CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SCHERING-PLOUGH CORPORATION

I. PREAMBLE

Schering-Plough Corporation (Schering-Plough) hereby enters 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 by Schering-Plough, all its relevant subsidiaries, its directors, and all Covered Persons (as defined below) 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) and the statutes, regulations and written directions of the Food and Drug Administration (FDA) (FDA requirements). Contemporaneously with this CIA, Schering-Plough is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement. Schering-Plough also will enter into settlement agreements with various States, and Schering-Plough's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA (as defined below), Schering-Plough established a voluntary compliance program (known as "Global Compliance and Business Practices") which, as represented by Schering-Plough, includes, among other things, the appointment of a Compliance Officer, the development and dissemination of a Code of Conduct, the establishment of written policies and procedures, a Disclosure Program, screening measures for Ineligible Persons, regular training to Covered Persons concerning Schering-Plough's Code of Conduct and policies and procedures, and regular internal auditing.

Schering-Plough shall continue the operation of its compliance measures in accordance with the terms set forth below for the term of this CIA. Schering-Plough may modify its voluntary compliance measures as appropriate, but, at a minimum, Schering-Plough shall ensure that during the term of this CIA, it shall comply with the integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Schering-Plough 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, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Schering-Plough's final Annual Report; or (2) any additional materials submitted by Schering-Plough 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 officers and employees of Schering-Plough's (1) U.S.-based Global Pharmaceutical Business (U.S. GPB),[1] (2) U.S. Managed Markets Finance; (3) U.S.-based Law Department (Law Department); and (4) U.S.-based Global Compliance and Business Practices (Global Compliance and Business Practices) engaged in or having responsibilities directly related to the following functions, as defined in Sections II.C.2.a-c: (a) Government Pricing and Medicaid Drug Rebate Related Functions; (b) Managed Care Contracting Related Functions; and (c) Promotional and Product Services Related Functions;[2]

b. all contractors, subcontractors, agents, and other persons who perform Managed Care Contracting Related Functions, Government Pricing and Medicaid Drug Rebate Related Functions, or Promotional and Product Services Related Functions (as those terms are defined below) on behalf of Schering-Plough.

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[1] The U.S. GPB contains the following functions: U.S. Primary Care Customer Group; Global Business Operations; World Wide Generics; U.S. Specialty Customer Group; Global Medical Affairs; Strategic Partnerships & U.S. Managed Markets; and U.S. Managed Markets.

[2] To the extent any other cross-organizational groups provide enabling functions relating to the three Functions listed in this Section II.C.1.a, employees of those groups with responsibilities directly relating to the three Functions shall also be included in the definition of Covered Persons.

Specifically excluded from the definition of "Covered Persons" are the marketing, sales or other personnel of entities with which Schering-Plough currently has (or may have in the future) agreements to co-promote its products, including Millennium Pharmaceuticals, Inc. Schering-Plough shall, however, in good faith seek to obtain assurances that such personnel have received appropriate training in proper marketing and sales techniques.

Also, specifically excluded from the definition of "Covered Persons" are the marketing, sales or other personnel of entities with which Schering-Plough currently has (or may have in the future) joint venture agreements, including Merck & Co., Inc. Schering-Plough shall, however, in good faith seek to obtain assurances that such personnel have received appropriate training in proper marketing and sales techniques. The term "Covered Persons" specifically includes all other personnel, apart from those acting under joint venture or co-promotion agreements, who comprise Schering-Plough's contract sales force, if any.

The term "Covered Persons" does not include any contractors or agents retained to provide consulting or business advice to Schering-Plough and who are not engaged directly in any Government Pricing and Medicaid Drug Rebate Related Functions, Managed Care Contracting Related Functions, or Promotional and Product Services Related Functions on behalf of Schering-Plough.

Finally, 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 calendar 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 the following groups:

a. <u>Government Pricing and Medicaid Drug Rebate Relevant Covered Persons</u>:

Government Pricing and Medicaid Drug Rebate Relevant Covered Persons shall include:

1) all employees of U.S. GPB and U.S. Managed Markets Finance whose job responsibilities relate to the gathering, calculation, verification or reporting of information for purposes of the Medicaid Drug Rebate Program (codified at

42 U.S.C. § 1396r-8, et seq.), the Medicare program, or otherwise (hereafter, "Government Pricing and Medicaid Drug Rebate Related Functions"). This group includes, but is not limited to, those individuals with responsibilities relating to the calculation and reporting of Average Sales Price, Average Manufacturer Price, Best Price, and all other price information reported and used in connection with Federal health care program reimbursement. It also includes individuals from Schering-Plough's Law Department and Global Compliance and Business Practices whose job responsibilities relate to Government Pricing and Medicaid Drug Rebate Related Functions; and

2) all contractors, subcontractors, agents, and other persons who perform Government Pricing and Medicaid Drug Rebate Related Functions on behalf of Schering-Plough.

b. Managed Care Relevant Covered Persons:

Managed Care Relevant Covered Persons shall include:

1) all employees of U.S. GPB and U.S. Managed Markets Finance whose job responsibilities relate to the promotion, sales, and marketing of prescription drug products to managed care entities and to contracting with managed care entities or other similar customers (hereafter "Managed Care Contracting Related Functions"). This group also includes individuals from Schering-Plough's Law Department and Global Compliance and Business Practices whose job responsibilities relate to Managed Care Contracting Related Functions; and

2) all contractors, subcontractors, agents, and other persons, who perform Managed Care Contracting Related Functions on behalf of Schering-Plough.

c. Promotional and Product Services Relevant Covered Persons:

Promotional and Product Services Relevant Covered Persons shall include:

1) all employees of U.S. GPB whose job responsibilities relate to the promotion, sales, or marketing of Schering-Plough products or to the provision of information about or services relating to Schering-Plough's products. This includes all sales representatives who are involved in detailing health care professionals (HCPs), and all individuals involved in contracting with HCPs for the provision of consulting or other services, or in the development or provision of information about off-label uses of Schering-Plough's products (collectively "Promotional and Product Services Related Functions"). This group also includes individuals from Schering-Plough's U.S. GPB Finance, Law Department and Global Compliance and Business Practices whose job responsibilities relate to Promotional and Product Services Related Functions; and

2) all contractors, subcontractors, agents, and other persons who perform Promotional and Product Services Related Functions on behalf of Schering-Plough.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Executive Management Team.

1. *Compliance Officer.* Schering-Plough presently has a Compliance Officer with responsibility for administering Schering-Plough's compliance program. Schering-Plough shall continue to employ an individual to serve as its Compliance Officer during the term of this CIA. The 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 and FDA requirements. The Compliance Officer is and shall continue to be a member of senior management of Schering-Plough. The Compliance Officer reports directly to the Chairman, Chief Executive Officer, and President and is a member of the Executive Management Team (as defined below). The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters to the Board of Directors of Schering-Plough, or its designated subcommittee, and shall be authorized to report on such matters to the Board of Directors or its designated subcommittee at any time, in such form or manner as the Board of Directors of Schering-Plough determines[3]. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Schering-Plough as well as for any reporting obligations created under this CIA.

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

2. *Executive Management Team.* Schering-Plough currently has an Executive Management Team (EMT). Members of the EMT meet regularly, operate as a top management team, and are accountable for the overall performance of the corporation. The EMT is also responsible for the performance of the business, including compliance oversight, and the functional units that the EMT members lead. The Senior Vice President, Global Compliance and Business Practices (*i.e.*, the Compliance Officer) is a member of the EMT[4] and regularly advises and makes recommendations to the EMT regarding compliance issues. The EMT supports the Compliance Officer in fulfilling his responsibilities (e.g., assists in the analysis of Schering-Plough's risk areas, and oversees the monitoring of internal and external audits and investigations). Accordingly, a separate Compliance Committee is not required under the terms of this CIA.

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[3] In these periodic reports, the Directors shall also be notified of Schering Plough's continuing activities and obligations under the CIA. Also, the Directors have previously adopted and currently adhere to the Schering-Plough Corporation Board of Directors Code of Business Conduct and Ethics.

[4] The other current members of the EMT are: the Chairman, Chief Executive Officer and President; Executive Vice President & Chief Financial Officer; Executive Vice President & General Counsel; Executive Vice President & President GPB; Group Head Global Specialty Operations and President Animal Health Care; Senior Vice President and President Schering-Plough Research Institute; and Senior Vice President, Global Human Resources. The membership of the EMT may be changed during the term of the CIA at the discretion of Schering-Plough.

If the EMT ceases to exist or function in its current capacity, Schering-Plough will establish a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his or her responsibilities (e.g., shall assist in the analysis of Schering-Plough's risk areas and shall oversee monitoring of internal and external audits and investigations).

B. Written Standards.

1. *Code of Conduct.* Schering-Plough currently requires all newly employed Covered Persons to certify, in writing, that they have received, read, understood, and shall abide by Schering-Plough's current Business Conduct Policy. To the extent not already accomplished, within 120 days after the Effective Date, Schering-Plough shall develop, implement, and distribute a new written Code of Conduct to all Covered Persons. To the extent not already accomplished, within 120 days after the Effective Date, each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Schering-Plough's Code of Conduct. Schering-Plough shall make the promotion of, and adherence to, the Code of Conduct (known as the "Standards of Global Business Practices") an element in evaluating the performance of all Covered Persons. The Code of Conduct shall, at a minimum, set forth:

a. Schering-Plough's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to comply with all government contracting and price reporting requirements, and to market, sell, promote, and advertise its products in accordance with Federal health care program and FDA requirements;

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

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

d. the possible consequences to both Schering-Plough and Covered Persons of failure to comply with Federal health care program and FDA requirements and with Schering-Plough'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.F; Schering-Plough's commitment to maintain confidentiality and anonymity, as appropriate; and its commitment to non-retaliation with respect to disclosures under the Program.

For purposes of this Section III.B.1, Schering-Plough may use such electronic methods of distribution and/or certification as it deems appropriate, provided that a record is maintained electronically of such distributions and certifications. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

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

2. *Policies and Procedures*. To the extent not already accomplished, within 150 days after the Effective Date, Schering-Plough shall implement written Policies and Procedures regarding the operation of Schering-Plough's compliance program and its compliance with Federal health care program and FDA requirements. At a minimum, the Policies and Procedures shall address:

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

b. gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare & Medicaid Services (CMS) and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program, the Medicare program, and as otherwise required by Federal or state government directives;

c. selling, marketing, and promoting Schering-Plough 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;

d. selling, marketing, promoting, advertising, and disseminating information about off-label uses of Schering-Plough's products in compliance with all applicable FDA requirements;

e. policies and procedures relating to compensation (including salaries and bonuses) for Covered Persons that are designed to ensure that financial incentives do not exist for the improper promotion, sales, and marketing of Schering-Plough's products;

f. disciplinary policies and procedures for violations of Schering-Plough's Policies and Procedures, including policies relating to Federal health care program and FDA requirements;

g. the manner in which Global Drug Information Services receives and responds to requests for information about off-label uses of Schering-Plough's products; the form and content of information disseminated by Global Drug Information Services in response to such requests; and the internal review process for the information disseminated;

h. speaker meetings, advisory board meetings, and all other consultant arrangements (including, but not limited to, those for speakers, mentors, etc.) or related events. These policies shall be designed to ensure that the consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program requirements and with FDA requirements relating to the dissemination of information about

off-label uses of products. The policies shall include requirements about the content and circumstances of such arrangements and events;

i. sponsorship or funding of continuing medical education (CME) programs that are designed to ensure that Schering-Plough's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements. The policies and procedures shall require the disclosure of Schering-Plough's financial support of the CME program and any financial relationships with faculty, speakers, or participants at such CME program; shall require that the CME program have an educational focus; shall require that the CME program be independent; and shall require that the CME program be balanced;

j. sponsorship or funding of grants (including educational grants) that are designed to ensure that Schering-Plough's funding and/or sponsorship of such grants complies with all applicable Federal health care program requirements and FDA requirements; and

k. sponsorship or funding of research or related activities (including clinical trials, market research, or authorship of articles or other publications) by U.S. GPB that are designed to ensure that Schering-Plough's funding or sponsorship of such activities complies with all applicable Federal health care program requirements and FDA requirements.

To the extent not already accomplished, within 150 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on Schering-Plough's intranet or other internal web site available to all Covered Persons. If Schering-Plough uses such an electronic method of distribution, it must notify the Covered Persons receiving the Policies and Procedures that the Policies and Procedures will be distributed in such a manner and it must track the distribution to ensure that all appropriate Covered Persons received the Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Schering-Plough shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any material revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures.

To the extent that changes in the laws regarding the Federal health care program and/or the FDA requirements require Schering-Plough to materially change its Policies and Procedures, Schering-Plough will have 120 days to implement such changes.

C. Training and Education.

1. *Training Requirements, General Description.* The training and education required under this section III.C may be provided by supervisory employees, knowledgeable staff, Schering-Plough trainers, and/or outside consultant trainers selected by Schering-Plough or may be satisfied by relevant, accredited continuing education programs provided they cover topics outlined below in Section III.C.3. The persons providing the training shall be knowledgeable about the subject areas of their training.

Schering-Plough provides training on a regular basis concerning a variety of topics to its employees. The training required by this CIA need not be separate and distinct from the regular training provided by Schering-Plough, but instead may be integrated fully into such regular training. The Compliance Officer shall be responsible for determining how many of the hours of regular training shall be credited toward the general and specific training requirements set forth in this Section III.C.

Schering-Plough may provide the training required under this CIA through appropriate computer-based approaches. In that event, all applicable references to "hours" in this section shall mean "normative hours" as that term is used in the computer-based training industry. If Schering-Plough chooses to provide computer-based training, it shall also make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals who are receiving such training. To the extent a Covered Person is on a leave of absence when the required training is offered, the Covered Person shall receive the training within 60 days of the conclusion of the leave of absence.

New Covered Persons shall receive the training outlined below in Sections III.C.2 and III.C.3 within 30 days after becoming a Covered Person or within 150 days after the Effective Date, whichever is later. A Schering-Plough employee who has completed the training shall review a new Covered Person's work, to the extent that the work relates to

Managed Care Contracting Related Functions, Government Pricing and Medicaid Drug Rebate Related Functions, or Promotional and Product Services Related Functions until such time as the new Covered Person completes the applicable training.

Schering-Plough shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program or FDA requirements, any issues discovered during internal audits or the IRO audits, and any other relevant information.

To the extent that Schering-Plough has provided training that satisfies the general or specific training requirements set forth below within 180 days prior to the Effective Date, the OIG shall credit that training for purposes of satisfying Schering-Plough's training obligations for the first year of the CIA.

2. *General Training Provided to Covered Persons.* Within 150 days after the Effective Date, Schering-Plough shall provide at least two hours of general training to each Covered Person. This general training, at a minimum, shall explain:

a. Schering-Plough's CIA requirements and Schering-Plough's compliance program (including the Code of Conduct and Policies and Procedures as they pertain to general compliance issues); and

b. in general, the proper methods of promoting, marketing and selling, and contracting for products; the need to calculate and report accurate pricing and other information in connection with the Federal health care program requirements, including the Medicaid Drug Rebate Program and the Medicare program; and a general discussion of Schering-Plough's systems for gathering and tracking relevant data, and calculating and verifying information reported for purposes of the Medicaid Drug Rebate Program and Medicare.

After receiving the initial general training described above, each Covered Person shall receive at least one hour of general training annually.

3. *Specific Training for Relevant Covered Persons.* Within 150 days after the Effective Date, Schering-Plough shall provide at least two hours of specific training, in addition to the general training required above, to Managed Care Relevant Covered Persons, Government Pricing and Medicaid Drug Rebate Relevant Covered Persons, and Promotional and Product Services Relevant Covered Persons. After receiving the initial

specific training described in this section, these Covered Persons shall receive at least two hours of specific training annually.

a. Specific Training for Managed Care Relevant Covered Persons

The specific training for the Managed Care Relevant Covered Persons shall include a discussion of:

1) all applicable Federal health care program requirements (including the sanctions for violations) relating to Managed Care Contracting and Medicaid Drug Rebate Related Functions (including, but not limited to, the Federal anti-kickback statute; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the civil False Claims Act, 31 U.S.C. §§ 3729-3733; and the Medicaid Drug Rebate statute);

2) the personal obligation of each individual to comply with the legal requirements outlined above in section III.C.3.a.1; and

3) examples of proper and improper Managed Care Contracting and Medicaid Drug Rebate program practices.

b. Specific Training for Government Pricing and Medicaid Drug Rebate Relevant Covered Persons

The specific training for Government Pricing and Medicaid Drug Rebate Relevant Covered Persons shall include a discussion of:

1) in detail, Schering-Plough's systems for gathering relevant data and calculating, verifying and reporting information to CMS and/or the State Medicaid Programs for purposes of the Medicaid Drug Rebate Program, the Medicare Program, or any other Federal or state government price reporting requirement;

2) all applicable Federal health care program requirements (including the sanctions for violations) relating to

Government Pricing and Medicaid Drug Rebate Related Functions;

3) the personal obligation of each individual to comply with the applicable legal requirements outlined above in section III.C.3.b.2 and to track and review any variations identified within Schering Plough's systems; and

4) examples of proper and improper practices related to Government Pricing and Medicaid Drug Rebate Related Functions.

c. Specific Training for Promotional and Product Services Relevant Covered Persons

The specific training for Promotional and Product Services Relevant Covered Persons shall include a discussion of:

1) all Federal health care program requirements regarding the proper methods for selling, marketing, and promoting Schering-Plough's products, including, but not limited to, the requirements of the Federal anti-kickback statute; the Civil Monetary Penalties Law; the civil False Claims Act; and the Medicaid Drug Rebate statute;

2) all applicable FDA requirements regarding the proper methods for selling, marketing, advertising, and promoting Schering-Plough's products (including the requirements relating to the dissemination of information about off-label uses), including but not limited to, the requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations;

3) the personal obligation of each Covered Person involved in the sales, marketing, promotion, advertising, or dissemination of information about off-label uses of Schering-Plough's products to comply with all applicable legal requirements;

4) the legal sanctions for violations of the Federal health care program or FDA requirements; and

5) examples of proper and improper sales, marketing, and promotion practices.

4. *Certification.* Each Covered Person who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Average Sales Price Reporting Requirements.

1. *General Statement of Purpose and Intent.*

As specified below in section III.D.2.a, Schering-Plough shall report pricing information that accurately reflects prices at which actual purchasers buy the Schering-Plough products set forth on Appendix A, List of Products for Which Average Sales Prices Are Reported (Covered Products).

2. *Specific Reporting Requirements.*

a. Average Sales Price Defined. For purposes of this CIA, "Average Sales Price" or "ASP" is defined to have the meaning of, and will be calculated in accordance with Average Sales Price as defined in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), including any refinement of that definition that may be made by the Secretary of the Department of Health and Human Services, through the issuance of regulations, written directives, or guidance. Schering-Plough shall report the Average Sales Price by National Drug Code (NDC) for each Covered Product.

b. Reporting Obligations for Covered Products. In addition to any reporting required by the MMA, within 30 days after the last day of each calendar quarter, Schering-Plough shall report, in accordance with section III.D.2.a above, the Average Sales Prices of each of the Covered Products identified by Schering-Plough's NDC to: 1) the Medicaid programs of those States who have executed a state

perform Engagements to assist Schering-Plough in assessing and evaluating its systems, processes, policies and practices related to the Government Pricing and Medicaid Drug Rebate Related Functions, to Managed Care Contracting Related Functions and to Promotional and Product Services Related Functions. Each IRO retained by Schering-Plough shall have expertise in the applicable requirements of the Medicaid Drug Rebate Program, the Medicare Program, and Federal health care program and FDA requirements concerning the promotion of products, as may be appropriate to the specific Engagement for which it is retained. Each IRO shall assess, along with Schering-Plough, whether it can perform the Engagements in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist.

The IRO(s) shall conduct three types of engagements. One engagement shall assess Schering-Plough's systems, processes, policies and practices relating to the Government Pricing and Medicaid Drug Rebate Related Functions (Government Pricing and Medicaid Drug Rebate Engagement). The second engagement shall assess Schering-Plough's systems, policies and practices with regard to managed care contracting (Managed Care Expenditures Engagement). The third engagement shall assess Schering-Plough's systems, processes, policies and practices relating to sales, marketing, and product services activities (Promotional and Product Services Engagement). Except as otherwise provided in Section III.E.b below, the IRO shall perform all components of each of the engagements.

b. Frequency of Engagements. Each of the following Engagements shall be performed annually and shall cover the following periods: 1) for the first year of the CIA, the period from the Implementation Report due date through the first anniversary of the Effective Date of the CIA; 2) for the second through fifth years of the CIA, each successive corresponding Reporting Period (*i.e.,* the period from the relevant anniversary of the Effective Date through the subsequent anniversary).

1) Government Pricing and Medicaid Drug Rebate Engagement. As set forth more fully in Attachment B and below, the Government Pricing and Medicaid Drug Rebate Engagement shall consist of two components - a Systems Review and a Transactions Review. If there are no material changes in Schering-Plough's Government Pricing and Medicaid Drug Rebate related systems, processes, policies, and practices during the term of the CIA, the IRO shall perform the Government Pricing and Medicaid Drug Rebate Engagement Systems Review covering the first and fourth Reporting Periods. If Schering-Plough materially changes its systems, processes, policies and practices relating to Average Sales Price or the Medicaid Drug Rebate Program, then the IRO shall perform a Government Pricing and Medicaid Drug Rebate Engagement for the Reporting Period in which such changes were made in addition to conducting the Medicaid Drug Rebate Engagement for the first and fourth Reporting Periods. The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

2) *Managed Care Expenditures Engagement.* As set forth more fully in Attachment C and below, the Managed Care Expenditures Engagement shall be performed annually and cover each of the five Reporting Periods.

3) *Promotional and Product Services Systems Engagement.* The Promotional and Product Services Engagement shall consist of two components - a Systems Review and a Transactions Review. If there are no material changes in Schering-Plough's systems, processes, policies, and practices relating to sales, marketing, and product services activities, the Promotional and Product Services Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If Schering-Plough materially changes its systems, processes, policies, and practices relating to sales, marketing, and product services activities, then the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods.

The Promotional and Product Services Transactions Review Engagement shall be performed annually and shall cover each of the five Reporting Periods.

c. Entity Performing Engagements. The Engagements shall each be performed by the IRO, as specified in this Section III.E and the Attachments to this CIA, during the five Reporting Periods of the CIA. However, after the IRO(s) performs the first three Government Pricing and Medicaid Drug Rebate Engagements, Managed Care Expenditures Engagements, and Promotional and Product Services Systems Engagement, Schering-Plough, at its option, may request the OIG to permit that those Engagements be conducted internally and subject only to verification by the IRO for the remainder of the term of the CIA. The OIG retains sole discretion over whether to permit those Engagements to be conducted internally by Schering-Plough and subject to validation by the IRO. In making its decision, the OIG will consider, among other factors, the results of these Engagements during the first three Reporting Periods of the CIA and Schering-Plough's demonstrated audit capabilities to perform the Engagements internally. If the OIG denies Schering-Plough's request to shift the audit responsibilities, Schering-Plough agrees to engage the IRO to complete the remaining Engagements in accordance with the CIA.

d. Retention of Records. The IRO and Schering-Plough shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Schering-Plough) related to the Engagements for a period of six years after the Effective Date.

2. *Government Pricing and Medicaid Drug Rebate Engagement.* As more fully set forth in Attachment B, Government Pricing and Medicaid Drug Rebate Systems Review shall be an assessment of Schering-Plough's systems, processes, policies and practices relating to the tracking, gathering, and accounting for all relevant data for purposes of properly calculating and reporting Average Sales Price (ASP), Average Manufacturer Price, and Best Price. The Government Pricing and Medicaid Drug Rebate Transactions Review shall include an IRO review of a sample of the transactions underlying the reported ASPs for Covered Products to evaluate whether they were calculated and reported in accordance with Schering-Plough's policies and

methodologies developed by Schering-Plough to address MMA requirements. The Transactions Review shall also include an IRO review of a sample of transactions to evaluate whether appropriate price terms were considered for purposes of determining the Best Price.

3. *Managed Care Expenditures Engagement.* As set forth more fully in Attachment C, the Managed Care Expenditures Engagement shall review the Managed Care Related Expenditures paid to a sample of Managed Care Customers during the relevant Managed Care Expenditures Testing Period.

4. *Promotional and Product Services Engagement.* The Promotional and Product Services Engagement shall be a two part engagement. First, the IRO shall perform a Promotional and Product Services Systems Review of Schering-Plough's systems, processes, policies, and practices relating to specified sales and marketing, product information, contracting, funding, and compensation practices. Second, the IRO shall perform a Promotional and Product Services Transactions Review of samples of identified sales, marketing, and product services related activities. The details of the Promotional and Product Services Engagement shall be set forth in a subsequent Attachment to this CIA to be negotiated and agreed to between the Parties.

5. *Engagement Reports.* The IRO shall prepare a report (or reports) based upon each Government Pricing and Medicaid Drug Rebate Engagement, Managed Care Expenditures Engagement, and Promotional and Product Services Engagement performed (the Engagement Reports). Information to be included in the Engagement Reports is detailed in Attachments B and C.

6. *Validation Review.* In the event OIG has reason to believe that: (a) Schering-Plough's Government Pricing and Medicaid Drug Rebate Engagement, Managed Care Expenditures Engagement, or Promotional and Product Services Engagement (collectively "the Engagements") fails to conform to the requirements of this CIA; or (b) the IRO's findings or the Engagement results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Engagement complied with the requirements of the CIA and/or the findings or Engagement results are inaccurate (Validation Review). Schering-Plough shall pay for the reasonable cost of any such Validation Review performed by OIG or any of its designated agents. Any Validation Review of Engagement Reports submitted, as part of Schering-Plough's final Annual Report must be initiated no later than one year after Schering-Plough's final submission (as described in section II) is received by the OIG.

settlement agreement with Schering-Plough; 2) to First DataBank Inc.[5] solely for the purpose of reporting pricing information based on those Average Sales Prices to the Medicaid programs of those States that have executed a state settlement agreement; and 3) to the OIG. The first report of Average Sales Prices for Covered Products shall be made no later than January 30, 2005.

c. Certification Requirement. A high managerial agent of Schering-Plough will certify that the Average Sales Prices reported are calculated in accordance with requirements of the MMA. Said certifications shall be made in the form attached hereto as Attachment A, and shall include an acknowledgment that the Average Sales Prices reported will be filed with and used in the administration of the Medicare and Medicaid programs. Schering-Plough agrees that this certification by an appropriate employee or agent of Schering-Plough constitutes a certification by Schering-Plough.

d. Document Retention. Schering-Plough shall retain all supporting work papers and documentation relating to the methodology for calculating Average Sales Prices of its Covered Products for six years after the Effective Date, and shall make such documentation available for inspection by the OIG or its duly authorized representative(s) in accordance with the provisions set forth more fully below in Sections VII and IX of this CIA.

E. Engagement Procedures

1. *General Description.*

a. Retention of Independent Review Organization. Within 120 days after the Effective Date, Schering-Plough shall retain an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to

[5] If appropriate to reflect changes in the sources from which the State Medicaid programs receive their pricing information, Schering-Plough agrees that, upon the receipt of a written request by any of the States, it will report the required information to a drug pricing reporting source other than, and in addition to, First DataBank Inc., subject to reasonable provisions equivalent to those agreed to by First DataBank Inc. to ensure the confidentiality of that information.

Prior to initiating a Validation Review, OIG shall notify Schering-Plough 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, Schering-Plough may request a meeting with OIG to: (a) discuss the results of any Engagement submissions or findings; (b) present any additional or relevant information to clarify the results of any Engagement or to correct the inaccuracy of any Engagement; and (c) propose alternatives to the proposed Validation Review. Schering-Plough shall provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Engagement issue with Schering-Plough 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.

7. *Independence/Objectivity Certification.* Schering-Plough shall undertake a good faith effort to obtain from each IRO a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, and with regard to the Engagement, and that it has concluded that it is, in fact, independent and/or objective. The IRO(s) shall include such certification(s) in its report(s) to Schering-Plough. After undertaking good faith efforts, the failure to obtain an independence certification from the IRO(s) shall not constitute a breach of this CIA by Schering-Plough (whether a material breach or otherwise) and shall not constitute a basis upon which the OIG may impose Stipulated Penalties; however, such a failure shall constitute a basis upon which the OIG may initiate a Validation Review, as described in Section III.E.6 above, the costs of which shall be borne by Schering-Plough.

F. Disclosure Program.

Schering-Plough presently has a disclosure program designed to facilitate communications relating to compliance with Federal health care program and FDA requirements and Schering-Plough's policies (the "Disclosure Program"). During the term of this CIA, Schering-Plough shall maintain a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Schering-Plough's policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. During the term of the CIA, Schering-Plough shall continue to 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, including on the company's intranet or internal web site available to all employees).

The Disclosure Program shall continue to 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 associated with Schering-Plough's policies, conduct, practices or procedures with respect to any Federal health care program, Federal health care program requirement or FDA requirement concerning the promotion of products (hereafter "Disclosure"), the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The 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, Schering-Plough shall conduct an internal review of the allegations set forth in the Disclosure and ensure that proper follow-up is conducted.

The 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.

G. Ineligible Persons.

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

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

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

2) 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:

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

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

2. *Screening Requirements.* Schering-Plough shall ensure that all current Covered Persons are not Ineligible Persons and that it will not hire or engage any prospective Covered Persons who are Ineligible Persons, by implementing the following screening requirements.

a. For all prospective Covered Persons, Schering-Plough shall screen all such individuals against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.

b. For all current Covered Persons, Schering-Plough shall screen all such Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

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

3. *Removal Requirement.* If Schering-Plough has actual notice that a Covered Person has become an Ineligible Person, Schering-Plough shall remove such person from responsibility for, or involvement with, Schering-Plough's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the 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 person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Schering-Plough has actual notice that a Covered 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 his or her employment or contract term, Schering-Plough shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at Schering-Plough's corporate headquarters in New Jersey, Schering-Plough shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Schering-Plough conducted or brought by a governmental entity or its agents involving an allegation that Schering-Plough has committed a crime or has engaged in fraudulent activities in the United States (including the United States, the District of Columbia, and the territories and possessions of the United States). 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. Schering-Plough 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.

I. Reporting

1. *Reportable Events.*

a. Definition of Reportable Event. For purposes of this CIA, a "Reportable Event" means anything that involves a matter, brought to the attention of senior management at Schering-Plough's corporate headquarters in New Jersey, that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or applicable to any FDA requirements relating to the off-label promotion of drugs, for which penalties or exclusion may be authorized. A Reportable Event may be the result of an isolated event or a series of occurrences.

b. Reporting of Reportable Events. If Schering-Plough determines (after a reasonable opportunity to conduct an appropriate review or

investigation of the allegations) through any means that there is a Reportable Event, Schering-Plough 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:

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

2) a description of Schering-Plough's actions taken to correct the Reportable Event; and

3) any further steps Schering-Plough plans to take to address the Reportable Event and prevent it from recurring.

Schering-Plough shall not be required to report any Reportable Event which is the subject of an ongoing investigation or legal proceeding by a governmental entity or its agents previously disclosed under Section III.H above.

Schering-Plough's submission to OIG of any Reportable Event pursuant to this CIA does not preclude Schering-Plough from making the same disclosure through the OIG's Self-Disclosure Protocol.

J. Notification of Communications Regarding Off-Label Uses Issues.

Within 30 days after the date of any written report, correspondence, or communication from Schering-Plough to the FDA in connection with Schering-Plough's or a Covered Person's promotion, discussion, or dissemination of information about off-label uses of Schering-Plough's products, Schering-Plough shall provide a copy of the report, correspondence, or communication to the OIG. Schering-Plough shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Schering-Plough establishes or acquires new business units engaged in Managed Care Contracting Related Functions, Government Pricing and Medicaid Drug Rebate Related Functions, or Promotional and Product Services Related Functions in the United States (including the United States, the District of Columbia, and the territories and possessions of the United States), Schering-Plough shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of the establishment or acquisition. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider and/or supplier number (if any), and the corresponding contractor's name and address that has issued each provider or supplier number. Each new business unit or location shall be subject to all the requirements of this CIA.

Schering-Plough shall use its best efforts to implement the requirements of this CIA in new business units or locations that participate in any Federal health care program as soon as practicable. Notwithstanding any other provision to the contrary, the requirements of this CIA shall not become effective for new business units or locations until 120 days after the purchase or establishment or acquisition of such new business units or locations. However, any joint-venture and co-promotion arrangements that Schering-Plough may have are specifically excluded from the requirements of this Section IV.

V. IMPLEMENTATION AND ANNUAL REPORTS

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

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer or any change in the membership or functions of the Executive Management Team described in Section III.A;

2. a copy of Schering-Plough's Code of Conduct required by Section III.B.1;

3. a copy of all Policies and Procedures required by Section III.B.2;

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

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; and

b. number of Covered Persons required to be trained, percentage of Covered Persons 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 description of the Disclosure Program required by Section III.F;

7. the following information regarding the IRO(s): (a) identity, address and phone number; (b) a copy of the engagement letter(s); (c) a summary and description of all current and prior engagements and agreements between Schering-Plough and the IRO(s); and (d) the proposed start and completion dates of the Engagements identified in section III.E;

8. a certification from the IRO(s) regarding its professional independence and/or objectivity with respect to Schering-Plough;

9. a description of the process by which Schering-Plough fulfills the requirements of Section III.G regarding Ineligible Persons;

10. the name, title, and responsibilities of any Covered Person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered, or prescribed by an Ineligible Person;

11. a list of all of Schering-Plough's locations (including locations and mailing addresses) which house Covered Persons, except for offices operated out of an individual's residence; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program, and/or supplier number(s) (if any); and the name and address of each Federal health care program contractor to which Schering-Plough currently submits claim, if any;

12. To the extent not already furnished to the OIG, an overall description of Schering-Plough's corporate structure, including identification of any parent and/or sister or subsidiary companies, and their respective lines of business; and

13. the certifications required by Section V.C.

B. Annual Reports. Schering-Plough shall submit to OIG annually a report with respect to the status of, and findings regarding, Schering-Plough' 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 Compliance Officer or any change in the membership or functions of the Executive Management Team described in Section III.A;

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in Federal health care program or FDA requirements concerning the promotion of products) and copies of any compliance-related Policies and Procedures related to compliance with Federal health care program or FDA requirements concerning the promotion of products;

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

4. 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; and

b. number of Covered Persons required to be trained, percentage of Covered Persons 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.

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

6. Schering-Plough's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

7. a summary/description of all current and prior engagements and agreements between Schering-Plough and the IRO(s), if different from what was submitted as part of the Implementation Report;

8. a certification from the IRO(s) regarding its professional independence and/or objectivity with respect to Schering-Plough;

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

10. a summary of the Disclosures in the Disclosure log required by Section III.F that relate to Federal health care programs or to FDA requirements;

11. any changes to the process by which Schering-Plough fulfills the requirements of Section III.G regarding Ineligible Persons;

12. the name, title, and responsibilities of any Covered Persons who is determined to be an Ineligible Person under Section III.G; the actions taken by Schering-Plough in response to the screening and removal obligations set forth in Section III.G;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. 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;

14. a description of all changes to the most recently provided list of Schering-Plough's locations (including addresses) as required by Section V.A.11; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider, and/or supplier number(s); and the name and address of each Federal health care program contractor to which Schering-Plough currently submits claims;

15. a description of all joint-venture arrangements or co-promotion arrangements entered between Schering-Plough and any entity other than Millennium Pharmaceuticals, Inc. or Merck & Co., Inc.; and

16. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 150 days after the end of the first Annual Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Report.

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

1. all policies and procedures, standardized contracts, promotional materials, and training materials relating to Government Pricing and Medicaid Drug Rebate Related Functions, Managed Care Contracting Related Functions, and Promotional and Product Services Related Functions have been reviewed by legal counsel and been found to be in compliance with all applicable Federal health care program and FDA requirements;

2. a Medicaid Drug Rebate and Average Sales Price certification as set forth in Attachment A;

3. to the best of his or her knowledge, except as otherwise described in the applicable report, Schering-Plough is in compliance with all of the requirements of this CIA, including that Schering-Plough has provided appropriate training to all Covered Persons that satisfies the requirements of Section III.C;

4. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and

5. if applicable, Schering-Plough has complied with its obligations under the Settlement Agreement: (i) 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; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information. Schering-Plough 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. Schering-Plough 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:

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

Schering-Plough:

Senior Vice President, Global Compliance and Business Practices
Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033
Phone: 908.298.5250
Facsimile: 908.298.7995

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail (such as Federal Express or its equivalent), messenger delivery, 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 Schering-Plough's books, records, and other documents and supporting materials (to the extent such items are not protected under appropriately asserted legal privilege) and/or conduct on-site reviews of any of Schering-Plough's locations for the purpose of verifying and evaluating: (a) Schering-Plough's compliance with the terms of this CIA; and (b) Schering-Plough's compliance with the requirements of the Federal health care programs in which it participates and with applicable FDA requirements. The documentation described above shall be made available by Schering-Plough 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 Schering-Plough'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. Schering-Plough shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Schering-Plough's employees may elect to be interviewed with or without a representative of Schering-Plough present.

Schering-Plough employees shall have the right to be represented by counsel and any such employee may, at his or her option, be accompanied by counsel for Schering-Plough and/or their personal counsel at any interview by the OIG. Notwithstanding such

arrangement, the OIG recognizes that individuals have the right to refuse to submit to interviews, and Schering-Plough shall not be obligated to require such individuals to submit to interviews. If any individual decides not to submit to an interview, such refusal shall not constitute a breach of this CIA.

VIII. DOCUMENT AND RECORD RETENTION

Schering-Plough 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 from the Effective Date (or longer if otherwise required by law).

IX. DISCLOSURES

The OIG shall follow all applicable Federal law concerning privacy and confidentiality, including the Federal Privacy Act, 5 U.S.C. § 553a, to the greatest extent allowed by law. Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Schering-Plough prior to any release by OIG of information submitted by Schering-Plough pursuant to its obligations under this CIA and identified upon submission by Schering-Plough as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Schering-Plough shall have the rights set forth at 45 C.F.R. § 5.65(d).

The OIG shall provide the pre-disclosure notice required pursuant to 45 C.F.R. § 5.65(d) to the Compliance Officer at the address provided in section VI. Nothing in this CIA or any communication or report made pursuant to this CIA shall constitute or be construed as a waiver by Schering-Plough of Schering-Plough's attorney-client, work product or other applicable privileges. Except as otherwise stated herein, the existence of any such privilege does not affect Schering-Plough's obligation to comply with the provisions of the CIA.

X. BREACH AND DEFAULT PROVISIONS

A breach of this CIA does not constitute a breach of the Settlement Agreement or Plea Agreement between Schering-Plough and the United States executed contemporaneously herewith or the settlement agreements with the individual States referred to in the Preamble. Any breach of the terms of those agreements does not constitute a breach of this CIA, except to the extent that such a breach independently also constitutes a breach of this CIA. Section X of this CIA specifies all of the remedies available to the OIG if Schering-Plough fails to satisfy its obligations under this CIA.

The remedies available to the OIG under this section X do not preempt or limit any actions that individual States may take against Schering-Plough under appropriate authorities not specified in this CIA.

Schering-Plough 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, Schering-Plough 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 Schering-Plough fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;
b. a Compliance Committee, if required;
c. a written Code of 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 Schering-Plough fails to engage an IRO as required in Section III.E and Appendices B-C.

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 Schering-Plough 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 Schering-Plough fails to submit any Engagement Report in accordance with the requirements of Section III.E and Appendices B-C.

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

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

7. A Stipulated Penalty of $1,000 for each day Schering-Plough fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Schering-Plough, stating the specific grounds for its determination that Schering-Plough has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Schering-Plough shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Schering-Plough 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. Schering-Plough 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 Schering-Plough 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 Schering-Plough 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 Schering-Plough 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 Schering-Plough in writing of: (a) Schering-Plough'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"). Such Demand Letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter,[6] Schering-Plough 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 Schering-Plough elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Schering-Plough 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 Schering-Plough 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 Schering-Plough to report a Reportable Event and take corrective action, as required in Section III.I;

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

[6] If the Demand Letter is received between December 20 of any given year and January 1 of the following year, the ten day period will commence on January 2 of that year.

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.E and Appendices B and C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Schering-Plough constitutes an independent basis for Schering-Plough's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Schering-Plough has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Schering-Plough of: (a) Schering-Plough'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.* Schering-Plough shall have 30 days after the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Schering-Plough 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) Schering-Plough has begun to take action to cure the material breach; (ii) Schering-Plough is pursuing such action with due diligence; and (iii) Schering-Plough has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Schering-Plough fails to satisfy the requirements of Section X.D.3, OIG may exclude Schering-Plough from participation in the Federal health care programs. OIG shall notify Schering-Plough in writing of its determination to exclude Schering-Plough (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 Schering-Plough'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, Schering-Plough 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 Schering-Plough 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, Schering-Plough 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[6] 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 Schering-Plough was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Schering-Plough 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 Schering-Plough to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Schering-Plough 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:

6 If the Demand Letter is received between December 20 of any given year and January 1 of the following year, the ten day period will commence on January 2 of that year.

a. whether Schering-Plough 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) Schering-Plough had begun to take action to cure the material breach within that period; (ii) Schering-Plough has pursued and is pursuing such action with due diligence; and (iii) Schering-Plough provided to OIG within that period a reasonable timetable for curing the material breach and Schering-Plough 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 Schering-Plough, only after a DAB decision in favor of OIG. Schering-Plough's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Schering-Plough 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 Schering-Plough 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. Schering-Plough shall waive its 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 Schering-Plough, Schering-Plough 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, and into which this CIA is incorporated, Schering-Plough and OIG agree as follows:

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

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 and the CIA will be subject to modifications if so required by any change in Federal health care program requirements or FDA requirements as referenced in the Preamble to this CIA;

D. The undersigned Schering-Plough 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 agreement.

ON BEHALF OF SCHERING-PLOUGH CORPORATION

BRENT SAUNDERS
Senior Vice President
Global Compliance and Business Practices
Schering-Plough Corporation

July 29, 2004
DATE

PAUL E. KALB, ESQ.
Sidley Austin Brown & Wood LLP

7/16/04
DATE

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

Larry J. Goldberg

LARRY J. GOLDBERG
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

14 July 2004
DATE

Appendix A to CIA between Schering-Plough Corporation and OIG

List of Products for Which Average Sales Prices Are Reported

The products on this list shall be defined as "Covered Products" for purposes of the requirements of Section III.D of the CIA and Attachment A thereto.

1. All Schering-Plough Corporation (Schering-Plough) products (including the products of Schering-Plough subsidiaries) for which Schering-Plough reported Average Sales Prices to the Centers for Medicare & Medicaid Services as of the Effective Date of the CIA.
2. Clarinex
3. Claritin
4. Isosorbide Mononitritate
5. Clotrimazole and Betamethoasone Dipropionate Creme
6. Ribavirin
7. Sucralfate Tablets
8. Clotrimazole Creme
9. Augmented Betamethasone Dipropoinate Ointment
10. Potassium Chloride

Attachment A

Certification for CIA with Schering-Plough Corporation

CERTIFICATION

In accordance with the Corporate Integrity Agreement (CIA) entered between Schering-Plough Corporation (Schering-Plough) and the OIG, the undersigned hereby certifies the following to the best of my knowledge, information, and belief:

1) Schering-Plough has in place policies and procedures describing in all material respects the methods for gathering, calculating, verifying and reporting the data and information reported to the Centers for Medicare and Medicaid Services (CMS) and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program (Medicaid Rebate Policies and Procedures);

2) the Medicaid Rebate Policies and Procedures have been designed to ensure compliance with Schering-Plough's obligations under the Medicaid Drug Rebate Program;

3) Schering-Plough's Medicaid Rebate Policies and Procedures were followed in all material respects in connection with the calculation of Average Manufacturer Price and Best Price for Schering-Plough's products for each of the following four quarters: [specifically identify each quarter]; and

3) In accordance with Section III.D of the CIA, Average Sales Prices for the products listed on Appendix A hereto for each of the following quarters [specifically identify each quarter] were reported to: 1) the Medicaid programs of those States that executed settlement agreements with Schering-Plough; 2) to First DataBank Inc. (and/or any other price reporting entity as specified in the CIA); and 3) to the OIG[1]. The Average Sales Prices reported were calculated in accordance with the definition of and requirements relating to Average Sales Price set forth in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and as reflected in the attached methodology. I hereby certify that the statements made in connection with the submission of Average Sales Prices and this Certification are true, complete, and current and are made in good faith. I understand that the Average Sales Prices reported were filed with the State Medicaid programs of those States that executed settlement agreements with Schering-Plough and may be used in the administration of the Medicaid programs of those States and/or may be used by those States for Medicaid reimbursement purposes.

_____
Signature
[Insert Name and Title]

_____
Date

[1] In the event that any product listed on Appendix A is discontinued, for purposes of meeting its CIA requirements Schering-Plough may cease reporting the ASP for that product one year after the expiration date of the last batch of the product manufactured.

Attachment B to the CIA for Schering-Plough Corporation
Government Pricing and Medicaid Drug Rebate Engagement

I. Government Pricing and Medicaid Drug Rebate Engagement - General Descriptions

As specified more fully below, Schering-Plough Corporation (SP) shall retain an Independent Review Organization (IRO) to perform testing to assist SP 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) Best Price (BP) and Average Manufacturer Price (AMP) under the Medicaid Drug Rebate Program; and (b) Average Sale Price (ASP) for Covered Products, as defined in Appendix A of the CIA. The IRO shall perform two types of engagements 1) a systems review of SP's systems, processes, policies and practices relating to the calculation and reporting of BP and AMP under Medicaid Drug Rebate Program and ASP for Covered Products, as defined by MMA (collectively "Systems Review Consulting Engagement"); and 2) testing of a sample of transactions to assess whether SP is calculating ASP for Covered Products and BP in accordance with its policies and procedures and methodologies developed by SP in regards to the Medicaid Drug Rebate Program and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Government Pricing and Medicaid Drug Rebate Transactions Engagement).

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

If there are no material changes in SP's systems, processes, policies and practices during the term of the CIA, then the IRO shall perform the Systems Review Consulting Engagement covering the first and fourth Reporting Periods. If SP materially changes its systems, processes, policies and practices as they relate to the calculation of AMP, BP, or ASP then the IRO shall perform a Systems Review Consulting Engagement covering the Reporting Period in which such changes were made in addition to conducting the Systems Review Consulting Engagement for the first and fourth Reporting Periods. The additional Systems Review Consulting Engagement shall consist of an identification of the material changes, an assessment of whether the systems, processes, policies and practices already reported on did not materially change, and an update on the systems, processes, policies and practices that materially changed.

The Government Pricing and Medicaid Drug Rebate Transactions Engagement shall be designed to test whether SP is calculating ASP and BP in accordance with its policies, procedures and methodologies developed by SP in regards to the Medicaid Drug Rebate Program and MMA. The Government Pricing and Medicaid Drug Rebate Transaction Engagement shall consist of two parts, the "Reported Prices Procedures for ASP," and the "Reported Prices Procedures for BP."

Consistent with Section III.E.1.c of the CIA, after the third Reporting Period, the OIG may, at its discretion and upon request of SP, permit SP to perform the engagements described in this Attachment B, subject to validation by the IRO or consultant, as appropriate.

II. Systems Review Consulting Engagement

A. Average Sale Price Systems Review

For at least the first and fourth Reporting Periods, the IRO shall review SP'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 reported to the Centers for Medicare and Medicaid Services (CMS) as required under MMA.

In general terms, the IRO shall review the following:

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

   a) The process, policies, and procedures used to determine whether and which particular transactions reflecting final sales prices are included in or excluded from the ASP calculation;
   b) a review of SP's methodology for applying transactions to the ASP calculations;
   c) the relevant flow of data and information by which price terms and transactions with SP customers are accumulated from source systems and entered and tracked in SP's ASP system for purposes of calculating ASP;
   d) a review of any SP inquiries to CMS regarding the ASP calculation and reporting requirements in accordance with MMA and any responses to those inquiries; and

e) the controls and processes in place to examine and address system reports that require critical evaluation (such as reports of variations, exceptions, or outliers).

B. Medicaid Rebate Systems Review

For at least the first and fourth Reporting Periods, the IRO shall review SP's systems, processes, policies and practices (including the controls on the systems, processes, policies, and practices) associated with the tracking, gathering, and accounting for all relevant data for purposes of calculating and reporting AMP and BP to CMS under the Medicare Drug Rebate Program.

In general terms, the IRO shall review the following:

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

   a) The process used to determine whether and which discounts or rebates in SP customer contracts, or other price terms or transactions with SP customers, are included in the calculation of BP and AMP for Medicaid rebate eligible products;
   b) a review of the methodology for applying transactions to the AMP and BP calculations;
   c) the relevant flow of data and information by which price terms and transactions with SP customers are accumulated from the source systems and entered and tracked in SP's information systems for purposes of calculating the AMP and BP;
   d) a review of any SP inquiries to CMS regarding the Medicaid Drug Rebate Program and any responses to those inquiries; and
   e) the controls and processes in place to examine and address system reports that require critical evaluation (such as reports of variations, exceptions, or outliers).

C. Systems Review Consulting Engagement Report

For each relevant Reporting Period, the IRO shall prepare a report based upon the Systems Review Consulting Engagement. This report may be combined with the report for the Government Pricing and Medicaid Drug Rebate Transactions Engagement as well as the reports generated by the IRO as required in Attachment C to the CIA, and shall include the following:

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

    a. The computer or other relevant systems (including the source systems, the ASP system, and any other information systems, as applicable) used to calculate and report AMP, BP and ASP;
    b. the information input into SP's relevant computer or other systems used to calculate AMP, BP and ASP;
    c. the system logic or decisional rationale used to determine whether contract terms, discounts, rebates and all other relevant transactions with SP customers are included/excluded when calculating AMP, BP and ASP; and
    d. the policies and practices of SP's government pricing group in examining system reports for variations that require critical evaluation, including the basis upon which variations, exceptions, or outliners are identified, and the follow up actions taken in response.

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

    a. SP's inquiries to CMS regarding Medicaid Drug Rebate Program and any responses to those inquiries;
    b. SP's inquiries to CMS regarding the calculation of ASP in accordance with MMA and any responses to those inquiries; and
    c. SP's systems and practices for reporting any adjustments or additional information related to the submissions.

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

III. Government Pricing and Medicaid Drug Rebate Transactions Engagement

A. <u>Reported Prices Procedures for ASP</u>

For each Reporting Period, the IRO shall conduct Reported Prices Procedures for a sample of transactions to test whether SP calculated and reported ASP for Covered Products in accordance with its stated policies and methodology developed by SP in regards to MMA requirements. The

Procedures shall require the IRO to select and test probe samples of Like Kind Transactions[1] (consisting of sales and sales-related activities, for individual Covered Products, to individual customers or other entities, that are specifically included in, or excluded from, the ASP calculation (hereafter defined as "Transactions")). The IRO will also select and test a probe sample of Estimated Transactions[2] used in the calculation of ASP for Covered Products in order to test SP's methodology.

1. Grouping and Testing of Transactions

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

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

a. Whether the Like Kind Transaction prices are supported by source documents; and
b. Whether SP included or excluded each Like Kind Transaction in the calculation of ASP in accordance with its policies and procedures and methodology developed by SP in regards to MMA requirements.

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

a. Whether the Estimated Transaction amounts were calculated in accordance with SP policies and procedures and methodology developed by SP in regards to MMA requirements, and were supported by relevant commercial arrangements or other source documentation; and
b. Whether the Estimated Transactions were included in or excluded from the ASP calculation in accordance with SP's policies and procedures and methodology developed by SP in regards to MMA requirements.

[1] Like Kind Transactions are defined as transactions that were finalized at the time of the sale and grouped together by transaction type. Examples of Like Kind Transactions include, but may not be limited to, sales and adjustment to original sales, chargebacks, and manual adjustments.
[2] Estimated Transactions may include volume discounts, free goods that are contingent on any purchase requirements, and/or rebates that are available on a lagged basis and SP, in accordance with the MMA, is required to apply a methodology based on the most recent 12-month period available to estimate costs attributable to these price concessions.

2. Sampling of Transactions

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

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

The OIG will determine (based on discussions with the IRO and SP, the results of the probe reviews, and findings following any Additional Investigation) whether the testing of a statistically valid random sample of additional Transactions will be required. The size of any statistically valid random sample(s) shall be agreed upon by the OIG, SP, 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 "RAT-STATS" or through the use of another method of random sampling acceptable to the OIG.

B. Reported Prices Procedures for BP

For each Reporting Period, the IRO shall conduct Reported Pricing Procedures for BP to test whether SP calculated and reported BP in accordance with SP policies and procedures and methodology developed by SP in regards to the Medicaid Drug Rebate Program.

The Reported Prices Procedures for BP shall consist of two parts:

1. Part One of Reported Prices and Procedures for BP

At the end of each Reporting Period, the IRO shall randomly select the quarter for review. The IRO will then obtain a listing of all SP Customers[3] to whom sales of Medicaid rebate eligible products were made at contracted prices during the relevant quarter of the Review Period. The IRO will randomly select a sample of 20 SP Customers using the following methodology. The IRO will aggregate the number of NDCs for each SP Customer and will categorize each SP Customer as "large" or "small" based upon the total number of contracted Medicaid rebate eligible NDCs for that SP Customer in the Reporting Period quarter selected. The IRO shall develop, and share with the OIG, a stratification system whereby the chance for selection in the large SP Customer pool is greater than the chance for selection in the small SP Customer pool. The IRO shall randomly select 15 SP Customers from the large SP Customer pool and five SP Customers from the small SP Customer pool.

For each SP Customer selected, the IRO will identify all contracts with SP and all corresponding Medicaid rebate eligible NDCs for which the SP Customer had a contract price with SP. The IRO will then test for each SP Customer selected that each contract price for each Medicaid rebate eligible NDC is accurately reflected in SP's contract tracking system(s) and that the contract price is appropriately considered for purposes of determining BP in accordance with SP's policies and procedures and methodology developed by SP in regards to the Medicaid Drug Rebate Program.

2. Part Two of Reported Prices Procedures for BP

The IRO will obtain the following information:

a. The five Medicaid rebate eligible NDCs for which SP paid the largest amount (e.g., total dollars) of Medicaid rebates in the quarter under review. If the quarterly Medicaid rebates for the selected quarter under review have not been filed or paid, the IRO will use the Medicaid rebates for the most recent quarter that have been filed and paid; and

   1. For each of the five Medicaid rebate eligible NDCs selected, obtain a copy of the report that identifies for each of the selected NDCs all unique prices lower than

[3] An SP Customer is any customer with whom SP contracts directly.

a. If additional Part One testing is required, test a random selection of an additional five SP Customers and contract prices associated with those Customers from the large SP Customer pool; and/or

b. If additional Part Two testing is required, test the next five Medicaid rebate eligible NDCs with the highest amounts of Medicaid rebates (total dollars) paid by SP.

B. Government Pricing and Medicaid Drug Rebate Transactions Report

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

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

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

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

The IRO shall include the following results for each engagement:

1. Reported Prices Procedures for ASP

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

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

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

the reported BP in the quarter identified within SP's systems used to determine BP; and

2. For each unique price lower than the reported BP in the quarter identified in this report, the IRO will review a minimum of five randomly selected contracted transactions associated with each of those unique lower prices to assess if each was properly excluded from the determination of BP for that Medicaid rebate eligible NDC in the quarter under review in accordance with SP's stated methodology and/or policies and procedures.

3. Additional Investigations

If the IRO identifies any prices reviewed in Part One or Part Two of the Reported Prices Procedures for BP that were not accurately reflected in SP's systems and/or were not appropriately included in, or excluded from, SP's BP determination in accordance with SP's policies and procedures and methodology developed by SP in regards to the Medicaid Drug Rebate Program, 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 this review and Additional Investigation, if warranted, the IRO will report to the OIG its findings relating to any errors and their root cause(s).

In the event the IRO finds more than one error for the quarter under review in Part One or Part Two testing the IRO will perform a second set of Part One or Part Two testing procedures (i.e., Part One or Part Two testing depending which Part of the Reported Prices Procedures for BP resulted in an Additional Investigation being warranted) after SP has submitted its management response to the IRO findings to the OIG, after the OIG has reviewed and considered SP's management response, and the OIG has determined that additional Part One or Part Two testing is warranted following consultations with SP and the IRO.

Should it be determined that additional Part One or Part Two testing is warranted, the IRO shall:

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

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

2. The Reported Prices Procedures for BP – Part One

a. A list of the 20 SP Customers selected under Part One, the number of contracts associated with each SP Customer, the NDCs tested, the contract prices for each NDC tested; and a list of any supporting documentation reviewed;

b. For each selected SP Customer, a description of the steps taken to test that the contract price(s) for each NDC selected was accurately reflected in SP's systems;

c. For each selected SP Customer, the results from testing whether each NDC contract price was accurately reflected in SP's contracting systems. If the correct price was not reflected in the systems, the IRO should identify the correct price term;

d. A detailed description of any Additional Investigation or review undertaken with regard to any price not accurately reflected in SP's systems and the results of any Additional Investigation or review undertaken with respect to any such price;

e. For each selected SP Customer, a description of the steps taken to test that each contract price term was appropriately considered in SP's determination of BP for that NDC in accordance with SP policy and procedure and methodology developed by SP in regards to the Medicaid Drug Rebate Program;

f. For each selected SP Customer a list of any price inappropriately included in, or excluded from, SP's BP determination for that quarter based on SP policy and procedure and methodology developed by SP in regards to the Medicaid Drug Rebate Program, a description of any

adjustments to BP reported to CMS; and a description of any additional follow-up action taken by SP;

g. A detailed description of any Additional Investigation or review undertaken with regard to any price not appropriately included in, or excluded from, SP's BP determination for that quarter, and the results of any Additional Investigation or reviews undertaken with respect to any such price; and

h. The IRO's recommendations for changes in SP's policies and procedures and/or methodology to correct or address any weaknesses or deficiencies uncovered during the review.

3. The Reported Prices Procedures for BP – Part Two

a. A narrative list of the five Medicaid rebate eligible 9-digit NDCs with the highest rebates paid by SP for the quarter under review and the BP reported by SP to the Medicaid Drug Rebate Program for each of the five NDCs for the quarter under review;

b. A description of the steps and the supporting documentation reviewed to assess the unique lower prices identified in the SP report for each of the selected NDCs, which were below BP reported by SP in the quarter. 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 included in, or excluded from, SP's BP determination for that quarter in accordance with SP policy and procedure and methodology developed by SP in regards to the Medicaid Drug Rebate Program; a description of any adjustments to BP reported to CMS; and a description of any additional follow-up action taken by SP;

d. A detailed description of any Additional Investigation or review undertaken with regard to any prices that were not accurately included in, or excluded from, SP's BP determination for the quarter under review and the results of any such investigation or review undertaken with respect to any such price; and

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

Attachment C to the CIA for Schering-Plough Corporation
Managed Care Expenditures Engagement

I. Managed Care Expenditures Engagement

The Managed Care Expenditures Engagement shall be a review of Discount Agreements and Control Documents (defined below), as per Schering-Plough's polices and procedures, relating to a sample of Managed Care Related Expenditures (defined below) associated with a sample of 25 Relevant Managed Care Customers (defined below), supplemented by, as necessary, interviews of relevant SP personnel to gain an understanding of the related systems, processes and practices supporting these policies and procedures. The Managed Care Expenditures Engagement shall be conducted annually and cover each Reporting Period.

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

Consistent with Section III.E.1.c of the CIA, after the third Reporting Period, the OIG may, at its discretion and upon request of SP, permit SP to perform the engagement described in this Attachment C (subject to validation by the IRO or consultant, as appropriate).

A. General Description of Managed Care Expenditures Engagement

SP's Policies and Procedures (referenced in Section III.B.2 of the CIA) set forth certain requirements relating to promotional activities, including those used in connection with Managed Care Customers. For each Reporting Period, the IRO shall select and test a sample of 50 Managed Care Related Expenditures to a randomly selected sample of 25 Relevant Managed Care Customers to assist SP in assessing whether the requisite documentation relating to the Managed Care Related Expenditure exists and whether the documentation was completed in accordance with SP's Policies and Procedures.

The following definitions apply for purposes of the Managed Care Expenditures Engagement:

A "Managed Care Customer" is a for profit or not-for-profit entity: (a) whose principal business is managing or providing pharmacy and/or other healthcare benefits, including but not limited to health maintenance

organizations, preferred provider organizations, and pharmacy benefit management companies; and (b) that has entered into a Discount Agreement with SP for a prescription product that was in effect during the relevant Reporting Period. The term "Managed Care Customer" does not include hospitals or health care providers.

A "Relevant Managed Care Customer," for purposes of this CIA, shall be a Managed Care Customer that received at least two Managed Care Related Expenditures (as defined below) during the Reporting Period.

A "Discount Agreement" is an agreement between SP and a Managed Care Customer for discount payments made in connection with SP pharmaceutical prescription products, and includes, but is not limited to, rebate agreements. For purposes of this Managed Care Expenditures Engagement, the IRO shall only review Discount Agreements executed later than 150 days after the Effective Date of the CIA.

A "Managed Care Related Expenditure" is a non-rebate, non-administrative fee payment by SP to a Managed Care Customer made during the relevant Reporting Period in connection with any promotional activities, including the following types of activities: (a) promotional support (including exhibits, displays, promotional events, SP-controlled screenings); (b) advisory boards; (c) patient education programs (including compliance letters, educational mailings, web-based education programs, health education programs); (d) physician education programs (educational mailings, formulary announcements, clinical consulting programs); (e) employer speaker programs; and (f) consulting arrangements.

"Control Documents" are all documents that support each type of Managed Care Related Expenditures, as defined in SP's policies and procedures (i.e., required documentation and follow-up documentation). Examples of Control Documents may include spending justification forms, request forms, contracts and/or agreements, management approvals in electronic or paper format, documentation of proof of payment (e.g., cancelled check), documentation of proof of performance, etc.

B. Selection of Managed Care Customers and Managed Care Related Expenditures

For each Managed Care Expenditures Engagement, the IRO shall test a sample of 50 Managed Care Related Expenditures paid to Relevant Managed Care Customers to assess if SP completed the Managed Care Related Expenditures in accordance with their policies and procedures.

The IRO shall obtain from SP a listing of all its Relevant Managed Care Customers for the Reporting Period and shall randomly select 25 of those Customers as the basis for the Engagement. For the 25 Relevant Managed Care Customers, SP shall aggregate all Managed Care Related Expenditures paid to those Relevant Managed Care Customers in the Reporting Period and categorize each Managed Care Related Expenditure by type (e.g., promotional support, advisory boards, consulting arrangement). SP shall submit a report to the IRO and the OIG that lists every Managed Care Related Expenditure paid to a Relevant Managed Care Customer in the Reporting Period from the highest dollar value to the lowest dollar value. The OIG, as soon as possible after receipt of this report from SP, shall notify the IRO of how many Managed Care Related Expenditures from each category, the total of which shall not exceed 50, shall be tested by the IRO.

Should the IRO determine that there are fewer than 50 Managed Care Related Expenditures associated with the available Relevant Managed Care Customers, Schering and the IRO will contact the OIG to determine how to proceed to obtain a pool of not more than 50 Managed Care Related Expenditures.

Once the IRO has identified the 50 Managed Care Related Expenditures for testing, SP shall provide the IRO with all Discount Agreements with the selected Relevant Managed Care Customers and all Control Documents relating to each of the 50 Managed Care Related Expenditures. The 50 Managed Care Related Expenditures shall be tested based upon the supporting documentation available at SP or under SP's control.

C. Attributes to be Tested

The IRO shall review each of the 50 Managed Care Related Expenditures to assess:

1. Whether the appropriate Control Documents and/or Discount Agreement(s) exist for each Managed Care Related Expenditure in accordance with SP's policies and procedures;

2. Whether the appropriate Control Documents and/or Discount Agreements were completed in accordance with the requirements set forth in SP's policies and procedures. This includes a review of whether all required approvals, either written or systemic, were obtained in accordance with SP's policies and procedures; and

3. Whether any corrective action has been taken to comply with SP's policies and procedures prior to the IRO testing of the relevant Reporting Period.

D. Definition of Material and Non-Material Errors

The IRO shall review the Control Documents using the criteria set forth above in Section I.C and shall identify any Non-Material Errors and Material Errors discovered. For purposes of this review, the Control Documentation will be found to have a Material Error if:

1. The appropriate and required Control Documents do not exist and no corrective action has been taken prior to the IRO review of the Managed Care Related Expenditure in the Reporting Period; or

2. Information or data is omitted from key field in the documentation that restricts the IRO's ability to understand the nature of the expenditure or activity and/or assess compliance with SP's policies and procedures and no corrective action has been taken prior to the IRO review of the Managed Care Related Expenditure in the Reporting Period.

All other errors shall be considered non-material, and shall be identified and explained in the Managed Care Expenditures Engagement Report.

E. Additional Engagement if Material Errors are Discovered

In the instances in which the IRO finds Material Errors, it shall conduct an Additional Engagement to further review the expenditures or activities reflected in the erroneous Control Documents. The IRO shall perform this Additional Engagement in a manner designed to determine the root cause of the Material Error. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the error.

II. Managed Care Expenditures Engagement Report

The IRO shall annually prepare a report based upon each Managed Care Expenditures Engagement performed. Each Report shall include the following:

A. Elements to Be Included

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

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

3. Sources of Data – a full description of Control Documents, the Discount Agreements and/or other relevant information relied upon by the IRO when performing the testing.

B. Results to Be Included

1. A general description of the types of Managed Care Related Expenditures received by Relevant Managed Care Customers during the Reporting Period; SP's policies and procedures associated with each type of Expenditure; the approval process associated with each type of Expenditure; the Control Documents associated with each type of Expenditure; and the control and/or accountability systems associated with each type of Expenditure.

2. The IRO shall describe, in general terms, the terms of any Discount Agreement with each selected Relevant Managed Care Customer and the types of expenditures received by each Customer during the Reporting Period and tested by the IRO. These descriptions may include a general description of the types of discounts, rebates, and/or administrative fees offered in the Discount Agreement.[1]

3. The IRO shall describe the procedures performed and state its findings and supporting rationale as to whether:

   a. Required Discount Agreements and Control Documents exist in connection with each reviewed Managed Care Related Expenditure in accordance with SP policy; and

   b. The Control Documents associated with each Expenditure were completed in accordance with the requirements set forth in SP's policies and procedures.

4. The IRO shall identify all Material Errors and Non-Material Errors discovered. For the Non-Material Errors, the IRO shall describe, in general terms, what the errors were. The IRO shall describe those situations when corrective action was taken prior to the IRO review, including a description of the circumstances requiring corrective action and the nature of the corrective action;

[1] If the Discount Agreement contains confidentiality language that prohibits the sharing of this information, the IRO will notify the OIG of this restriction and report on the information permitted. In addition, for purposes of maintaining confidentiality, the IRO will not identify the Relevant Managed Care Customer by name in its report; rather the IRO will identify the Relevant Managed Care Customer by a single unique reference number that will track to the IRO's workpapers.

5. If any Material Errors were discovered, the IRO shall describe the error and the Additional Engagement procedures it performed, and shall state its findings as to the root causes of the Material Errors; and

6. Based on the procedures performed, the IRO shall report any findings and supporting rationale regarding any weakness in SP's policies and procedures relating to promotional activities with Managed Care Customers, if any, and any recommendations to improve any of the reviewed polices and procedures.