CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
AVENTIS INC., AVENTIS PHARMACEUTICALS INC., SANOFI-AVENTIS U.S. INC. AND SANOFI-AVENTIS U.S. LLC

I. PREAMBLE

Aventis Inc.; Aventis Pharmaceuticals Inc.; sanofi-aventis U.S. Inc.; and sanofi-aventis U.S. LLC (hereafter referred to collectively as "API") hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). API has represented that Aventis, Inc. and Aventis Pharmaceuticals Inc. have no ongoing business operations and no employees. API has further represented that sanofi-aventis U.S. Inc. and sanofi-aventis U.S. LLC are the successors in interest to the operations of Aventis Pharmaceuticals Inc. and Aventis Inc.

Contemporaneously with this CIA, Aventis Pharmaceuticals Inc. is entering into a Settlement Agreement with the United States. Aventis Pharmaceuticals Inc. will also enter into settlement agreements with various states (Related State Settlement Agreements) and API's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date, API established a voluntary compliance program applicable to its United States operations. API's United States compliance program (Compliance Program) includes the appointment of a United States Corporate Compliance Officer, a United States Compliance Committee, a United States Code of Business Conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program, and internal review procedures designed, as represented by API, to promote compliance with applicable laws and the promotion of high ethical standards.

API shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. API may modify its compliance

measures as appropriate, but, at a minimum, API shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by API under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) API's final Annual Report; or (2) any additional materials submitted by API pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

   a. all owners of API who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), all officers and directors, and all employees of API in the United States Pharmaceutical Operations group (U.S. Pharmaceutical Operations). If there are future changes in the organizational structure of API, all API employees engaged in functions other than manufacturing functions and pre-market research functions shall be considered Covered Persons; and

   b. all contractors, subcontractors, agents, and other persons who perform functions on behalf of U.S. Pharmaceutical Operations for any API product that is reimbursed by Federal health care programs (Government Reimbursed Products). This includes all persons who perform Government Pricing and Contracting Functions (as defined below in Section II.C.3) and promotion, sales, and marketing functions relating to Government Reimbursed Products.

   Notwithstanding the above, the term "Covered Persons" does not include part-time or per diem employees, contractors, subcontractors,

agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes: 1) all Covered Persons whose job responsibilities relate to Government Pricing and Contracting Functions (as defined below in Section II.C.3); and 2) all Covered Persons whose job responsibilities relate to the promotion, sales, or marketing of Government Reimbursed Products by the Oncology Sales and Marketing Group.

3. The term "Government Pricing and Contracting Functions" refers to the collection, calculation, verification, or reporting of pricing or other information for purposes of the Medicaid Drug Rebate program (codified at 42 U.S.C. § 1396r-8), the Medicare program (42 U.S.C. §§ 1395-1395hhh), and other government programs (including the 340B Drug Pricing program, codified at 42 U.S.C. § 256B (the 340B Program).) This includes individuals whose job responsibilities include the calculation and reporting of Average Wholesale Price (AWP), Average Sales Price (ASP), Average Manufacturer Price (AMP), Best Price, and all other pricing information reported and used in connection with Federal health care programs.

4. The term "Third Party Personnel" shall mean personnel of the entities with whom API has or may in the future enter into agreements to co-promote an API product or engage in joint promotional activities relating to an API product. API has represented that: 1) the Third Party Personnel are employed by other independent entities; 2) API does not control Third Party Personnel; and 3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. API agrees to promote compliance by Third Party Personnel with Federal health care program requirements by complying with the provisions set forth below in Sections III.B.2, V.A.4, and V.B.3 related to Third Party Personnel. Provided that API complies with the requirements of Sections III.B.2, V.A.4, and V.B.3, API shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

To the extent not already accomplished, API shall establish and maintain a Compliance Program throughout the term of this CIA that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Prior to the Effective Date, API appointed an individual to serve as its United States corporate compliance officer (U.S. Corporate Compliance Officer), and API shall maintain a U.S. Corporate Compliance Officer for the term of the CIA. The U.S. Corporate Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The U.S. Corporate Compliance Officer shall be a member of senior management of API, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board(s) of Directors of API, and shall be authorized to report on such matters to the Board(s) of Directors of API at any time. Beginning within 120 days after the Effective Date, and for the remainder of the term of the CIA, the U.S. Corporate Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The U.S. Corporate Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by API as well as for any reporting obligations created under this CIA.

API shall report to OIG, in writing, any changes in the identity or position description of the U.S. Corporate Compliance Officer, or any actions or changes that would affect the U.S. Corporate Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, API appointed a United States compliance committee for its United States operations (U.S. Compliance Committee). The U.S. Compliance Committee includes and shall, at a minimum, continue to include the U.S. Corporate Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., the President/CEO and senior executives of relevant departments, such as U.S. Scientific and Medical Affairs, U.S. Market Access and Business Development, U.S. Legal, U.S. Quality and Compliance, U.S. Pharmaceutical Operations, U.S. Human Resources). The U.S. Corporate Compliance Officer shall continue to chair the U.S. Compliance Committee

and the U.S. Compliance Committee shall support the U.S. Corporate Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

API shall report to OIG, in writing, any changes in the composition of the U.S. Compliance Committee, or any actions or changes that would affect the U.S. Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, API established a United States code of business conduct (known as its "U.S. Code of Business Conduct"). To the extent not already accomplished, within 90 days after the Effective Date, API shall distribute the U.S. Code of Business Conduct to all Covered Persons. API shall make the promotion of, and adherence to, the U.S. Code of Business Conduct an element in evaluating the performance of all employees. The U.S. Code of Business Conduct shall, at a minimum, set forth:

a. API's commitment to full compliance with all Federal health care program requirements, including the commitment to comply with all requirements relating to Government Pricing and Contracting Functions, and to promote, sell, and market Government Reimbursed Products (as defined above in Section II.C.1.b) in accordance with Federal health care program requirements;

b. API's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with API's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

c. the requirement that all of API's Covered Persons shall be expected to report to the U.S. Corporate Compliance Officer, or other appropriate individual designated by API, suspected violations of any Federal health care program requirements or of API's own Policies and Procedures;

d. the possible consequences to both API and Covered Persons of failure to comply with Federal health care program requirements and

with API's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.E, and API's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 90 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by API's U.S. Code of Business Conduct. New Covered Persons shall receive the U.S. Code of Business Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

API shall periodically review the U.S. Code of Business Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised U.S. Code of Business Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised U.S. Code of Business Conduct within 30 days after the distribution of the revised U.S. Code of Business Conduct.

2. *Third Party Personnel.*

Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, API shall send a letter to each entity employing Third Party Personnel. The letter shall outline API's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements. The letter shall include a description of API's Compliance Program. API shall attach a copy of its U.S. Code of Business Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of API's U.S. Code of Business Conduct and a description of API's Compliance Program available to its Third Party Personnel; or (b) represent to API that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, API shall implement written policies and procedures regarding the operation of API's Compliance Program and its compliance

with Federal health care program requirements (Policies and Procedures). At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the U.S. Code of Business Conduct identified in Section III.B.1;

b. Government Pricing and Contracting Functions;

c. the promotion, sales, and marketing of API products in compliance with all applicable Federal health care program requirements, including, but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b; and

d. disciplinary policies and procedures for violations of API's Policies and Procedures, including policies relating to Federal health care programs requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures. These Policies and Procedures may be made available through the publishing of the Policies and Procedures on API's intranet site.

At least annually (and more frequently, if appropriate), API shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, API shall provide at least two hours of general training (General Training) to each Covered Person. This training, at a minimum, shall explain API's:

a. CIA requirements; and

b. API's U.S. Compliance Program (including the U.S. Code of Business Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

To the extent that General Training provided to Covered Persons during the 180 days immediately prior to the Effective Date of this CIA satisfies the requirements of Section III.C.1.b above, the OIG shall credit the training toward the requirements of Section III.C.1.b for the first Reporting Period. API may satisfy the remaining General Training obligations in Section III.C.1.a for the Covered Persons who received the training described above by notifying them in writing or in electronic format of the fact that API entered a CIA and providing an explanation of API's requirements and obligations under the CIA.

To the extent that a Covered Person is on a leave of absence during the entire period when the required General Training is offered, the Covered Person shall receive the training within 30 days of the conclusion of the leave of absence.

2. *Specific Training.* To the extent not already accomplished, within 120 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of specific training (Specific Training) in addition to the General Training required above.

For those Relevant Covered Persons engaged in Government Pricing and Contracting Functions, this Specific Training shall include a discussion of:

a. API's systems and procedures for performing Government Pricing and Contracting Functions;

b. all applicable Federal health care program requirements relating to Government Pricing and Contracting Functions;

c. the personal obligation of each individual involved in Government Pricing and Contracting Functions to ensure that all pricing and other information reported is accurate;

d. the legal sanctions for violations of Federal health care program requirements; and

e. examples of proper and improper practices related to Government Pricing and Contracting Functions.

For those Relevant Covered Persons in the Oncology Sales and Marketing groups whose job responsibilities relate to the promotion, sales, or marketing of Government Reimbursed Products, this Specific Training shall include a discussion of:

a. all applicable Federal health care program requirements relating to the promotion, sales, and marketing of Government Reimbursed Products;

b. Policies and Procedures and other requirements applicable to promotion, sales, and marketing of Government Reimbursed Products;

c. the personal obligation of each individual involved in the promotion, sales, or marketing of Government Reimbursed Products to comply with applicable legal requirements;

d. the legal sanctions for violations of the Federal health care program requirements; and

e. examples of proper and improper practices related to the promotion, sales, and marketing of Government Reimbursed Products.

New Relevant Covered Persons shall receive this Specific Training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. An employee of API who has completed the Specific Training shall review a new Relevant Covered Person's work and the work of a Relevant Covered Person returning from a leave of absence, to the extent that the work relates to (as applicable) Government Pricing and Contracting

Functions or to the promotion, sales, and marketing of Government Reimbursed Products until such time as the applicable Relevant Covered Person completes his or her applicable Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least two hours of Specific Training in each subsequent Reporting Period.

To the extent that Specific Training provided to Relevant Covered Persons during the 180 days immediately prior to the Effective Date of this CIA satisfies the requirements set forth above in this Section III.C.2 above, the OIG shall credit the training toward the Specific Training requirements for the first Reporting Period.

To the extent that a Relevant Covered Person is on a leave of absence during the entire period when the required Specific Training is offered, the Relevant Covered Person shall receive the training within 30 days of the conclusion of the leave of absence.

3. *Certification.* Each individual who is required to attend General or Specific Training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The U.S. Corporate Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the General or Specific Training shall be knowledgeable about the subject area of their training.

5. *Update of Training.* API shall review the General and Specific Training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the IRO Reviews, and any other relevant information.

6. *Computer-based Training.* API may provide the General and Specific Training required under this CIA through appropriate computer-based training approaches. If API chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or to provide additional information to the individuals receiving such training. In addition, if API chooses to provide computer based General or Specific Training, all applicable

requirements to provide a number of "hours" of training in this Section III.C. may be met with respect to computer-based training by providing the required number of "normative" hours as that term is used in the computer-based training industry.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, API shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist API in assessing and evaluating the obligations pursuant to this CIA. The applicable requirements relating to the IRO are outlined in Attachment A, which is incorporated by reference.

Each IRO engaged by API shall have expertise in auditing and in applicable Federal health care program requirements (including the requirements of the Medicaid Drug Rebate program and the Medicare Part B program as they relate to AMP and ASP, respectively). Each IRO shall assess, along with API, whether it can perform the IRO review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist.

b. *Types and Frequency of Reviews.* The IRO shall conduct two types of reviews. Both of the reviews shall be focused on: (a) the AMP for the AMP Covered Products, as defined in Attachment C, and (b) the ASP for the ASP Covered Products as defined in Attachment C.

First, as set forth more fully in Attachment B, the IRO shall perform an AMP/ASP Systems Review (Systems Review) that shall address API's systems, processes, policies, and practices associated with tracking, gathering, and accounting for all relevant data for purposes of calculating AMPs and ASPs in accordance with the requirements of the Medicaid Drug Rebate program and the Medicare Part B program, respectively. Second, as set forth more fully in Attachment B, the IRO shall conduct an AMP/ASP Transactions Review

(Transactions Review) that shall address and analyze API's systems, policies, and practices with regard to specific transactions affecting the calculation of AMPs and ASPs for purposes of the Medicaid Drug Rebate program and the Medicare Part B program, respectively.

If there are no material changes in API's AMP/ASP related systems, processes, policies, and practices during the term of this CIA, the IRO shall perform the AMP/ASP Systems Review for the second and fourth Reporting Periods. If API materially changes the systems, processes, policies, and practices, then the IRO shall perform an AMP/ASP Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the second and fourth Reporting Periods. The IRO shall not be required to conduct an AMP/ASP Systems Review for the first Reporting Period.

The AMP/ASP Transactions Review shall be performed annually. However, for the first Reporting Period only, as set forth more fully in Appendix B, the time period covered by the Transactions Review will be the last two quarters of the Reporting Period. For the second and all subsequent Reporting Periods, the Transactions Review shall cover the entire Reporting Period. The IRO shall perform all components of each review.

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

2. *Review Reports*. The IRO shall prepare a report based upon each Systems Review and each Transactions Review performed. These reports shall be known as the Systems Review Report and the Transactions Review Report, respectively. Information to be included in the Systems Review Reports and the Transactions Review Reports (collectively "Reports") is described in Attachment B.

3. *Validation Review*. In the event OIG has reason to believe that: (a) API's Systems Review or Transaction Review (collectively "Reviews") fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are

inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Systems and/or Transactions Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). API shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of API's final Annual Report shall be initiated no later than one year after API's final submission (as described in Section II.B) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify API of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, API may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. API agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with API prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to API a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Prior to the Effective Date, API established a disclosure program that includes a mechanism (a toll-free compliance telephone line known as the "Helpline") to enable individuals to disclose, to the U.S. Corporate Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with API's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law (Disclosure Program). API shall maintain the Disclosure Program throughout the term of this CIA. API shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy,

and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the U.S. Corporate Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The U.S. Corporate Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, API shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The U.S. Corporate Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).

c. "Screened Persons" includes prospective and current owners of API (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), and current and prospective officers, directors, and employees of API. Screened Persons also includes all prospective and current contractors and agents of API who are Covered Persons.

2. *Screening Requirements.* API shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements:

a. API shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons;

b. API shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter; and

c. API shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) API to refrain from billing (if applicable) Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. API understands that items or services furnished by excluded persons are not payable by Federal health care programs and that API may be liable for overpayments (if applicable) and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether API meets the requirements of Section III.F.

3. *Removal Requirement.* If API has actual notice that a Screened Person has become an Ineligible Person, API shall remove such Screened Person from responsibility for, or involvement with, API's business operations related to the Federal

health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Screened Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If API has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b) (1)-(3), or is proposed for exclusion during the Screened Person's employment or contract term, API shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at United States corporate headquarters, API shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to API conducted or brought by a governmental entity or its agents involving an allegation that API has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. API shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reporting.

1. *Reportable Events.*

a. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or

ii. the filing of a bankruptcy petition by API.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. *Reporting of Reportable Events.* If API determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, API shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

ii. a description of API's actions taken to correct the Reportable Event; and

iii. any further steps API plans to take to address the Reportable Event and prevent it from recurring.

iv. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities implicated.

I. Drug Price Reporting Requirements.

1. *General Statement of Purpose and Intent.* On a quarterly basis, API 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, API will report an ASP, as defined in Section III.I.2.a below, for the "ASP Covered Products" described in Attachment C, and API will also report an AMP, as defined in Section III.I.2.b below, for the "AMP Covered Products" described in Attachment C. The Pricing Information shall be provided subject to the confidentiality provisions and conditions set forth herein, in the Related State Settlement Agreements, in any commercial drug price reporting service confidentiality agreements as referenced in Section III.I.2.e below, or as 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, the requirements for Average Sales Price as defined in 42 U.S.C. § 1395w-3a and all applicable requirements of the Medicare Part B program. API shall report under this CIA the same ASPs for the same formulations of the ASP Covered Products that it reports to CMS on a quarterly basis for purposes of the Medicare Part B program. The ASPs shall be reported under this CIA in the same electronic format used to report ASPs to CMS.

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, the requirements for Average Manufacturer Price as defined in 42 U.S.C. § 1396r-8(k)(1) and all applicable requirements of the Medicaid Drug Rebate program. API shall report, under this CIA, the same AMPs for the same formulations of the AMP Covered Products that it reports to CMS on a quarterly basis, along with any retroactive AMP adjustments that API reports to CMS for purposes of the Medicaid Drug Rebate program. The AMPs shall be reported under this CIA in the same electronic format used to report AMPs to CMS.

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, API shall report, in accordance with Sections III.I.2.a and b above, the ASPs for the ASP Covered Products and the AMPs (and prior-quarter AMP adjustments) for the AMP Covered Products that API reported for the applicable calendar quarter to CMS pursuant to the Medicare Part B and Medicaid Drug Rebate programs, respectively. API shall make these reports to: 1) the Medicaid programs of

those States that have entered into a Related State Settlement Agreement with API (Settlement States); and 2) to a commercial drug price reporting service (such as First DataBank, Inc.) designated by any Settlement State that has received API's ASPs and AMPs pursuant to a Related State Settlement Agreement. If appropriate to reflect changes in the sources from which the State Medicaid programs receive their Pricing Information, API agrees that, upon the receipt of a written request by any of the Settlement States, 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 Settlement State, subject to the confidentiality provisions referenced in Section III.I.2.e relating to Pricing Information. The Pricing Information shall be reported to the commercial drug price reporting service solely for the purposes of reporting pricing information to the Medicaid programs of Settlement States and the Pricing Information shall be 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 Settlement State, and to the commercial drug price reporting service (such as First DataBank, Inc.) designated by any Settlement 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. API shall certify that the ASPs and AMPs reported hereunder are calculated in accordance with requirements of the Medicare Part B and Medicaid Drug Rebate programs as they relate to ASP and AMP and the definitions set forth in Section III.I.2.a-b above. Said certifications shall be made in the form attached hereto as Attachment D, and shall include an acknowledgment that the ASPs, AMPs, and prior-quarter AMP adjustments were reported to CMS and are the same prices that were reported to CMS. API agrees that this certification by the employee or agent of API constitutes a certification by API.

e. Confidentiality of Reported Pricing Information. API represents that it contends that the Pricing Information it reports under this Section III.I is confidential commercial or financial information and proprietary trade secrets that if disclosed may cause substantial injury to the competitive position of API. The Related State Settlement Agreements will contain certain confidentiality provisions governing the treatment of Pricing Information. API 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 API to the commercial drug price reporting service. Among other provisions, such confidentiality agreement shall: a) permit the commercial drug price reporting service to disclose API's Pricing Information only to the Medicaid programs of Settlement States that have entered into a subscription agreement with the commercial drug price reporting service and the disclosure shall be made pursuant to the terms of the Related State Settlement Agreement; and b) require API's Pricing Information to otherwise be kept strictly confidential or, in the case of AMP Pricing Information, to be kept confidential until CMS makes such Pricing Information publicly available.

f. Document Retention. API 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 CIA 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.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, API changes locations or sells, closes, purchases, or establishes a new business unit or location engaged in Government Pricing and Contracting Functions or in the promotion, sales, or marketing of Government Reimbursed Products, API shall notify OIG of this fact as soon as possible, but no later

than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, any Federal health care program provider or supplier number, and any corresponding contractor's name and address that issued each Federal health care program provider or supplier number. Each new business unit or location meeting the criteria set forth in this Section IV shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, API shall submit a written report to OIG summarizing the status of the implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the U.S. Corporate Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the U.S. Corporate Compliance Officer may have;

2. the names and positions of the members of the U.S. Compliance Committee required by Section III.A;

3. a copy of API's U.S. Code of Business Conduct required by Section III.B.1;

4. with regard to the entities employing Third Party Personnel: (a) a copy of the letter (including all attachments) required by Section III.B.2 to be sent to each entity employing the Third Party Personnel; (b) a list and description of all existing co-promotion or other agreements between API and the entities employing Third Party Personnel; and (c) a description of the entities' response to API's letter;

5. a copy of all Policies and Procedures required by Section III.B.3;

6. the number of individuals required to complete the U.S. Code of Business Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

7. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

8. a description of the Disclosure Program required by Section III.E;

9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between API and the IRO; and (d) the proposed start and completion dates of the Systems and Transaction Reviews;

10. a certification from the IRO regarding its professional independence and objectivity with respect to API;

11. a description of the process by which API fulfills the requirements of Section III.F regarding Ineligible Persons;

12. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; and the actions taken in response to the screening and removal obligations set forth in Section III.F;

13. a list of all of API's United States locations (including locations and mailing addresses); the corresponding name under which each United States location is doing business; the corresponding phone numbers and fax numbers; each such United States location's Federal healthcare program provider or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which API currently submits claims (if applicable);

14. a description of API's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

15. the certifications required by Section V.C.

B. Annual Reports. API shall submit to OIG annually a report with respect to the status of, and findings regarding, API's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the U.S. Corporate Compliance Officer and any change in the membership of the U.S. Compliance Committee described in Section III.A;

2. the number of individuals required to complete the U.S. Code of Business Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

3. with regard to the entities employing Third Party Personnel: (a) a copy of the letter (including all attachments) required by Section III.B.2 to be sent to each entity employing the Third Party Personnel; (b) a list and description of all existing co-promotion or other agreements between API and the entities employing Third Party Personnel; and (c) a description of the entities' response to API's letter;

4. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B.3 and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;

5. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

6. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);

7. API's response and corrective action plan(s) related to any issues raised by the Reports prepared pursuant to Section III.D;

8. a summary and description of any and all current and prior engagements and agreements between API and the IRO, if different from what was submitted as part of the Implementation Report;

9. a certification from the IRO regarding its professional independence and objectivity with respect to API;

10. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

11. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs;

12. any changes to the process by which API fulfills the requirements of Section III.F regarding Ineligible Persons;

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; and the actions taken by API in response to the screening and removal obligations set forth in Section III.F;

14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

15. a description of all changes to the most recently provided list of API's United States locations (including addresses) as required by Section V.A.13; the corresponding name under which each such United States location is doing business; the corresponding phone numbers and fax numbers; each such United States location's Federal health care program provider or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which API currently submits claims (if applicable); and

16. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the U.S. Corporate Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, API is in compliance with all of the requirements of this CIA;

2. he or she has reviewed the Implementation or Annual Report (as applicable) and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;

3. if applicable, API has complied with the obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs; and

4. all of API's: 1) Policies and Procedures referenced in Section III.B.3 above; 2) templates for standardized contracts and other similar documents; 3) training materials used for purposes of Section III.C, above; and 4) promotional materials used in connection with Government Reimbursed Products have been reviewed by competent legal counsel and have been found to be in compliance with the applicable Federal health care program requirements.

In addition, each Implementation Report and the Annual Report shall include a copy of the certifications provided pursuant to Attachment D. API agrees that these certifications constitute certifications by API.

D. Designation of Information. API shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure

under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. API shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:
Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

API:
Stephen M. Kanovsky
U.S. Corporate Compliance Officer and
Vice President, U.S. Corporate Compliance
55 Corporate Drive
P.O. Box5925
Bridgewater, NJ 08807-5925
Telephone: 908.981.5000
Facsimile: 908.981.7898

With a copy to:
U.S. General Counsel
55 Corporate Drive
P.O. Box 5925
Bridgewater, NJ 08807-5925
Telephone: 908.981.5000
Facsimile: 908.635.7898

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal

facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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 API's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of API's locations for the purpose of verifying and evaluating: (a) API's compliance with the terms of this CIA; and (b) API's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by API 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 API'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. API shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. API's employees may elect to be interviewed with or without a representative of API present.

VIII. DOCUMENT AND RECORD RETENTION

API shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify API prior to any release by OIG of information submitted by API pursuant to its obligations under this CIA and identified upon submission by API as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, API shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

API is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, API and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day API fails to establish and implement any of the following obligations as described in Section III:

a. a U.S. Corporate Compliance Officer;

b. a U.S. Compliance Committee;

c. a written Code of Conduct (currently known as "the U.S. Code of Business Conduct");

d. written Policies and Procedures;

e. the training of Covered Persons;

f. a Disclosure Program;

g. Ineligible Persons screening and removal requirements; and

h. notification of Government investigations or legal proceedings.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day API fails to engage an IRO as required in Section III.D and Attachments A-B.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day API fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day API fails to submit the annual Transaction Review Report and/or System Review Report (if applicable) in accordance with the requirements of Section III.D and Attachment B.

5. A Stipulated Penalty of $1,500 for each day API fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date API fails to grant access.)

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of API as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or as otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day API fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to API, stating the specific grounds for its determination that API has failed to comply fully and adequately with the CIA obligation(s) at issue and steps API shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after API receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. API may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after API fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after API receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that API has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify API of: (a) API's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, API shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event API elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until API cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that API has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

a. a failure by API to report a Reportable Event, and take corrective action as required in Section III.H;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

c. a failure to respond to a Demand Letter concerning the payment

of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.D and Attachments A-B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by API constitutes an independent basis for API's exclusion from participation in the Federal health care programs. Upon a determination by OIG that API has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify API of: (a) API's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* API shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. API is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) API has begun to take action to cure the material breach; (ii) API is pursuing such action with due diligence; and (iii) API has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, API fails to satisfy the requirements of Section X.D.3, OIG may exclude API from participation in the Federal health care programs. OIG shall notify API in writing of its determination to exclude API (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of API's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, API may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to API of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, API shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether API was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. API shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders API to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless API requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether API was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) API had begun to take action to cure the material breach within that period; (ii) API has pursued and is pursuing such action with due diligence; and (iii) API provided to OIG within that period a reasonable timetable for curing the material breach and API has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for API, only after a DAB decision in favor of OIG. API's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude API upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that API may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. API shall waive the right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of API, API shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, API and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of API;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. The undersigned API signatories represent and warrant that they are authorized

to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF API

/John M. Spinnato/

JOHN M. SPINNATO
Authorized Signatory for API

8/29/07
DATE

/Laurent Gilhodes/

LAURENT GILHODES
Authorized Signatory for API

8/29/07
DATE

/Lynn Shapiro Snyder/

Lynn Shapiro Snyder, Esq.
Constance Wilkinson, Esq.
Counsel for API

8/29/07
DATE

LSS

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

/Gregory E. Demske/

8/30/07

Gregory E. Demske
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

ATTACHMENT A TO CIA
INDEPENDENT REVIEW ORGANIZATION

This Attachment A contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement.

API shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D, below. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify API if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, API may continue to engage the IRO.

If API engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Attachment. If a new IRO is engaged, API shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify API if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, API may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the ASP and AMP Systems Reviews and Transactions Reviews engagements who have expertise in all applicable Federal health care program requirements relating to Government Pricing and Contracting Functions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which API products are reimbursed;

2. assign individuals to design and select the Transactions Review samples who are knowledgeable about appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the Reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each ASP and AMP Systems Review and Transactions Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare Part B program and Medicaid Drug Rebate program rules and requirements in making assessments in the AMP and ASP Systems and Transactions Reviews;

3. if in doubt of the application of a particular Medicare Part B program or Medicaid Drug Rebate program policy or regulation, request clarification from the appropriate authority (e.g., CMS);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Attachment B.

D. IRO Independence and Objectivity.

The IRO must perform the applicable AMP and ASP Systems Review(s) and/or Transactions Review(s) in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and API.

E. IRO Removal/Termination.

1. *Provider.* If API terminates its IRO during the course of an engagement, API must submit a notice explaining its reasons to OIG no later than 30 days after termination. API must engage a new IRO in accordance with Section A of this Attachment.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require API to engage a new IRO in accordance with Paragraph A of this Attachment.

Prior to requiring API to engage a new IRO, OIG shall notify API of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, API may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. API shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO

with API prior to requiring API to terminate the IRO. However, the final determination as to whether or not to require API to engage a new IRO shall be made at the sole discretion of OIG.

ATTACHMENT B TO CIA

AMP/ASP Price Reporting Engagement

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

As specified more fully below, API shall retain an Independent Review Organization (IRO) to perform testing to assist API 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 Attachment C of the CIA) and (b) Average Sales Price (ASP) under the Medicare Part B program for ASP Covered Products (as defined in Attachment C of the CIA). The IRO shall perform two types of engagements: 1) a systems review of API's systems, processes, policies, and practices relating to the calculation and reporting of AMP for AMP Covered Products pursuant to the Medicaid Drug Rebate program and the calculation and reporting of ASP for ASP Covered Products pursuant to the Medicare Part B program (the "AMP/ASP Systems Review"); and 2) testing of a sample of transactions to assess whether API is calculating AMP for AMP Covered Products and ASP for ASP Covered Products in accordance with the policies, procedures, and methodologies developed by API in accordance with the requirements of the Medicaid Drug Rebate program and the Medicare Part B program, respectively (the "AMP/ASP Transactions Review"). The AMP/ASP Systems Review and the AMP/ASP Transactions Review are herein referred to collectively as the "AMP/ASP Government Price Reporting Engagement."

If there are no material changes in API's AMP/ASP related systems, processes, policies, and practices during the term of the CIA, then the IRO shall perform the AMP/ASP Systems Review for the second and fourth Reporting Periods. If API materially changes its AMP/ASP related systems, processes, policies, and practices, then the IRO shall perform an AMP/ASP Systems Review covering the Reporting Period in which such changes were made, in addition to conducting the AMP/ASP Systems Review for the second and fourth 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 did not materially change; and 3) an update on the systems, processes, policies, and practices that materially changed. The IRO shall not be required to conduct an AMP/ASP Systems Review for the first Reporting Period.

The AMP/ASP Transactions Review shall be designed to test whether API is calculating AMPs and ASPs in accordance with the policies, procedures, and methodologies developed by API in accordance with the requirements of the Medicaid Drug Rebate program and the Medicare Part B program, respectively. The AMP/ASP Transactions Review shall consist of two parts, the "ASP Reported Prices Procedures" and the "AMP Reported Prices Procedures." The IRO shall conduct the AMP/ASP Transactions Review annually.

II. AMP/ASP Systems Review

A. ASP Systems Review

The IRO shall review API'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 ASP as reported to the Centers for Medicare and Medicaid Services (CMS) for ASP Covered Products. More specifically, the IRO shall review the following:

a) The systems, processes, policies, and practices used to determine which API customers are included or excluded for purposes of calculating ASP;

b) The systems, processes, policies, and practices used to determine whether and which particular transactions (e.g., discounts, rebates) are included in or excluded from ASP calculations;

c) A review of API's methodology for applying transactions to the ASP calculations;

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

e) A review of API's inquiries to CMS regarding ASP calculations and reporting requirements under the Medicare Part B 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.

B. AMP Systems Review

The IRO shall review API'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 AMP as reported to CMS for AMP Covered Products. More specifically, the IRO shall review the following:

a) The systems, processes, policies, and practices used to determine which API customers are included or excluded for purposes of calculating AMP;

b) The systems, policies, processes, and practices used to determine whether and which particular transactions (e.g., discounts, rebates) are included in or excluded from AMP calculations;

c) A review of API's methodology for applying transactions to the AMP calculations;

d) The flow of data and information by which price, contract terms, and transactions with API customers are accumulated from the source systems and entered and tracked in API's information systems for purposes of calculating AMP;

e) A review of any API's 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 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 is not required to be) combined with the report for the AMP/ASP Transactions Review described in Section III below, 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 API 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 track data for and to calculate and report AMP and ASP;

   b) The information input into API's relevant computer or other systems used to calculate AMP and ASP;

   c) The system logic or decisional rationale used to determine which customers are included or excluded for purposes of calculating AMP and ASP;

d) The system logic or decisional rationale used to determine whether contract terms, discounts, rebates and all other relevant transactions with API customers are included or excluded when calculating AMP and ASP; and

e) API's policies and practices in examining system reports for variations that require critical evaluation, including the basis on which variations, exceptions, or outliers 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) API's inquiries to CMS regarding the calculation of AMP and any responses to those inquiries;

b) API's inquiries to CMS regarding the calculation of ASP and any responses to those inquiries;

c) API's systems and practices for reporting AMP and ASP to CMS as required by the Medicaid Drug Rebate program and the Medicare Part B program; and

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

3. Observations, findings, and recommendations for any improvements to API's systems, processes, policies, and practices, including any changes recommended in order to improve compliance with the requirements of the Medicaid Drug Rebate program or the Medicare Part B program.

III. AMP/ASP Transactions Review

A. General Description and Definitions

For each Reporting Period, the IRO shall select and review a sample of transactions to test whether API calculated and reported AMP and ASP in accordance with the policies, procedures, and methodologies developed by API in accordance with Medicaid Drug Rebate program and Medicare Part B program requirements, respectively. At the end of each Reporting Period, the IRO shall randomly select the quarter to be reviewed for purposes of the AMP/ASP Transactions Review. For the first Reporting Period only, the quarter selected for the Transactions Review shall be one of the last two quarters of Reporting Period. For the second and subsequent Reporting Periods, the IRO shall select the quarter to be reviewed in the Transactions Review from among all four quarters of the Reporting Period. 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.

For purposes of the AMP/ASP Transactions Review, the following definitions shall apply:

1. "Finalized Transaction Types" are defined as those transactions that are finalized at the time of the sale. As of the Effective Date of the CIA, API had one category of Finalized Transaction Types, namely direct sales. The category of direct sales shall be considered a universe of Finalized Transaction Types from which the IRO shall draw samples as detailed below in Section III.B.1 and III.C.1. If, during the term of the CIA, API establishes additional categories of Finalized Transaction Types, each of the new categories shall be considered an additional universe of transactions from which samples of Finalized Transaction Types shall be selected for purposes of the AMP Reported Prices Review and the ASP Reported Prices Review. Each transaction within the Finalized Transaction Types group shall be referred to as a "Finalized Transaction."

2. "Estimated Transaction Types" are defined as those transaction types that are sales, adjustments, and/or rebates that are available on a lagged basis. For the Estimated Transaction Types, API uses a methodology based on the most recent 12-month period available to estimate costs attributable to these price concessions. As of the Effective Date of the CIA, API had three categories of Estimated Transaction Types, namely indirect sales, rebates/fees, and government programs. Each of these categories shall be considered a universe of Estimated Transaction Types from which the IRO shall draw samples as detailed below in Sections III.B.1 and III.C.1. If, during the term of the CIA, API establishes additional categories of Estimated Transaction Types, each of those new categories shall be considered an additional universe of transactions from which samples of Estimated Transaction Types shall be selected for purposes of the AMP Reported Prices Review and the ASP Reported Prices Review. Each transaction within the Estimated Transaction Types group shall be referred to as an "Estimated Transaction".

The AMP Reported Prices Procedures and the ASP Reported Prices Procedures described below in Sections III.B and III.C shall require the IRO to select and test samples from the selected quarter of Finalized Transaction Types and Estimated Transaction Types (collectively "Transaction Types").

B. AMP Reported Prices Procedures

1. Grouping and Testing of Transaction Types.

   For each Reporting Period, the IRO shall review a sample of transactions to test whether API calculated and reported AMP for AMP Covered Products in accordance with its policies, procedures, and methodologies (AMP Reported Prices Procedures). The IRO shall conduct its AMP Reported Prices Procedures by selecting and testing samples from each universe of the applicable Transaction Type, as grouped by API, for the selected quarter of the Reporting Period.

a) Finalized Transactions

For the direct sales universe of Finalized Transaction Types (and any other universe of Finalized Transaction Types), the IRO shall select a probe sample and shall test for the following attributes:

i) Whether the Finalized Transactions are supported by source documents; and

ii) Whether the Finalized Transactions were included in or excluded from the AMP calculation in accordance with API's policies, procedures, and methodologies.

b) Estimated Transactions

For the indirect sales, rebates/fees, and government programs universes of Estimated Transaction Types (and any other universe of Estimated Transaction Types), the IRO shall select a probe sample and shall test for the following attributes:

i) Whether the Estimated Transaction amounts were calculated in accordance with API's policies, procedures, and methodologies, and were supported by relevant commercial arrangements or other source documentation; and

ii) Whether the Estimated Transactions were included in or excluded from the AMP calculation in accordance with API's policies, procedures, and methodologies.

2. Additional Investigation of Transactions

The IRO shall test a probe sample of 30 transactions from each universe of Transactions Types for the selected quarter. If the IRO finds a net dollar error rate of 5% or more of the total sample size in any probe sample, API and the IRO shall hold an interim conference with the OIG to discuss the IRO's preliminary findings. The IRO shall present its findings, API shall present its management response, and the OIG shall review and consider API's management response. In its discretion, and following consultations with API and the IRO, the OIG shall determine whether an Additional Investigation shall be required. For any Additional Investigation that the OIG determines is required, the IRO shall 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, for each universe of transactions, the IRO shall report to the OIG its final findings, if any, for these probe samples.

In its discretion, the OIG will determine (based on discussions with the IRO and API, the results of the probe reviews, and findings following any Additional Investigation) whether the testing of a statistically valid random sample of additional transactions from the applicable universe shall be required. The size of any statistically valid random sample(s) shall be agreed upon by the OIG, API, 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. ASP Reported Prices Procedures

1. Grouping and Testing of Transactions Types

For each Reporting Period, the IRO shall review a sample of transactions to test whether API calculated and reported ASPs for ASP Covered Products in accordance with its policies, procedures, and methodologies (ASP Reported Prices Procedures). The IRO shall conduct its ASP Reported Prices Procedures by selecting and testing samples from each universe of the applicable Transaction Type, as grouped by API, for the selected quarter of the Reporting Period.

a) Finalized Transactions

For the direct sales universe of Finalized Transaction Types (and any other universe of Finalized Transaction Types), the IRO shall select a probe sample and shall test for the following attributes:

i) Whether the Finalized Transactions are supported by source documentation; and

ii) Whether the Finalized Transactions were included in or excluded from the ASP calculation in accordance with API's policies, procedures, and methodologies.

b) Estimated Transactions

For the indirect sales, rebates/fees, and government programs universes of Estimated Transaction Types (and any other universe of Estimated Transaction Types), the IRO shall select a probe sample and shall test for the following attributes:

i) Whether the Estimated Transaction amounts were calculated in accordance with API's policies, procedures, and methodologies, and were supported by relevant commercial arrangements or other source documentation; and

ii) Whether the Estimated Transactions were included in or excluded from the ASP calculation in accordance with API's policies, procedures, and methodologies.

2. Additional Investigation of Transactions

The IRO shall test a probe sample of 30 transactions from each 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 in any probe sample, API and the IRO will hold an interim conference with the OIG to discuss the IRO's preliminary findings. The IRO shall present its findings, API shall present its management response, and the OIG shall review and consider API's management response. In its discretion, and following consultations with API and the IRO, the OIG shall determine whether an Additional Investigation is warranted. For any required Additional Investigation, the IRO shall 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, for each universe of transactions, the IRO shall report to the OIG its final findings, if any, for these probe samples.

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

D. AMP/ASP Transactions Review Report

1. General Requirements

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 both the AMP Reported Prices Procedures and the ASP Reported Prices Procedures:

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

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

c) 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 also include the following information in each ASP/AMP Review report.

2. AMP Reported Prices Procedures

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

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

c) For each universe of Transaction Types for which the OIG determined that an Additional Investigation was required, the IRO shall state its findings and supporting evidence;

d) For each universe of Transaction Types for which the IRO conducted testing on a full statistically valid sample, the IRO shall state its findings and supporting evidence; and

e) The IRO shall report any recommendations for changes to API's policies and procedures and/or methodologies to correct or address any weaknesses or deficiencies uncovered during the AMP Reported Prices Procedures.

3. ASP Reported Prices Procedures

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

b) For each universe of Transaction Type tested, the IRO shall state the net dollar error rate discovered;

c) For each universe of Transaction Type(s) for which the OIG determined that an Additional Investigation was required, the IRO shall state its findings and supporting evidence;

d) For each universe of Transaction Type(s) for which the IRO conducted testing on a full statistically valid sample, the IRO shall state its findings and supporting evidence; and

e) The IRO shall report any recommendations for changes to API's policies and procedures and/or methodologies to correct or address any weaknesses or deficiencies uncovered during the ASP Reported Prices Procedures.

ATTACHMENT C TO CIA

PRODUCTS FOR WHICH API GOVERNMENT PRICING INFORMATION WILL BE REPORTED UNDER THE CIA

The products described in this Attachment C are the "ASP Covered Products" and the "AMP Covered Products" for purposes of the requirements of the CIA and the Attachments thereto.

"ASP Covered Products" are all API products for which API reports an Average Sales Price (ASP) for Medicare Part B covered drugs to the Centers for Medicare & Medicaid Services (CMS) pursuant to 42 U.S.C. § 1395w-3a and the applicable requirements of the Medicare Part B program.

"AMP Covered Products" are all Medicaid "covered outpatient drugs" as defined in 42 U.S.C. § 1396r-8 (k)(2), (k)(3) and (k)(4); that is, API products for which API reports an Average Manufacturer Price (AMP) to CMS pursuant to the applicable requirements of the Medicaid Drug Rebate program.

ATTACHMENT D TO CIA

CERTIFICATION

In accordance with the Corporate Integrity Agreement (CIA) entered between API and the OIG, I the undersigned hereby certify the following to the best of my knowledge, information, and belief:

1) API has in place policies and procedures describing in all material respects the methods for performing Government Pricing and Contracting Functions (hereafter "Government Price Reporting Policies and Procedures");

2) The Government Price Reporting Policies and Procedures have been designed to ensure API's compliance with price reporting obligations under the Medicare Part B and Medicaid Drug Rebate programs;

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

4) The ASPs and AMPs that were reported to the Settlement States and to the designated commercial drug price reporting service(s), if any, for the ASP Covered Products and the AMP Covered Products in accordance with Section III.I of the CIA were identical to the corresponding ASPs and AMPs that were reported to CMS for purposes of the Medicare Part B and the Medicaid Drug Rebate programs, respectively;

5) In accordance with Section III.I of the CIA, the ASPs for the ASP Covered Products for these quarters were: 1) calculated in accordance with the definitions and requirements of the Medicare Part B program, and 2) reported to the Medicaid programs of the Settlement States and to any commercial drug price reporting service(s) as required by Section III.I.2.c of the CIA;

6) In accordance with Section III.I of the CIA, the AMPs and prior-quarter AMP adjustments for the AMP Covered Products for these quarters were: 1) calculated in accordance with the definitions and requirements of the Medicaid Drug Rebate program; and 2) reported to the Medicaid programs of the Settlement States and to any commercial drug price reporting service(s) as required by Section III.I.2.c of the CIA; and

7) The statements made by API in the submission of ASPs and AMPs, in any submission of related supporting materials, 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 Settlement States may be used in the administration of the State Medicaid programs of the Settlement States and/or may be used by the Settlement States for Medicaid reimbursement purposes.

_____

Signature of CEO, CFO, or Authorizing Official (as defined in 42 C.F.R. § 414.804(a)(6))

[Insert Name and Title]

_____

Date

ADDENDUM TO CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND AVENTIS INC., AVENTIS PHARMACEUTICALS INC., SANOFI-AVENTIS U.S. INC. AND SANOFI-AVENTIS U.S. LLC

I. PREAMBLE

Effective August 30, 2007, Aventis Inc.; Aventis Pharmaceuticals Inc.; sanofi-aventis U.S. Inc.; and sanofi-aventis U.S. LLC (hereafter referred to collectively as "API") entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS). API hereby enters into this Addendum to the CIA (Addendum). Contemporaneously with this Addendum, Aventis Pharmaceuticals Inc. is entering into a Settlement Agreement with the United States. Aventis Pharmaceuticals Inc. is also prepared to enter into related settlement agreements with various States, and API's agreement to the CIA and to this Addendum is a condition precedent to those agreements.

II. TERM AND SCOPE OF THE CIA AND ADDENDUM

A. Continuation of CIA and Term of Addendum

All of the obligations assumed by API 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. API shall comply with all new obligations set forth in this Addendum.

The term of the compliance obligations assumed by API under this Addendum shall be concurrent with the term of the CIA. The CIA and Addendum obligations shall terminate according to the timeframes set forth in Sections II.A and B of the CIA. The Effective Date of this Addendum shall be the date on which the final signatory to this Addendum executes the document.

The first Reporting Period of this Addendum shall begin on the Effective Date of the Addendum and end on August 29, 2009. Thereafter, the Reporting Periods for purposes of the Addendum shall coincide with the Reporting Periods defined in the CIA. That is, the second and subsequent Addendum Reporting Periods will begin on August 30 and end on August 29 of each applicable year.

B. Definitions

The definitions of "Covered Persons," "Relevant Covered Persons," "Government Pricing and Contracting Functions," and "Third Party Personnel" set forth in the CIA shall apply for purposes of this Addendum.

III. CIA AND ADDENDUM OBLIGATIONS

Throughout the term of this Addendum, API shall maintain a Compliance Program that includes all the elements specified in the CIA and the additional obligations created by this Addendum:

A. Compliance Officer and Committee

The terms of Sections III.A.1 and III.A.2 of the CIA remain in effect and API shall continue its obligations under Sections III.A.1-2 through the term of this Addendum. In addition, the following new sections shall be added to Section III.A of the CIA. API shall comply with the terms of Sections III.A.3 and III.A.4, as set forth below, through the term of the Addendum.

3. *Board of Directors.* API has represented that Aventis Inc. and Aventis Pharmaceuticals Inc. have no ongoing business operations and no employees. API has further represented that sanofi-aventis U.S. Inc. and sanofi-aventis U.S. LLC are the successors in interest to the operations of Aventis Inc. and Aventis Pharmaceuticals Inc. API has represented that sanofi-aventis U.S. Inc. and sanofi-aventis U.S. LLC are the only U.S. operating legal entities with employees that engage in Government Pricing and Contracting Functions or in the promotion, sales, and marketing of Government Reimbursed Products. The Board of sanofi-aventis U.S. Inc. and the Board of sanofi-aventis U.S. LLC (collectively "the Boards") shall retain responsibility for the review and oversight of matters related to API's compliance with Federal health care program requirements and the obligations of the CIA and Addendum. The Boards shall, at a minimum, be responsible for the following:

a. Oversight: Each of the Boards shall meet at least quarterly to review and oversee API's Compliance Program, including but not limited to the performance of the U.S. Corporate Compliance Officer, API's U.S. Corporate Compliance Department, and the U.S. Compliance Committee.

b. Board Resolution: For each Reporting Period, each of the Boards shall adopt a resolution, signed by the individual members of each Board, summarizing its review and oversight of API's compliance with Federal health care program requirements and the obligations of the CIA and Addendum.

At a minimum, the resolution shall include the following language:

"The Board of Directors of [insert name of appropriate entity] has made a reasonable and due inquiry into the operations and effectiveness of API's U.S. Compliance Program for the period [insert description of time period], including the performance of the U.S. Corporate Compliance Officer, the U.S. Compliance Committee, and API's U.S. Corporate Compliance Department. The Board has concluded that, to the best of its knowledge, API has implemented an effective compliance program to meet the applicable Federal health care program requirements and the obligations set forth in the CIA and the Addendum."

If either Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective compliance program at API.

Within 30 days after the Effective Date of this Addendum, API shall report to the OIG, in writing, the names of the members of each Board. API shall also report to the OIG, in writing, any changes in the composition of either of the Boards or any actions or changes that would affect either Board's ability to perform the duties necessary to meet the obligations of this Addendum within 15 days after such change. The Boards' resolutions shall be provided to the OIG with the Annual Report, as set forth in Section V.B below.

4. *Management Accountability and Certification.* API represents that API makes the promotion of, and adherence to, the U.S. Code of Business Conduct an element in evaluating the performance of all employees. In addition to the responsibilities set forth in the CIA and Addendum for all Covered Persons, certain API employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify in writing or

electronically that, to the best of their knowledge, the applicable area of authority is compliant with applicable Federal health care program requirements and with the obligations of the CIA and Addendum. The Certifying Employees include: (1) Vice President, Market Access and Business Development, and (2) Vice President, Contract and Pricing Management. In the event of organizational changes at API such that no employee holds the titles listed above, the Certifying Employees shall be those employees who occupy comparable positions.

For each Reporting Period, each Certifying Employee shall certify in writing or electronically that:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of the department or functional area.] To the best of my knowledge, except as otherwise described herein, the [insert name of the department or functional area] of API is in compliance with all applicable Federal health care program requirements and the obligations of the CIA and Addendum."

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall include in the certification a written explanation of the reasons why he or she is unable to provide the conclusion and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards

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

C. Training and Education

With the modification described immediately below, the terms of Section III.C of the CIA remain in effect, and API shall continue its obligations under Section III.C through the term of this Addendum. Section III.C.1.a shall be modified to read as follows: "CIA and Addendum requirements."

D. Review Procedures

The Review Procedures set forth in Section III.D of the CIA shall remain in effect for the term of the CIA. In addition, Section III.D shall be amended to include obligations

relating to the performance of systems reviews and transactions reviews relating to Best Price. These obligations relating to Best Price shall be known generally as the "Additional Review Procedures." Specifically, Section III.D of the CIA shall be amended to include the following additional provisions.

5. *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, API shall retain an entity (or entities) such as an accounting, auditing, or consulting firm (hereafter "Independent Review Organization" or "IRO") to perform two Additional Review Procedures as specified below and more fully described in Attachment E to the Addendum. API may select the same IRO to conduct the Additional Review Procedures as it previously selected under the CIA, or API may select a different IRO. However, the IRO(s) must meet two conditions. First, each IRO retained by API shall have expertise in auditing and in the applicable Federal health care programs requirements (including the requirements of the Medicaid Drug Rebate program and the Medicare Part B program as they relate to average manufacturer price (AMP), average sales price (ASP), and Best Price, respectively). Second, each IRO shall assess, along with API, whether it can perform the IRO reviews in a professionally independent and 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 objective fashion.

b. Types and Frequency of Additional Reviews. The IRO retained pursuant to this Addendum shall conduct two types of Additional Review Procedures (in addition to those set forth in the CIA).

> First, as set forth more fully in Attachment E to this Addendum, the IRO shall perform Best Price Systems Reviews that shall address API's systems, processes, policies, and practices associated with tracking, gathering, and accounting for all relevant data for purposes of appropriately determining Best Price reported under the Medicaid Drug Rebate program. Second, as set forth more fully in Attachment E to this Addendum, the IRO shall conduct BP [Best Price] Transactions Reviews which shall address and analyze API's systems, policies, and practices with regard to specific transactions affecting the determination of Best Price.

If there are no material changes in API's Best Price related systems, processes, policies, and practices during the term of this Addendum, the IRO shall perform the Best Price Systems Review for the first and third Addendum Reporting Periods. If API materially changes its systems, processes, policies, and practices, then the IRO shall perform a Best Price Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and third Addendum Reporting Periods. The BP Transactions Reviews shall be performed annually. The IRO shall perform all components of each Review.

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

6. *Additional Review Procedures Report(s).* The IRO shall prepare a report (or reports) based upon each Best Price Systems Review and BP Transactions Review performed (the "Additional Review Procedures Report"). Information to be included in each Additional Review Procedures Report is detailed in Attachment E to this Addendum.

7. *Validation Review and Independence and Objectivity Certification.* The provisions of Sections III.D.3 and 4 of the CIA shall apply in the same manner specified therein to each of the Additional Review Procedures required by this Addendum.

8. *Notification Regarding IRO for Additional Review Procedures.* Within 90 days after the Effective Date of the Addendum, API shall notify the OIG of the following information regarding the IRO engaged to perform the Additional Review Procedures: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between API and the IRO; (d) the proposed start and completion dates of the Best Price Systems Reviews and BP Transactions Reviews; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to API.

E. Disclosure Program

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

F. **Ineligible Persons**

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

G. **Notification of Government Investigation or Legal Proceedings**

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

H. **Reporting (of Reportable Events)**

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

I. **Drug Price Reporting Requirements**

With the exception described immediately below, the terms of Section III.I of the CIA remain in effect, and API shall continue its obligations under Section III.I through the term of this Addendum. Attachment D to this Addendum shall be substituted for Attachment D to the CIA.

IV. NEW BUSINESS UNITS OR LOCATIONS

Section IV of the CIA shall be replaced with the following:

A. Change or Closure of Unit or Location. In the event that, after the Effective Date of this Addendum, API changes locations or closes a business unit or location engaged in Government Pricing and Contracting Functions or in the promotion, sales, or marketing of Government Reimbursed Products, API shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, API purchases or establishes a new business unit or location engaged in Government Pricing and Contracting Functions or in the promotion, sales, or marketing of Government Reimbursed Products, API shall notify OIG no later than the date that the purchase or establishment is publicly disclosed by API. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider or supplier number (if applicable), and the name and address of the contractor that issued each number (if applicable). Each new business

unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA and its Addendum.

C. Sale of Unit or Location. In the event that, after the Effective Date, API proposes to sell any or all of its business units or locations that are subject to this CIA or its Addendum, API shall notify OIG of the proposed sale no later than the date that the sale of such business unit or location is publicly disclosed by API. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA and its Addendum shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. ANNUAL REPORTS

B. Annual Reports

Consistent with its CIA obligations, API shall submit to OIG Annual Reports with respect to the status of, and findings regarding, API's compliance activities for each CIA Reporting Period and Addendum Reporting Period. API shall annually submit an Annual Report that addresses its compliance obligations under both the CIA and the Addendum. The Annual Report shall be submitted according to the timetable set forth in the CIA.

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 of the CIA is amended to include the following additional provisions:

17. the Boards' resolutions adopted pursuant to Section III.A.3.b of the Addendum;

18. copies of the certifications of the Certifying Employees as required by Section III.A.4 of the Addendum, and a list of the names and positions of the Certifying Employees;

19. an explanation of any changes in the membership of either of the Boards described in Section III.A.3 of the Addendum or the group of Certifying Employees described in Section III.A.4; and

20. the steps being taken to address issues identified in the certifications of Certifying Employees pursuant to Section III.A.4 of the Addendum.

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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

VIII. DOCUMENTATION AND RECORD RETENTION

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

IX. DISCLOSURES

The terms of Section IX of the CIA remain in effect through the term of this Addendum.

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 of the CIA apply to the new obligations contained in this Addendum in the same manner in which they apply to the compliance obligations contained in the CIA.

Sections X.A.1.g-i are amended to read as follows:

g. ineligible Persons screening and removal requirements;

h. notification of Government investigations or legal proceedings; and

i. the Boards' resolutions (or statements) as described in Section III.A.3.b of the Addendum.

Section X.A.2 of the CIA is amended to read: "A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day

API fails to engage an IRO as required in Section III.D, Attachments A and B to the CIA, and Attachment E of the Addendum."

Section X.A.4 of the CIA is amended to read: "A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day API fails to submit the annual Transaction Review Report and/or System Review Report (if applicable) in accordance with the requirements of Section III.D, Attachment B to the CIA, and Attachment E of the Addendum."

Section X.C.3 (*Form of Payment*) is revised to read as follows:

"Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter."

XI. Effective and Binding Agreement

Section XI of the CIA shall remain in effect, and API shall continue its obligations under Section XI through the term of this Addendum.

ON BEHALF OF API

/John M. Spinnato/ _____ 5-21-09

John M. Spinnato
Authorized Signatory for API — DATE

/Laurent Gilhodes/

_____ May 21, 2009

Laurent Gilhodes
Authorized Signatory for API — DATE

/Thomas D. Forrester/

_____ May 21, 2009

Thomas D. Forrester
Authorized Signatory for API — DATE

/Lynn Shapiro Snyder/ _____ 5.22.09

Lynn Shapiro Snyder
Constance A. Wilkinson
Counsel for API — DATE

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

/Gregory E. Demske/

Gregory E. Demske
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

5/22/09

Date

ATTACHMENT D TO CIA

CERTIFICATION

In accordance with the Corporate Integrity Agreement (CIA) entered between API and the OIG, I the undersigned hereby certify the following to the best of my knowledge, information, and belief:

1) API has in place policies and procedures describing in all material respects the methods for performing Government Pricing and Contracting Functions (hereafter "Government Price Reporting Policies and Procedures");

2) The Government Price Reporting Policies and Procedures have been designed to ensure API's compliance with price reporting obligations under the Medicare Part B and Medicaid Drug Rebate programs;

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

4) API's Government Price Reporting Policies and Procedures were followed in all material respects in connection with the calculation of Best Price for API's products for each of the below-listed four quarters: [specifically identify the applicable quarter];

5) The ASPs and AMPs that were reported to the Settlement States (as defined in the CIA) and to the designated commercial drug price reporting service(s), if any, for the ASP Covered Products and the AMP Covered Products in accordance with Section III.I of the CIA were identical to the corresponding ASPs and AMPs that were reported to CMS for purposes of the Medicare Part B and the Medicaid Drug Rebate programs, respectively;

6) In accordance with Section III.I of the CIA, the ASPs for the ASP Covered Products for these quarters were: 1) calculated in accordance with the definitions and requirements of the Medicare Part B program, and 2) reported to the Medicaid programs of the Settlement States and to any commercial drug price reporting service(s) as required by Section III.I.2.c of the CIA;

7) In accordance with Section III.I of the CIA, the AMPs and prior-quarter AMP adjustments for the AMP Covered Products for these quarters were: 1) calculated in accordance with the definitions and requirements

of the Medicaid Drug Rebate program; and 2) reported to the Medicaid programs of the Settlement States and to any commercial drug price reporting service(s) as required by Section III.I.2.c of the CIA; and

8) The statements made by API in the submission to CMS of ASPs, AMPs and Best Prices, in any submission of related supporting materials, 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 Settlement States in accordance with the terms of the CIA may be used in the administration of the State Medicaid programs of the Settlement States and/or may be used by the Settlement States for Medicaid reimbursement purposes.

_____

Signature of CEO, CFO, or Authorizing Official (as defined in 42 C.F.R. § 414.804(a)(6))

[Insert Name and Title]

_____

Date

ATTACHMENT E TO CIA

Additional Review Procedures

I. Additional Review Procedures – General Description

As specified more fully below, API shall retain an Independent Review Organization (IRO) to assist API in assessing and evaluating its systems, processes, policies, and practices (including the controls on the systems, processes, policies, and practices) related to the requirements for Best Price under the Medicaid Drug Rebate program. The IRO shall perform two types of engagements: 1) a systems review of API's systems, processes, policies, and practices relating to the determination and reporting of Best Price pursuant to the Medicaid Drug Rebate program (Best Price Systems Review); and 2) reviews of samples of transactions to assess whether API is determining Best Price in accordance with the requirements of the Medicaid Drug Rebate program (the "BP Transactions Review").

If there are no material changes in API's Best Price related systems, processes, policies, and practices during the term of the Addendum, then the IRO shall perform the Systems Review for the first and third Addendum Reporting Periods. This Systems Review may be combined with the AMP/ASP Systems Review described in Attachment B to the CIA. If API materially changes its Best Price related systems, processes, policies, and practices, then the IRO shall perform a Best Price Systems Review covering the Reporting Period in which such changes were made, in addition to conducting the Best Price Systems Review for the first and third Addendum Reporting Periods. The additional Best Price 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 did not materially change; and 3) an update on the systems, processes, policies, and practices that materially changed.

In order to conduct the BP Transactions Review, the IRO shall review samples of transactions to assess whether API is determining Best Price in a manner consistent with the policies, procedures, and methodologies developed by API in accordance with the requirements of the Medicaid Drug Rebate program. The IRO shall conduct the BP Transactions Review annually.

II. Best Price Systems Review

The IRO shall review API'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 determining Best Price as reported to CMS for purposes of the Medicaid Drug Rebate program. More specifically, the IRO shall review the following:

a) The systems, processes, policies, and practices used to determine which API customers are included or excluded for purposes of determining Best Price;

b) The systems, policies, processes, and practices used to determine whether and which particular price terms, contract terms, or transactions (e.g., discounts, rebates, other price or sales terms) are included in or excluded from Best Price determinations;

c) A review of API's methodology for applying transactions to the Best Price determinations;

d) The flow of data and information by which price, contract terms, and transactions with API customers are accumulated from the source systems and entered and tracked in API's information systems for purposes of determining Best Price;

e) A review of any API's inquiries to CMS regarding Best Price determinations 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.

III. Best Price Systems Review Report

For each Addendum Reporting Period for which a Best Price Systems Review is performed hereunder, the IRO shall prepare a report (Best Price Systems Review Report) based upon the Review. The Best Price Systems Review report may be (but is not required to be) combined with the report for the BP Transactions Review described in Section IV below, 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 API customers that are relevant to the determination and reporting of Best Price, 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 track data for and to determine and report Best Price;

   b) The information input into API's relevant computer or other systems used to determine Best Price;

c) The system logic or decisional rationale used to determine which customers are included or excluded for purposes of determining Best Price;

d) The system logic or decisional rationale used to determine whether price and contract terms, discounts, rebates and other relevant transactions with API customers are included or excluded when determining Best Price; and

e) API's policies and practices in examining system reports for variations that require critical evaluation, including the basis on which variations, exceptions, or outliers 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) API's inquiries to CMS regarding the determination of Best Price and any responses to those inquiries;

b) API's systems and practices for reporting Best Price to CMS as required by the Medicaid Drug Rebate program; and

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

3. Observations, findings, and recommendations for any improvements to API's systems, processes, policies, and practices, including any changes recommended to improve compliance with the requirements of the Medicaid Drug Rebate program.

IV. BP Transactions Review

For each Addendum Reporting Period, the IRO shall conduct a BP Transactions Review to determine whether API determined and reported Best Price in accordance with the policies, procedures, and methodologies developed by API in accordance with the requirements of the Medicaid Drug Rebate Program. The IRO shall select and review a sample of transactions from a randomly selected quarter within each Reporting Period. The selected quarter shall be identified through the use of the OIG's Office of Audit Services Statistical Sampling Software known as "RAT-STATS" or through the use of another method of random sampling acceptable to the OIG.

The BP Transactions Review shall consist of two parts:

1. Part One of BP Transactions Review

API shall provide the IRO with a list of all API Customers[1] who purchased or contracted for Medicaid rebate eligible products during the selected quarter of the Reporting Period. The IRO shall randomly select a sample of 20 API Customers using the following methodology. The IRO shall categorize each API Customer as "large" or "small" based upon the total volume of sales[2] of the contracted Medicaid rebate eligible NDCs[3] to that API Customer in the selected quarter of the Reporting Period. The IRO shall randomly select 15 API Customers from the large API Customer category and 5 API Customers from the small API Customer category.

For each of the "large" and "small" API Customers identified by the IRO, the IRO's review shall cover the fifteen NDCs for which API paid the largest amount (i.e., total dollars) of Medicaid rebates during the most recent quarter for which complete data is available prior to the selected quarter of the Reporting Period and five randomly selected NDCs (collectively, the "Selected BP NDCs"). However for purposes of determining the Selected BP NDCs, if API paid less than $20,000 in Medicaid rebates during the relevant quarter for any randomly selected NDC, the IRO will replace that NDC with a randomly selected NDC for which API paid at least $20,000 in Medicaid rebates for the relevant quarter.

For each API Customer selected, the IRO shall identify all contracts with API and all corresponding Medicaid rebate eligible NDCs for which the API Customer had a contract price with API. The IRO shall determine whether the contract price for each Selected BP NDC for products sold to the API Customer is accurately reflected in API's systems relevant for purposes of determining Best Price. The IRO shall determine whether the contract price is appropriately considered for purposes of determining Best Price in accordance with the policies, procedures, and methodologies developed by API in accordance with the requirements of the Medicaid Drug Rebate program.

API shall also provide the IRO with information and documentation about all non-price-related arrangements or relationships in effect during the Review Period between API and the "large" and "small" API Customers identified by the IRO ("Other Arrangements"). These Other Arrangements could include, by way of example only, grants provided to the API Customer or data or service fee arrangements entered with the API Customer. The IRO shall review documentation and information about the Other Arrangements sufficient to identify the nature of the Other Arrangements, describe the terms of the Other Arrangements (including any amounts paid or other benefits conferred by API in connection with the Other Arrangements and the time periods of the

[1] "API Customer" means the entities as identified in API's GPCS system whose purchases or contracted prices are eligible for inclusion in the determination of Best Price (BP-eligible).

[2] For purposes of this Section IV, "volume of sales" means for the most recent quarter for which complete data is available: (i) for purchasers, gross sales minus all price concessions; or (ii) for third party payers, utilization multiplied by wholesale acquisition cost (WAC) minus all price concessions.

[3] For purposes of this Attachment E, "NDC" means a single dosage, form, and strength of a pharmaceutical product, without regard to package size (i.e., NDC 9).

arrangements), and identify any NDCs and/or API drugs that were the subject of the Other Arrangements.

2. Part Two of BP Transactions Review

API shall provide the IRO with the following information:

a) a listing of the five Medicaid rebate eligible NDCs for which API paid the largest amount (i.e., total dollars) of Medicaid rebates during the most recent quarter for which complete data is available prior to the selected quarter of Reporting Period;

b) for each of the five Medicaid rebate eligible NDCs selected, a listing of all unique prices paid to API for the product that were lower than the reported Best Price for the selected quarter and were identified in the GPCS system as BP-eligible.

For each BP-eligible unique price that was lower than the reported Best Price, the IRO shall review a minimum of five randomly selected contracted transactions associated with each of those unique lower prices (or, if there are fewer than five such transactions, all such transactions) to determine whether each was properly excluded from the determination of Best Price for that Medicaid rebate eligible NDC in accordance with the policies, procedures, and methodologies developed by API in accordance with the Medicaid Drug Rebate program requirements.

3. Additional Investigation

If the BP Transactions Review reveals any prices that were not accurately reflected in API's systems and/or were not appropriately included in, or excluded from, API's Best Price determination in accordance with the policies, procedures, and methodologies developed by API in accordance with the Medicaid Drug Rebate program requirements, such prices shall be considered an error. The IRO shall conduct such Additional Investigation as may be necessary to determine the root cause of the error. For example, the IRO may need to review additional documentation, conduct additional interviews with appropriate personnel, and/or review additional contracts to identify the root cause of the error.

Upon completion of these reviews and any Additional Investigation(s) that may have been warranted, the IRO shall report its findings to the OIG.

In the event the IRO discovers more than one error for the quarter under review in Part One or Part Two of the BP Transactions Review, API and the IRO shall hold an interim conference with the OIG to discuss the IRO's findings. The IRO shall present its findings, API shall present its management response, and the OIG shall review and consider the information provided by the IRO and API. Following consultations with API and the IRO, the OIG, in its discretion, shall determine

whether further review is warranted. Should the OIG determine that further review is warranted, the IRO shall randomly select and review a second sample as set forth below in this Section IV.3, using the same seed number, and repeat Part One and/or Part Two of the BP Transactions Review (depending on whether one or both parts of the BP Transactions Review warranted an Additional Investigation).

Should the OIG determine that further review is warranted, the IRO shall:

a) If additional Part One review is required, randomly select five additional API Customers from the large API Customer category; and/or

b) If additional Part Two review is required, review the next five Medicaid rebate eligible NDCs for which API paid the largest amount (i.e., total dollars).

V. BP Transactions Review Report

1. General Requirements

The IRO shall prepare a report annually based upon each BP Transactions Review performed. The report shall contain the following general elements pertaining to the BP Transactions Review:

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

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

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

The IRO shall also include the following information in each BP Transaction Review Report:

2. BP Transactions Review – Part One

a) a description/identification of the following: (i) the 20 API Customers selected under Part One; (ii) the number of contracts associated with each API Customer; (iii) the Selected BP NDCs tested; (iv) the contract prices for each NDC tested; and (v) a description of any supporting documentation reviewed;

b) a description of the IRO's stratification system for identifying the "large" and "small" Customers and documentation supporting the random selection of the Customers;

c) for each selected API Customer, a description of the steps taken to determine whether the contract price(s) for each Selected BP NDC were accurately reflected in API's systems;

d) for each selected API Customer, the IRO's determination regarding whether each Selected BP NDC contract price was accurately reflected in API's contracting systems. If the correct price was not reflected in the systems, the IRO should identify the correct price;

e) a detailed description of any Additional Investigation or further review undertaken with regard to any Selected BP NDC price not accurately reflected in API's systems and the results of any Additional Investigation or further review undertaken with respect to any such price;

f) for each selected API Customer, a description of the steps taken to determine whether each contract price(s) was (were) appropriately considered in API's determination of the Best Prices for the Select BP NDCs in accordance with Medicaid Drug Rebate program requirements;

g) for each selected API Customer: (i) a list of any price not properly included in, or excluded from, API's BP determination for the applicable quarter; (ii) a description of any adjustments to Best Price reported to CMS; and (iii) a description of any additional follow-up action taken by API;

h) a detailed description of any Additional Investigation or further review undertaken with regard to any price not appropriately included in, or excluded from, API's Best Price determination for the selected quarter, and the results of any Additional Investigation or further review undertaken with respect to any such price;

i) for each selected API Customer: (i) a description of the nature of all Other Arrangements in effect between API and the API Customer; (ii) a description of the terms of all Other Arrangements (including any amounts paid or other benefits conferred by API in connection with the Other Arrangements and the time periods of the arrangements); (iii) an identification of any NDCs and/or API drugs that were the subject of the Other Arrangements; and (iv) a description of the documentation or information reviewed with regard to all Other Arrangements; and

j) the IRO's recommendations for changes in API's policies, procedures, and/or methodologies to correct or address any weaknesses or deficiencies discovered during the review.

3. BP Transactions Review – Part Two

a) a list of: (i) the five Medicaid rebate eligible NDCs with the highest rebates paid by API during the Reporting Period; (ii) the Best Price reported by API to CMS for the Medicaid Drug Rebate program for each of the five NDCs under review; and (iii) a description of the underlying documentation supporting the random selection of the five contacted transactions associated with each unique BP-eligible price lower than the reported BPs;

b) a description of the steps and the supporting documentation reviewed to assess the unique BP-eligible lower prices for each of the selected NDCs which were below the BPs reported by API to CMS. If more than five contracted transactions are associated with any of the unique lower prices, the IRO shall also identify how many such transactions exist for each unique lower price;

c) a list of any prices not properly excluded from API's BP determination for any of the five NDCs reviewed; a description of any adjustments to Best Price reported to CMS; and a description of any additional follow-up action taken by API for any of the five NDCs reviewed;

d) a detailed description of any Additional Investigation or further review undertaken with regard to any prices that were not properly excluded from API's Best Price determination for any of the five NDCs reviewed and the results of any such Additional Investigation or further review; and

e) the IRO's recommendations for changes in API's policies, procedures, and/or methodologies to correct or address any weaknesses or deficiencies discovered during the review.