclose GlaxoSmithKline's Pricing Information only to the Medicaid programs of those states that have entered into a Related State Settlement Agreement with GlaxoSmithKline and the disclosure shall be made pursuant to the terms of the Related State Settlement Agreement; and b) require GlaxoSmithKline's Pricing Information to otherwise be kept strictly confidential.

f. Document Retention. GlaxoSmithKline shall retain all supporting work papers and documentation relating to the ASPs of its ASP Covered Products and the AMPs of its AMP Covered Products for the longer of six years after the Effective Date of this Addendum or as otherwise required by law, and shall make such documentation available for inspection by the

OIG or its duly authorized representative(s) in accordance with the provisions set forth in Sections VII and VIII of the CIA.

IV. NEW BUSINESS UNITS OR LOCATIONS

Section IV of the CIA shall be amended to read as follows and shall remain in effect through the term of this Addendum.

In the event that, after the Effective Date of this Addendum, GlaxoSmithKline establishes or acquires new business units engaged in contracting with managed care entities or in functions relating to the Medicaid Drug Rebate Program, the Drug Pricing Program, or sales and marketing of Government Reimbursed Products, GlaxoSmithKline shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of such establishment or acquisition. This notification shall include the address of the new business unit, phone number, fax number, Federal health care provider number (if any), and the corresponding contractor's name and address that has issued each Federal health care program provider number. All Covered Persons and Additional Covered Persons at each such business unit shall be subject to the applicable requirements in this CIA and Addendum (e.g., completing certifications and undergoing training.)

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 180 days after the Effective Date of the Addendum, GlaxoSmithKline shall submit a written report to the OIG summarizing the status of its implementation of its requirements under this Addendum. This Implementation Report shall include:

1. a certification by the Compliance Officer that:

   a. all Additional Covered Persons have completed the Code of Conduct certification required by Section III.B.1;

   b. the Policies and Procedures required by Section III.B.2 have been amended to address the calculation of ASP, and have been distributed to all appropriate Additional Covered Persons; and

   c. all Additional Covered Persons have completed the applicable training and executed the certifications required by Section III.C.

2. the identity of the IRO(s) retained to perform the Additional Reviews required by Section III.D of this Addendum, a summary/description of all engagements between GlaxoSmithKline

and the IRO, including, but not limited to, any outside financial audits or consulting engagements, and the proposed start and completion dates of the AMP/ASP Systems Review and the AMP/ASP Transactions Review;

3. a certification from the IRO(s) regarding its professional independence and/or objectivity with respect to GlaxoSmithKline;

4. the certification set forth in Attachment B to this Addendum;

5. the certification required by Section V.C of the CIA; and

6. the information required by Section II.B.4.a.2 of this Addendum.

B. Annual Reports. GlaxoSmithKline shall submit to OIG Annual Reports with respect to the status of, and findings regarding, GlaxoSmithKline's compliance activities for each CIA and Addendum Reporting Period. GlaxoSmithKline shall annually submit an Annual Report that addresses its compliance obligations under both the CIA and the Addendum. The first such Annual Report shall be received by OIG not later than 60 days after the end of the first Addendum Reporting Period except that the GlaxoSmithKline shall submit the items required by Sections V.B.5-6 of the CIA (relating to the IRO reports) to the OIG no later than 90 days after the end of the first Addendum Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date(s) of the due date(s) of the first combined Annual Report.

Unless otherwise indicated, each Annual Report shall include, at a minimum, all the elements set forth in Section V.B of the CIA.

In addition, Section V.B.2 of the CIA is amended to read as follows:

2. The certification set forth in Attachment B to the CIA and/or Attachment B to the Addendum as applicable, consistent with the terms of the Addendum, and a certification by the Compliance Officer that:

a. all Covered Persons and Additional Covered Persons have completed any Code of Conduct Certifications required by Section III.B.1; and

b. all Covered Persons and Additional Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C.

The documentation supporting these certifications shall be made available to OIG, upon request.

Section V.B.5 of the CIA is amended to read as follows:

5. a complete copy of all reports prepared pursuant to the IRO's Medicaid Rebate Systems Review, Contract Pricing Review, AMP/ASP Systems Review and/or AMP/ASP Transactions Review, as applicable, including a copy of the methodology used, and a copy of the IRO's engagement letter(s);

Section V.B.14 of the CIA is amended to read as follows:

14. the information required by Section II.B.4.a.2 of the Addendum.

Sections V.C-D of the CIA remain in effect and GlaxoSmithKline shall continue its obligations under Sections V.C-D through the term of the Addendum.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

The terms of Section VI of the CIA remain in effect and GlaxoSmithKline shall continue its obligations under Section VI through the term of this Addendum.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

Section VII of the CIA shall be amended to read as follows and shall remain in effect through the term of this Addendum.

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of GlaxoSmithKline's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of GlaxoSmithKline's locations for the purpose of verifying and evaluating: (a) GlaxoSmithKline's compliance with the terms of this CIA and the Addendum; and (b) GlaxoSmithKline's compliance with the applicable requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by GlaxoSmithKline to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of GlaxoSmithKline's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. GlaxoSmithKline's employees, contractors and agents shall have the right to be represented by counsel and any such individual may, at his or her option, be accompanied by counsel for GlaxoSmithKline and/or personal counsel at any

interview by the OIG. GlaxoSmithKline shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Notwithstanding such arrangement, the OIG recognizes that individuals have the right to refuse to submit to interviews, and GlaxoSmithKline shall not be obligated to require such individuals to submit to interviews. If any individual decides not to submit to an interview, such refusal shall not constitute a breach of this CIA or Addendum. GlaxoSmithKline's employees may elect to be interviewed with or without a representative of GlaxoSmithKline present.

VIII. DOCUMENTATION AND RECORD RETENTION

The terms of Section VIII of the CIA remain in effect, and GlaxoSmithKline shall continue its obligations under Section VIII through the term of this Addendum.

IX. DISCLOSURES

Section IX of the CIA shall be amended to read as follows and shall remain in effect through the term of this Addendum.

Consistent with HHS's FOIA procedures set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify GlaxoSmithKline prior to any release by OIG of information submitted or made available by GlaxoSmithKline pursuant to its obligations under this CIA and Addendum and identified upon submission by GlaxoSmithKline as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, GlaxoSmithKline shall have the rights set forth at 45 C.F.R. § 5.65(d). The OIG shall provide the pre-disclosure notice required pursuant to 45 C.F.R § 5.65(d) to the Compliance Officer at the address provided in Section VI.

X. BREACH AND DEFAULT PROVISIONS

Except as otherwise specified below, the terms of Section X of the CIA remain unchanged and shall continue in effect through the term of this Addendum. The terms of Section X apply to the new obligations contained in the Addendum to the CIA in the same manner in which they apply to the compliance obligations contained in the CIA.

Section X.A.1 is amended to include two additional items:

g. Ineligible Persons screening and removal requirements; and

h. Notification of Government investigations or legal proceedings.

XI. EFFECTIVE AND BINDING AGREEMENT

The terms of Section XI of the CIA remain unchanged and shall remain in effect through the term of this Addendum.

ON BEHALF OF SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE

Arjun Rajaratnam
Vice President & Compliance Officer
Global Pharmaceuticals
GlaxoSmithKline

9/2/05
DATE

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ON BEHALF OF SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE

Arjun Rajaratnam
Vice President & Compliance Officer
Global Pharmaceuticals
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Sept. 2 2005
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9/2/05

DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Lewis Morris
Chief Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

9/2/05
DATE

Appendix A to CIA Addendum

LIST OF PRODUCTS FOR WHICH GLAXOSMITHKLINE GOVERNMENT PRICING INFORMATION WILL BE REPORTED

The products described in this Appendix are the "ASP Covered Products" and the "AMP Covered Products" for purposes of the requirements of Section III.I of the CIA Addendum and Attachments A and B thereto.

"ASP Covered Products" are all GlaxoSmithKline products for which GlaxoSmithKline reports an Average Sales Price (ASP) for Medicare Part B Covered Drugs to the Centers for Medicare & Medicaid Services (CMS) pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

"AMP Covered Products" are all Medicaid "Covered Outpatient Drugs" as defined in Sections 1927(k)(2), (k)(3) and (k)(4) of the Social Security Act, 42 U.S.C. § 1396r-8 (k)(2), (k)(3) and (k)(4); that is, products for which GlaxoSmithKline reports an Average Manufacturer Price (AMP) to CMS pursuant to the Medicaid Drug Rebate Program.

Attachment A to the CIA Addendum

AMP/ASP GOVERNMENT PRICE REPORTING ENGAGEMENT

I. AMP/ASP Government Price Reporting Engagement - General Description

As specified more fully below, GlaxoSmithKline shall retain an Independent Review Organization (IRO) to perform testing to assist GlaxoSmithKline in assessing and evaluating its systems, processes, policies and practices (including the controls on the systems, processes, policies, and practices) related to its government price reporting requirements for (a) Average Manufacturer Price (AMP) under the Medicaid Drug Rebate Program for AMP Covered Products as defined in Appendix A of the CIA Addendum; and (b) Average Sales Price (ASP) for ASP Covered Products, as defined in Appendix A of the CIA Addendum. The IRO shall perform two types of engagements: 1) a systems review of GlaxoSmithKline's systems, processes, policies, and practices relating to the calculation and reporting of AMPs pursuant to the Medicaid Drug Rebate Program and the calculation and reporting of ASPs for ASP Covered Products, pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (the "AMP/ASP Systems Review"); and 2) testing of a sample of transactions to assess whether GlaxoSmithKline is calculating AMPs for AMP Covered Products and ASPs for ASP Covered Products in accordance with the policies and procedures and methodologies developed by GlaxoSmithKline pursuant to the requirements of the Medicaid Drug Rebate Program and the MMA respectively (the "AMP/ASP Transactions Review"). The AMP/ASP Systems Review and the AMP/ASP Transactions Review are referred to herein collectively as the "AMP/ASP Government Price Reporting Engagement."

Prior to performing the AMP/ASP Government Price Reporting Engagement, the IRO and GlaxoSmithKline shall design Consulting Procedures outlining the specific work to be performed by the IRO, and the Consulting Procedures shall be submitted to the OIG for comment. However, any comments or recommendations made by the OIG in connection with a review of the submitted workplan(s) will not preclude the OIG from making further comments or recommendations for future workplan(s) after reviewing the reports from the AMP/ASP Government Price Reporting Engagement.

If there are no material changes in GlaxoSmithKline's systems, processes, policies and practices during the term of the CIA Addendum, then the IRO shall perform the AMP/ASP Systems Review covering the first and fourth Addendum Reporting Periods (as defined in Section II.B.5 of the CIA Addendum) following the Effective Date of the CIA Addendum. If GlaxoSmithKline materially changes its systems, processes, policies and practices as they relate to the calculation of AMP or ASP then the IRO shall perform an AMP/ASP Systems Review covering the Addendum Reporting Period in which such

changes were made, in addition to conducting the AMP/ASP Systems Review for the first and fourth Addendum Reporting Periods. The additional AMP/ASP Systems Review shall consist of: 1) an identification of the material changes; 2) an assessment of whether the systems, processes, policies and practices already reported on did not materially change; and 3) an update on the systems, processes, policies and practices that materially changed.

The AMP/ASP Transactions Review shall be designed to test whether GlaxoSmithKline is calculating AMPs and ASPs in accordance with the policies and procedures and methodologies developed by GlaxoSmithKline pursuant to the requirements of the Medicaid Drug Rebate Program and the MMA. The AMP/ASP Transaction Review shall consist of two parts, the "Reported Prices Procedures for ASP" and the "Reported Prices Procedures for AMP."

II. AMP/ASP Systems Review

A. Average Sales Price Systems Review

For at least the first and fourth Addendum Reporting Periods following the Effective Date of this Addendum, the IRO shall review GlaxoSmithKline's systems, processes, policies and practices (including the controls on the systems, processes, policies, and practices) associated with the tracking, gathering, and accounting for all relevant data for purposes of calculating ASPs reported for ASP Covered Products to the Centers for Medicare and Medicaid Services (CMS) as required under the MMA.

In general terms, the IRO shall review the following:

1. The systems, processes, and practices in place to track, gather, and appropriately account for price terms and transactions with GlaxoSmithKline customers that are relevant for purposes of the ASP calculations and reporting requirements. Specifically, this includes:

   a) The systems, processes, policies, and practices used to determine which GlaxoSmithKline customers are considered for purposes of calculating ASP for ASP Covered Products;

   b) The systems, processes, policies, and practices used to determine whether and which particular transactions are included in or excluded from ASP calculations for ASP Covered Products;

c) a review of GlaxoSmithKline's methodology for applying transactions to the ASP calculations;

d) the relevant flow of data and information by which price terms and transactions with GlaxoSmithKline customers are accumulated from source systems and entered and tracked in GlaxoSmithKline's information system for purposes of calculating ASP;

e) a review of any GlaxoSmithKline inquiries to CMS regarding ASP calculations and reporting requirements under the MMA, including requests for interpretation or guidance, and any responses to those inquiries; and

f) the controls and processes in place to examine and address system reports that require critical evaluation (such as reports of variations, exceptions, or outliers). This shall include a review of the bases upon which variations, exceptions, and outliers are identified and the follow-up activities undertaken to identify the cause of any variations.

B. Average Manufacturer Price Systems Review

For at least the first and fourth Addendum Reporting Periods, the IRO shall review GlaxoSmithKline's systems, processes, policies, and practices (including the controls on the systems, processes, policies, and practices) associated with the tracking, gathering, and accounting for all relevant data for purposes of calculating and reporting AMPs to CMS for AMP Covered Products as required by the Medicaid Drug Rebate Program.

In general terms, the IRO shall review the following:

1. The systems, processes, policies, and practices that are in place to track, gather, and appropriately account for contract terms and transactions with GlaxoSmithKline customers that are relevant to the calculation of AMP under Medicaid Drug Rebate Program. Specifically, this includes a review of:

   a) The systems, processes, policies, and practices used to determine which GlaxoSmithKline customers are considered for purposes of calculating AMP for AMP Covered Products;

b) The systems, processes and practices used to determine whether and which particular transactions are included in or excluded from AMP calculations for AMP Covered Products;

c) a review of GlaxoSmithKline's methodology for applying transactions to the AMP calculations;

d) the relevant flow of data and information by which price terms and transactions with GlaxoSmithKline customers are accumulated from the source systems and entered and tracked in GlaxoSmithKline's information systems for purposes of calculating the AMPs;

e) a review of any GlaxoSmithKline inquiries to CMS regarding AMP calculations and reporting requirements pursuant to the Medicaid Drug Rebate Program, including requests for interpretation or guidance, and any responses to those inquiries; and

f) the controls and processes in place to examine and address system reports that require critical evaluation (such as reports of variations, exceptions, or outliers). This shall include a review of the bases upon which variations, exceptions, and outliers are identified and the follow-up activities undertaken to identify the cause of any variations.

C. AMP/ASP Systems Review Report

For each Addendum Reporting Period for which an AMP/ASP Systems Review is performed hereunder, the IRO shall prepare a report based upon the AMP/ASP Systems Review. This report may be (but need not be) combined with the report for the AMP/ASP Transactions Review as well as the reports generated by the IRO as required in Attachment A to the CIA, and shall include the following:

1. A description of the systems, processes, policies, and practices in place to track, gather, and account for price terms, contract terms, and transactions with GlaxoSmithKline customers that are relevant to the calculation and reporting of AMP and ASP, including, but not limited to:

a) The computer or other relevant systems (including the source systems and any other information systems, as applicable) used to calculate and report AMPs and ASPs;

b) the information input into GlaxoSmithKline's relevant computer or other systems used to calculate AMPs and ASPs

c) the system logic or decisional rationale used to determine which customers are considered for purposes of calculating AMP and ASPs;

d) the system logic or decisional rationale used to determine whether contract terms, discounts, rebates and all other relevant transactions with GlaxoSmithKline customers are included/excluded when calculating AMPs and ASPs; and

e) the policies and practices of GlaxoSmithKline's government pricing group in examining system reports for variations that require critical evaluation, including the basis upon which variations, exceptions, or outliners are identified, and the follow up actions taken in response.

2. A description of the documentation, information, and systems reviewed and the personnel interviewed, if any, including a description of the following:

a) GlaxoSmithKline's inquiries to CMS regarding the calculation of AMP and any responses to those inquiries;

b) GlaxoSmithKline's inquiries to CMS regarding the calculation of ASP in accordance with the MMA and any responses to those inquiries;

c) GlaxoSmithKline's systems and practices for reporting AMP and ASP to CMS on a quarterly basis as required by the Medicaid Drug Rebate Program and the MMA; and

d) GlaxoSmithKline's systems and practices for reporting any adjustments or additional information related to the submissions.

3. Observations, findings, and recommendations on possible improvements to GlaxoSmithKline's systems, processes, policies and practices.

III. AMP/ASP TRANSACTIONS REVIEW

For each Addendum Reporting Period, the IRO shall conduct Reported Prices Procedures for a sample of transactions to test whether GlaxoSmithKline calculated and reported AMP and ASP in accordance with the stated policies, procedures, and methodology developed by GlaxoSmithKline pursuant to the Medicaid Drug Rebate Program and MMA requirements, respectively. At the end of each Addendum Reporting Period, the IRO shall randomly select the quarter for the AMP/ASP Transactions Review. The selected quarter shall be generated through the use of the OIG's Office of Audit Services Statistical Sampling Software, also known as "RATS-STATS" or through the use of another method of random sampling acceptable to the OIG. In order to complete the Transactions Review before the deadline for the Annual Report, GlaxoSmithKline and the IRO may request, in writing, that the OIG approve an alternative approach for selecting quarters.

A. Reported Prices Procedures for AMP

For each Addendum Reporting Period, the IRO shall conduct Reported Prices Procedures for a sample of transactions to test whether GlaxoSmithKline calculated and reported AMP for AMP Covered Products in accordance with the stated policies, procedures, and methodology developed by GlaxoSmithKline pursuant to the Medicaid Drug Rebate Program. The Procedures shall require the IRO to select and test probe samples from the selected quarter of Potentially AMP-eligible Transactions Types[3] in accordance with GlaxoSmithKline policies and procedures.

1. Testing of Transactions

The IRO shall begin its Reporting Prices Procedures for AMP by selecting and testing samples from the selected quarter of Potentially AMP-eligible Transactions Types, as grouped by GlaxoSmithKline, from the Reporting Period. Each Potentially

[3] Potentially AMP-eligible Transactions Types include may sales, credits (including rebates and chargebacks), bill only, free issue and returns transactions.

AMP-eligible Transactions Type will be considered a separate universe from which the IRO will test a probe sample.

For the universes of Potentially AMP-eligible Transactions Types, the IRO will test for the following attributes:

i Whether the Potentially AMP-eligible Transactions are supported by source documents; and

ii. Whether GlaxoSmithKline included or excluded each Potentially AMP-eligible Transaction in the calculation of AMP in accordance with its policies and procedures and methodology developed by GlaxoSmithKline pursuant to the Medicaid Drug Rebate Program.

2. Sampling of Transactions

The IRO shall test a probe sample of 30 Transactions from each universe of Potentially AMP-eligible Transactions Type for the selected quarter. In the event the IRO finds a net dollar error rate of 5% or more of the total sample size, the IRO will perform an Additional Investigation after GlaxoSmithKline and the IRO hold an interim conference with the OIG to discuss the IRO's preliminary findings. The IRO shall present its findings, GlaxoSmithKline shall present its management response and the OIG shall review and consider GlaxoSmithKline's management response. The OIG shall determine whether an Additional Investigation is warranted following consultations with GlaxoSmithKline and the IRO. For the Additional Investigation, should it be determined that one is required, the IRO may review additional documentation and/or conduct additional interviews with appropriate personnel necessary to identify the root cause of the net dollar error rate of 5% or more.

Upon completion of the probe reviews, and any Additional Investigation, if required, for each universe of Transactions, the IRO will report to the OIG its final findings, if any, for these probe samples.

The OIG will determine (based on discussions with the IRO and GlaxoSmithKline, the results of the probe reviews, and findings following any Additional Investigation) whether the testing of a statistically valid random sample of additional Transactions will be

required. The size of any statistically valid random sample(s) shall be agreed upon by the OIG, GlaxoSmithKline, and the IRO.

The probe samples shall be generated through the use of the OIG's Office of Audit Services Statistical Sampling Software, also known as "RATS-STATS" or through the use of another method of random sampling acceptable to the OIG.

B. Reported Prices Procedures for ASP

For each Addendum Reporting Period, the IRO shall conduct Reported Prices Procedures for a sample of transactions to test whether GlaxoSmithKline calculated and reported ASPs for ASP Covered Products in accordance with its stated policies and methodology developed by GlaxoSmithKline pursuant to the MMA's requirements. The Procedures shall require the IRO to select and test probe samples from the selected quarter of Like Kind Transactions Types[4] consisting of sales and sales-related activities, for individual ASP Covered Products, to individual customers or other entities, that are specifically included in, or excluded from, the ASP calculation. The IRO will also select and test a probe sample of Estimated Transactions Types[5] used in the calculation of ASP for ASP Covered Products in order to test GlaxoSmithKline's methodology.

1. Grouping and Testing of Transactions

The IRO shall begin its Reporting Prices Procedures for ASP by selecting and testing samples from the selected quarter of Like Kind Transactions Types and Estimated Transactions Types, as grouped by GlaxoSmithKline, from the Reporting Period. Each type of Like Kind Transaction and Estimated Transaction will be considered a separate universe from which the IRO will test a probe sample.

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[4] Like Kind Transactions are defined as Transaction Types that were finalized at the time of the sale and grouped together by transaction type. Examples of Like Kind Transaction Types are sales, adjustments to original sales, and manual adjustments in accordance with GlaxoSmithKline's policies and procedures.

[5] Estimated Transactions include Transactions Types that are sales, adjustments and/or rebates that are available on a lagged basis, in accordance with GlaxoSmithKline's policies and procedures, and for which GlaxoSmithKline is required to apply a methodology based on the most recent 12-month period available to estimate costs attributable to these price concessions. Examples of such Transactions include sales under federal Medicare card programs of PHS 340 B program, or credits such as chargebacks, rebates and administrative service fees or free goods.

For the universes of Like Kind Transactions, the IRO will test for the following attributes:

a) Whether the Like Kind Transaction prices are supported by source documents; and

b) Whether GlaxoSmithKline included or excluded each Like Kind Transaction in the calculation of ASP in accordance with its policies and procedures and methodology developed by GlaxoSmithKline pursuant to MMA requirements.

For the universes of Estimated Transactions, the IRO will test for the following attributes:

a) Whether the Estimated Transaction amounts were calculated in accordance with GlaxoSmithKline policies and procedures and methodology developed by GlaxoSmithKline pursuant to MMA requirements, and were supported by relevant commercial arrangements or other source documentation; and

b) Whether the Estimated Transactions were included in or excluded from the ASP calculation in accordance with GlaxoSmithKline's policies and procedures and methodology developed by GlaxoSmithKline pursuant to MMA requirements.

2. Sampling of Transactions

The IRO shall test a probe sample of 30 Transactions from each type of Like Kind Transaction and Estimated Transaction for the selected quarter. In the event the IRO finds a net dollar error rate of 5% or more of the total sample size, the IRO will perform an Additional Investigation after GlaxoSmithKline and the IRO hold an interim conference with the OIG to discuss the IRO's preliminary findings. The IRO shall present its findings, GlaxoSmithKline shall present its management response and the OIG shall review and consider GlaxoSmithKline's management response. The OIG shall determine whether an Additional Investigation is warranted following consultations with GlaxoSmithKline and the IRO. For the Additional Investigation, should it be determined that one is required, the IRO may review

additional documentation and/or conduct additional interviews with appropriate personnel necessary to identify the root cause of the net dollar error rate of 5% or more.

Upon completion of the probe reviews, and any Additional Investigation, if required, for each universe of Transactions, the IRO will report to the OIG its final findings, if any, for these probe samples.

The OIG will determine (based on discussions with the IRO and GlaxoSmithKline, the results of the probe reviews, and findings following any Additional Investigation) whether the testing of a statistically valid random sample of additional Transactions will be required. The size of any statistically valid random sample(s) shall be agreed upon by the OIG, GlaxoSmithKline, and the IRO.

The probe samples shall be generated through the use of the OIG's Office of Audit Services Statistical Sampling Software, also known as "RATS-STATS" or through the use of another method of random sampling acceptable to the OIG.

C. AMP/ASP Transactions Review Report

The IRO shall prepare a report annually based upon each ASP/AMP Transactions Review performed. The report shall contain the following general elements pertaining to the Reported Prices Procedures for AMP and the Reported Prices Procedures for ASP (Part One and Part Two):

1. Testing Objective – a clear statement of the objective(s) intended to be achieved by each engagement;

2. Testing Protocol – a detailed narrative description of: (a) the procedures performed; (b) sampling units; and (c) the universe from which the sample was selected; and

3. Sources of Data – a full description of documentation and/or other relevant information relied upon by the IRO when performing the testing.

The IRO shall include the following results for each review:

1. Reported Prices Procedures for AMP

a) For each universe of Potentially AMP-eligible Transaction Types tested, the IRO shall state its findings and supporting evidence as to whether the AMP-eligible Transaction Types tested satisfied the corresponding testing criteria outlined above in Section III.A.1;

b) For each universe of Potentially AMP-eligible Transaction Types tested, the IRO shall state the net dollar error rate discovered;

c) For each universe of Potentially AMP-eligible Transaction Types for which the OIG determined, after consultation with GlaxoSmithKline and the IRO, that an Additional Investigation was warranted, the IRO shall state its findings and supporting evidence;

d) For each universe of Potentially AMP-eligible Transaction Types for which the IRO conducted testing on a full statistically valid sample, after consultation with the OIG and GlaxoSmithKline, the IRO shall state its findings and supporting evidence; and

e) The IRO shall report any recommendations for changes to GlaxoSmithKline's policies and procedures and/or methodology to correct or address any weaknesses or deficiencies uncovered during the review.

2. Reported Prices Procedures for ASP

a) For each universe of Like Kind Transaction and Estimated Transaction tested, the IRO shall state its findings and supporting evidence as to whether the Like Kind Transactions and Estimated Transactions tested satisfied the corresponding testing criteria outlined above in Section III.B.1;

b) For each universe of Like Kind Transaction and Estimated Transaction tested, the IRO shall state the net dollar error rate discovered;

c) For each universe of Like Kind Transaction and Estimated Transaction for which the OIG determined, after consultation with GlaxoSmithKline and the IRO, that an Additional Investigation was warranted, the IRO shall state its findings and supporting evidence;

d) For each universe of Transactions for which the IRO conducted testing on a full statistically valid sample, after consultation with the OIG and GlaxoSmithKline, the IRO shall state its findings and supporting evidence; and

e) The IRO shall report any recommendations for changes to GlaxoSmithKline's policies and procedures and/or methodology to correct or address any weaknesses or deficiencies uncovered during the review.

Attachment B to CIA Addendum

Certification for GlaxoSmithKline CIA Addendum

CERTIFICATION

In accordance with the Corporate Integrity Agreement (CIA) and Addendum thereto entered between SmithKline Beecham Corporation, d/b/a GlaxoSmithKline (GlaxoSmithKline) and the OIG, the undersigned hereby certifies the following to the best of my knowledge, information, and belief:

1) GlaxoSmithKline has in place policies and procedures describing in all material respects the methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services (CMS) pursuant to the reporting requirements of the Medicaid Drug Rebate program and pursuant to the reporting requirements of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), as amended (the "Government Price Reporting Policies and Procedures");

2) the Government Price Reporting Policies and Procedures have been designed to ensure compliance with GlaxoSmithKline's price reporting obligations under the Medicaid Drug Rebate Program and the MMA;

3) GlaxoSmithKline's Government Price Reporting Policies and Procedures were followed in all material respects in connection with the calculation of Average Manufacturer Prices (AMPs) for GlaxoSmithKline's AMP Covered Products and in connection with the calculation of Average Sales Prices (ASPs) for GlaxoSmithKline's ASP Covered Products for each of the following four quarters: [specifically identify each quarter];

4) In accordance with Section III.I of the CIA Addendum, the Average Sales Prices (ASPs) for the ASP Covered Products described on Appendix A to the CIA Addendum for these quarters were: 1) calculated in accordance with the definitions and requirements of the MMA, as amended (including any refinement of that definition that may be made by the Secretary of the Department of Health and Human Services, through the issuance of regulations, written directives, or guidance), and 2) reported to the Medicaid programs of those States that entered into a Related State Settlement Agreement with GlaxoSmithKline and to any commercial drug price reporting service(s) as required by Section III.I.2.c of the CIA Addendum.

5) In accordance with Section III.I of the CIA Addendum, the Average Manufacturer Prices (AMPs) and prior-quarter AMP adjustments for the AMP Covered Products described on Appendix A to the CIA Addendum for these quarters were: 1) calculated in accordance with the definitions and requirements relating to the Medicaid Drug Rebate Program and 2) reported to the Medicaid programs of those States that entered into a Related State Settlement Agreement with GlaxoSmithKline and to any commercial drug price reporting service(s) as required by Section III.I.2.c of the CIA Addendum.

6) I hereby certify that the statements made in connection with the submission of ASPs and AMPs and in this Certification are true, complete, and current and are made in good faith. I understand that the ASPs and AMPs reported or made available to the State Medicaid programs of those States that executed Related State Settlement Agreements with GlaxoSmithKline may be used in the administration of the Medicaid programs of those States and/or may be used by those States for Medicaid reimbursement purposes.

_____

Signature
[Insert Name and Title]

_____

Date