UNIFIED CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MERCK & CO., INC.

I. PREAMBLE

Effective February 5, 2008, Merck & Co., Inc. entered into a Corporate Integrity Agreement (Merck Legacy CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements).

Prior to February 5, 2008, the effective date of the Merck Legacy CIA (Merck Effective Date), Merck & Co., Inc. voluntarily established a comprehensive Compliance Program. The Compliance Program now includes: a Vice-President, Global Support/U.S. Compliance Officer (who is the Compliance Officer for Global Human Health-U.S. Markets (GHH-U.S.), Merck Vaccines (MV) and the Global Commercial Support Organization (GCSO) (referred to hereafter as the "Compliance Officer")), a Compliance Committee, and the Global Support/U.S. Business Practices and Compliance Organization that works in conjunction with the head of Merck's Office of Ethics (Ethics Officer) (as addressed in more detail on page 2, on November 3, 2009, Merck & Co., Inc. was renamed Merck Sharp & Dohme Corp. The name "Merck" in this agreement refers to Merck Sharp & Dohme Corp.). The Compliance Program also includes: a code of conduct; Merck's Ethical Operating Standards; written Policies and Guidance Documents which address ethics and integrity, compliance with Federal laws and regulations, and appropriate business practices; mandatory training concerning Merck's Ethical Operating Standards and Policies and Guidance Documents; internal review procedures; a multi-faceted Disclosure Program; and screening measures for Ineligible Persons. As represented by Merck, the existing Compliance Program is designed to meet Merck's goals of promoting ethical standards in all aspects of its business practices and compliance with all policies and guidance.

Contemporaneously with the Merck Legacy CIA, Merck & Co., Inc. entered into two Settlement Agreements (Settlement Agreements) with the United States. Merck & Co., Inc. also entered into settlement agreements with various states and Merck & Co., Inc.'s agreement to the Merck Legacy CIA was a condition precedent to those settlement agreements.

Subsequently, on November 3, 2009, Merck & Co., Inc. and Schering-Plough Corporation (Schering) completed a previously-announced merger (the "Merger"). In the Merger, Schering acquired all of the shares of Merck & Co., Inc., which became a wholly-owned subsidiary of Schering and was renamed Merck Sharp & Dohme Corp. Schering continued as the surviving public company and was renamed Merck & Co., Inc. As set forth above, in this document, "Merck" shall refer to the principal operating subsidiary, Merck Sharp & Dohme Corp.

Prior to the Merger, Schering had its own CIA, effective date July 29, 2004 (Schering-Plough CIA), and an Addendum to the CIA, effective date August 25, 2006 (Schering-Plough Addendum). Merck & Co., Inc. on behalf of itself and its U.S.-based subsidiaries, including Merck is now entering into this Unified CIA, which shall supersede the Merck Legacy CIA and the Schering-Plough Addendum.

Merck & Co., Inc. now enters into this Unified CIA with the OIG of HHS to promote compliance with the statutes, regulations, and written directives of Federal health care program requirements and the statutes, regulations, and written directives of the Food and Drug Administration (FDA) (FDA Requirements).

Merck shall continue its Compliance Program throughout the term of this Unified CIA and shall do so in accordance with the terms set forth below. Merck may modify its Compliance Program as appropriate, but, at a minimum, Merck shall ensure that during the term of this Unified CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE UNIFIED CIA

A. The effective date of the Unified CIA shall be the date of the final signature to the Unified CIA (Unified Effective Date). The period of the compliance obligations assumed by Merck under this Unified CIA shall be five years from the Merck Effective Date of February 5, 2008, unless otherwise specified. Each one-year period, beginning with the one-year period following the Merck Effective Date, shall be referred to as a "Reporting Period." The Unified CIA reflects the new obligations assumed by Merck as a result of the Merger. A "Modification Period" will be established in which the obligations of the Schering Addendum shall be implemented by Merck. The "Modification Period" will be one hundred and twenty days (120) from the Unified Effective Date. Prior to the termination of the Modification Period, the CIA obligations of the Schering Addendum shall remain in effect.

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

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

1. "Covered Persons" includes:

   a. all owners of Merck & Co., Inc. who are natural persons (other than shareholders who: (1) have an ownership interest of more than 5%; and (2) acquired the ownership interest through public trading);

   b. all officers of Merck and Merck & Co., Inc.;

   c. all directors of Merck & Co., Inc.;

   d. Merck's Ethics Officer and Compliance Officer;

   e. employees of Merck's Office of General Counsel who are engaged in, or have responsibilities that directly support, the Covered Functions (as defined below in Section II.C.7);

   f. employees of Merck's Corporate Finance Organization who are engaged in, or have responsibilities that directly

support, the Covered Functions as defined below in Section II.C.7;

g. U.S.-based personnel who are assigned to GHH-U.S., MV, GCSO, or any other Merck divisions and who are engaged in, or have responsibilities that directly support, the Covered Functions (as defined below in Section II.C.7); and

h. all contractors, subcontractors, agents, and other persons who perform Covered Functions (as defined below in Section II.C.7) on behalf of Merck.

If, during the term of this Unified CIA, there are changes in the organizational structure of Merck, all employees of GHH-U.S., MV, GCSO, and/or all other Merck components who are engaged in, or have responsibilities that directly support, Covered Functions (as defined below in Section II.C.7) shall be considered "Covered Persons."

Notwithstanding the above, the term "Covered Persons" does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons described above in Sections II.C.1 (a)-(i) who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes those Covered Persons whose job responsibilities relate to Covered Functions (as defined below in Section II.C.7) .

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

4. The term "Government Reimbursed Products" refers to those Merck products (including vaccines) that are reimbursed by Federal health care programs. This definition is intended to encompass all of the post-Merger Merck products that are reimbursed by Federal Health Care Programs.

5. The term "Promotional and Product Services Related Functions" refers to the promotion, marketing, sales, or provision of information about, or services relating to, Government Reimbursed Products in or for the United States market.

6. The term "Managed Care Functions" refers to the promotion, sales, and marketing of prescription drug products to managed care entities, and to contracting with managed care entities or other similar organizations in or for the United States market.

7. The term "Covered Functions" refers to "Government Pricing and Contracting Functions," "Promotional and Product Services Related Functions," and "Managed Care Functions" collectively.

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

9. The term "Acknowledge" as used in this Unified CIA means a written verification that the signatory agrees with the statements set forth in the verification.

10. The term "Schering Legacy Products" as used in the Unified CIA shall mean the products under the control and management of Schering immediately prior to the time of the Merger.

11. The term "Schering Legacy Specialized Products" as used in the Unified CIA shall mean the Hepatitis, Virology, Oncology, and Coronary products under the control and management of Schering immediately prior to the time of the Merger.

III. CORPORATE INTEGRITY OBLIGATIONS

Merck shall maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Generally.* Prior to the Merck Effective Date, Merck established the Global Support/U.S. Business Practices & Compliance Organization (BP&C). Among other things, BP&C has responsibility for the design, development, and implementation of compliance practices and processes guiding sales and marketing activities for Global Pharmaceuticals, GHH-US, MV, and GCSO. BP&C is headed by the Compliance Officer. The President of GHH-U.S. (the President) and the Compliance Officer co-chair the Compliance Committee (the "Compliance Committee"). The members of the Compliance Committee include the Compliance Officer, the president of MV, the head of GCSO, and the head of the Office of Ethics.

2. *Compliance Officer.* Prior to the Unified Effective Date, Merck appointed an individual to serve as its Compliance Officer. Merck maintains and shall continue to maintain a Compliance Officer during the term of the Unified CIA. The Compliance Officer is responsible and shall continue to be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Unified CIA and with Federal health care program requirements. The Compliance Officer reports to Merck's Executive Vice President/Chief Compliance Officer who heads the Global Compliance Organization and reports directly to the Chief Executive Officer. The Compliance Officer is and shall continue to be a member of senior management of GHH-U.S. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Merck. The Compliance Officer is authorized and shall continue to be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The Compliance Officer is responsible and shall continue to be responsible for monitoring the day-to-day compliance activities engaged in

by GHH-U.S., MV, and GCSO, as well as for any reporting obligations created under this Unified CIA.

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

3. *Compliance Committee.* Prior to the Unified Effective Date, Merck established the Compliance Committee, which, in conjunction with the Compliance Officer, has primary responsibility for promoting compliance within GHH-U.S., MV, and GCSO. Merck shall continue the Compliance Committee during the term of this Unified CIA. The Compliance Committee shall, at a minimum, continue to include the Compliance Officer, the President, the head of the Office of Ethics, and other members of senior management necessary to meet the requirements of this Unified CIA (e.g., senior executives of relevant Merck business units, finance, human resources, and the Office of General Counsel). The Compliance Officer (along with the President) chairs and shall continue to chair the Compliance Committee, and the Committee supports and shall continue to support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Generally.* Prior to the Unified Effective Date, Merck created, disseminated, and implemented written standards regarding ethics and integrity, compliance with Federal laws and regulations, and appropriate business practices related to both the Federal health care programs and the sales and marketing activities of GHH-U.S., MV, and GCSO.

2. *Code of Conduct.* Prior to the Unified Effective Date, Merck established both a general corporate Code of Conduct and a set of Ethical Operating Standards. Merck's Ethical Operating Standards provide guidance relating to the Covered Functions, including the promotion, marketing, and sale of Merck's products in the United States. Merck has made (or, within 90 days after

the Unified Effective Date, shall make) the Ethical Operating Standards available to all Covered Persons. Merck makes, and shall continue to make, adherence to these Ethical Operating Standards an element in evaluating the performance of all employees who are Covered Persons.

The Ethical Operating Standards include, shall continue to include, or shall be revised during the Modification Period to include:

a. Merck's commitment to full compliance with all Federal health care program requirements and FDA Requirements, including its commitment to comply with all requirements relating to Government Pricing and Contracting Functions and to promote, sell, advertise, and market its products in accordance with Federal health care program requirements and FDA Requirements;

b. Merck's requirement that all of its Covered Persons shall be expected to comply with all applicable legal requirements, with all Federal health care program requirements, FDA Requirements, and with Merck's own Policies and Guidance Documents (defined below in Section III.B.4), including but not limited to, the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);

c. Merck's requirement that Covered Persons are responsible for adhering to the Ethical Operating Standards and are expected to report suspected violations of any Federal health care program requirements, FDA Requirements, or of Merck's own Ethical Operating Standards;

d. the personal obligations of each Covered Person to comply with Federal health care program requirements, FDA Requirements, and the Ethical Operating Standards;

e. the possible consequences to both Merck and Covered Persons of failure to comply with Federal health care program requirements, FDA requirements, and/or with Merck's own Ethical Operating Standards, or the failure to report such noncompliance; and

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

To the extent not already accomplished, during the Modification Period, each Covered Person shall Acknowledge in writing or in electronic form (if applicable) that he or she has received, read, understood, and shall abide by the Ethical Operating Standards. New Covered Persons shall receive the Ethical Operating Standards and shall complete the required Acknowledgement within 30 days after becoming a Covered Person or within 120 days after the Unified Effective Date, whichever is later.

Merck represents that it reviews its Ethical Operating Standards annually to determine if revisions are appropriate and makes any necessary revisions based on such review. Merck shall continue such reviews and revisions throughout the term of the Unified CIA. Within 30 days after the effective date of any revisions, the relevant portions of the revised Ethical Operating Standards shall be made available on Merck's intranet site or through another means to Covered Persons. Each Covered Person shall Acknowledge, in writing or electronically, within 30 days after the revised Ethical Operating Standards are made available to him or her, that he or she has received, read, understood, and shall abide by the revised Ethical Operating Standards.

3. *Third Party Personnel.* During the Modification Period, Merck shall send a letter to each entity employing Third Party Personnel. The letter shall describe Merck's obligations under the Unified CIA and its commitment to full compliance with all Federal health care program requirements and FDA requirements. The letter shall include a description of Merck's Compliance Program. Merck shall attach a copy of its Ethical Operating Standards to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of Merck's Ethical Operating Standards and a description of Merck's Compliance Program available to its employees who meet the definition of Third Party Personnel as set forth in Section II.C.8; or (b) represent to Merck that it has and enforces a substantially comparable set of Ethical Operating Standards (or code of conduct) and Compliance Program for its employees who meet the definition of Third Party Personnel as set forth in Section II.C.8.

4. *Policies and Procedures.* Prior to the Merck Effective Date, Merck established and implemented Field Policy Letters and Headquarters Guidance Documents related to Promotional and Product Services Related

Functions, and Managed Care Functions. Prior to the Merck Effective Date, Merck also established and implemented written Government Price Reporting Policies regarding Government Pricing and Contracting Functions (Customer Contract Management Policies).

These Field Policy Letters, Headquarters Guidance Documents, and Customer Contract Management Policies, which are collectively known as "Policies and Guidance Documents," address, shall continue to address, or shall during the Modification Period be revised to address:

a. selling, marketing, advertising, and promoting Merck's products in compliance with all applicable Federal healthcare program requirements, including, but not limited to, the Federal anti-kickback statute and the False Claims Act, and with FDA Requirements;

b. consultant arrangements entered into with health care professionals (including, but not limited to, speaker programs, speaker meetings, advisory board meetings, training programs, colloquiums, roundtables, and forums, as applicable) and all events relating to these arrangements. 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 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;

c. sponsorship or funding of grants (including educational grants). These policies shall be designed to ensure that Merck's funding and/or sponsorship complies with all applicable Federal health care program requirements and FDA requirements;

d. sponsorship or funding of research or related activities by GHH-US. These policies shall be designed to ensure that Merck's funding and/or sponsorship complies with all applicable Federal health care program requirements and 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, advertising, and marketing of Merck's products;

f. 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;

g. the manner in which the Global Medical Information and Operations (GMIO) receives and responds to requests for information about the discussion and dissemination of information about non-FDA approved uses of Merck's products (off-label uses); the form and content of information disseminated by GMIO in response to such requests; and the internal review process for the information disseminated;

h. sponsorship or funding of continuing medical education (CME) programs that are designed to ensure that Merck's funding and/or sponsorship of such programs satisfies all applicable Federal health care programs and FDA Requirements. The policies and procedures shall require the disclosure of Merck'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 be independent; and shall require that the CME program be balanced;

i. Government Pricing and Contracting Functions;

j. Managed Care Functions; and

k. policies and procedures relating to disciplinary action for violations of Merck's Policies and Guidance Documents.

Prior to the Unified Effective Date, Merck made the Policies and Guidance Documents required by the Merck Legacy CIA available to all Covered Persons who are employees and whose job functions relate to those Policies and Guidance Documents. Within 120 days after the Unified Effective Date, Merck shall make the Policies and Guidance Documents revised in accordance with the Unified CIA available to all Covered Persons whose job functions relate to those Policies and Guidance Documents. Appropriate and knowledgeable staff is, and shall continue to be, available to explain the Policies and Guidance documents.

At least annually (and more frequently, if appropriate), Merck assesses and revises as necessary, the Policies and Guidance Documents. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Guidance Documents are made available to all individuals whose job functions relate to those Policies and Guidance Documents. Merck shall continue the practices described in this paragraph during the term of this Unified CIA.

C. Training and Education.

1. *Generally.* Prior to the Unified Effective Date, Merck provided two levels of training to Covered Persons who are employees: Awareness Training and Knowledge Training. Merck shall provide or continue to provide Awareness Training and Knowledge Training to all Covered Persons throughout the term of this Unified CIA as set forth in Sections III.C.2-3 below.

2. *Awareness Training.* Merck shall provide annual training to Covered Persons on the Ethical Operating Standards through an in-person or computer-based training program. Prior to the Unified Effective Date, this training (known as "Awareness Training") consisted of a one-hour session that covered Merck's Compliance Program, the content of the Ethical Operating Standards described in Section III.B.2, and Merck's obligations under the Merck Legacy CIA. Following the Unified Effective Date, the Awareness Training shall cover:

a. Merck's Compliance Program (including the Ethical Operating Standards); and

b. Merck's obligations under the Unified CIA.

Merck shall provide one hour of Awareness Training to, and obtain an Acknowledgement (as set forth in Section III.C.4) from, each Covered Person.

With respect to employees who are entering a Covered Persons position for the first time (i.e., new Covered Persons) on or after the Unified Effective Date, Merck shall conduct two hours of Awareness Training, within 45 days after such person's entering such position or within 90 days after the Unified Effective Date (whichever is later), which shall cover:

> c. Merck's Compliance Program (including the Ethical Operating Standards) and obligations under the Unified CIA; and
>
> d. In general, the proper methods of promoting, marketing and selling and/or 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/or a general discussion of Merck's systems for gathering and tracking relevant data, and/or calculating and verifying information reported for purposes of the Medicaid Drug Rebate Program and Medicare.

To the extent that Merck provided Awareness Training to Covered Persons during the 180 days immediately prior to the Unified Effective Date that satisfied the requirements set forth in Section III.C.2.a above, the OIG shall credit that training for purposes of satisfying Merck's Awareness Training obligations of Section III.C.2. Merck may satisfy its remaining Awareness Training obligations for the Covered Persons who received the training described in the preceding sentence by notifying them within 90 days after the Unified Effective Date in writing or in electronic format of the fact that Merck has entered into the Unified CIA and providing an explanation of Merck's new requirements and obligations under the Unified CIA.

3. *Knowledge Training.* Merck shall provide annual training to each Relevant Covered Person relating to his or her specific job responsibilities. This training is known as "Knowledge Training."

For those Relevant Covered Persons engaged in Promotional and Product Services Related Functions, to the extent not covered by Awareness Training, Knowledge Training includes, and shall continue to include or be revised during the Modification Period to include, a discussion of:

a. all applicable Federal health care program requirements and FDA Requirements relating to the promotion, sales, advertising, and marketing of Government Reimbursed Products (as defined above in Section II.C.4);

b. all Merck policies, procedures, and other requirements applicable to promotion, sales, advertising, and marketing of Government Reimbursed Products;

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

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

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

For those Relevant Covered Persons engaged in Government Pricing and Contracting Functions, to the extent not covered by Awareness Training, Knowledge Training includes, and shall continue to include or be revised during the Modification Period to include, a discussion of:

f. Merck's systems and processes relating to Government Pricing and Contracting Functions;

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

h. in detail, Merck'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;

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

j. the legal sanction for violations of Federal health care program requirements; and

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

For those Relevant Covered Persons engaged in Managed Care Functions, to the extent not covered by Awareness Training, Knowledge Training includes, and shall continue to include or be revised during the Modification Period to include, a discussion of:

l. all applicable Federal health care program requirements (including the sanctions for violations) related to Managed Care Functions and Medicaid Drug Rebate Program (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);

m. the personal obligation of each individual to comply with the legal requirements outlined above in Section III.C.3.l; and

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

To the extent not already accomplished, by the end of the Third Reporting Period, Merck shall provide two hours of Knowledge Training to, and obtain an Acknowledgement (described in Section III.C.4) from, each Relevant Covered Person. Each Relevant Covered Person shall receive at least two hours of Knowledge Training in each of the Fourth and Fifth Reporting Periods.

Individuals who become Relevant Covered Persons on or after the Unified Effective Date (*i.e.*, new Relevant Covered Persons) shall receive the Knowledge Training and provide an Acknowledgement within 45 days after becoming a Relevant Covered Person or within 120 days after the Unified Effective Date, whichever is later. A Relevant Covered Person who has completed the Knowledge Training shall review the work of a new Relevant Covered Person, to

the extent that the work relates to Covered Functions until such time as the new Relevant Covered Person completes his or her Knowledge Training.

4. *Acknowledgement.* Each Covered Person who is required to complete Awareness Training and each Relevant Covered Person who is required to also complete Knowledge Training shall acknowledge, in writing or in electronic form, if applicable, that he or she has received such training and the date such training was received. The Compliance Officer (or designee) shall retain these Acknowledgements, along with all course materials. These shall be made available to OIG, upon request.

5. *Qualifications of Trainer.* Persons responsible for providing the Awareness Training and the Knowledge Training shall be knowledgeable about the subject area of the training.

6. *Update of Training.* Merck represents that it reviews its training annually, and, where appropriate, updates the training to reflect changes in Federal health care program requirements, FDA Requirements, any issues discovered during internal audits or the IRO Reviews, and any other relevant information. Merck shall continue the reviews and updates described in the preceding sentence during the term of the Unified CIA.

7. *Computer-based Training.* Merck may provide the training required under this Unified CIA through appropriate computer-based training approaches. If Merck chooses to provide computer-based training, it makes and shall continue to make available appropriately qualified and knowledgeable trainers to answer questions or provide additional information to the individuals receiving such training. If Merck chooses to provide computer-based Awareness or Knowledge Training, all applicable requirements to provide a number of "hours" of training as set forth in this Section III.C may be met with respect to computer-based training by providing the required number of "normative" hours as that term is used in the computer-based training industry.

D. Review Procedures.

1. *General Description of Merck's Internal Review Procedures.* Merck represents that prior to the Unified Effective Date, Merck designed and implemented oversight and reporting mechanisms by which it monitors certain activities of Covered Persons including those involving Government Pricing and Contracting Functions and those involving Promotional and Product Services

Related Functions. Merck shall continue oversight and reporting mechanisms throughout the term of this Unified CIA.

2. *Description of Reviews Required by Unified CIA.* During the term of the Unified CIA, Merck and the Independent Review Organization (IRO) (as defined below) shall perform two general types of reviews designed to assess and evaluate Merck's Government Pricing and Contracting Functions (Medicaid Drug Rebate Review) and its Promotional and Product Services Related Functions (Promotional and Product Services Review). As more fully explained below and in Appendix A, which is incorporated by reference, the Medicaid Drug Rebate Review shall consist of reviews of samples of transactions relevant to the Average Manufacturer Prices and Best Prices reported to CMS for purposes of the Medicaid Drug Rebate Program. As more fully explained below and in Appendix B, which is incorporated by reference, the Promotional and Product Services Review shall consist of two components – a systems review (the Promotional and Product Services Systems Review) and a transactions review (Promotional and Product Services Transactions Review). The IRO shall conduct all parts of the Promotional and Product Services Systems Review. Merck may conduct the Medicaid Drug Rebate Review and/or the Promotional and Product Services Transactions Review using its internal audit resource with prior annual approval of the OIG. If Merck elects to conduct the aforementioned reviews using internal audit resources, the IRO shall conduct Verification Reviews of Merck's Reviews as set forth more fully in Appendices A and B. If Merck does not elect to conduct the Medicaid Drug Rebate Review and the Promotional and Product Services Transactions Review using internal audit resources, the IRO shall conduct all components of the reviews. The reviews conducted by Merck and the IRO shall be referred to generally as the "Reviews."

3. *General Description of Independent Review Organization.*

a. *Engagement of Independent Review Organization.* To the extent not already accomplished, within 90 days after the Unified Effective Date, Merck shall engage an entity (or entities), such as an accounting, auditing, or consulting firm, as an IRO to perform the Reviews described in Section III.D.2. The applicable requirements relating to the IRO are outlined in Appendix C to this Unified CIA, which is incorporated by reference.

Each IRO engaged by Merck shall have expertise in the applicable requirements of the Medicaid Drug Rebate

Program, the Medicare and Medicaid programs generally (as applicable), other applicable Federal health care program requirements, and FDA Requirements. Each IRO shall assess, along with Merck, whether it can perform the IRO review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist.

b. *Frequency of Reviews.* The Medicaid Drug Rebate Review and the Promotional and Product Services Transactions Review shall each be performed annually. The Promotional and Product Services Systems Reviews was performed in the First Reporting Period and shall be performed in the Fourth Reporting Period.

Merck represents that, for a period of time subsequent to the Unified Effective Date, it plans to maintain a separate price reporting system for Schering Legacy Products. While the separate price reporting system is in effect, Merck may conduct the annual Medicaid Drug Rebate review in two parts. Merck shall conduct the Medicaid Drug Rebate Review for Government Reimbursed Products except Schering Legacy Products in or around January 2011, January 2012, and January 2013.

Merck shall conduct the Medicaid Drug Rebate Review for Schering Legacy Products in or around September 2010, September 2011, and September 2012. The review of Schering Legacy Products shall include the first two quarters of the current year and the last two quarters of the preceding year. For example, the review conducted in September 2010 shall include the first two quarters of 2010 and the final two quarters of 2009.

If there are no material changes in Merck's systems, processes, policies, and practices relating to Promotional and Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. As set forth in Appendix B, if Merck materially changes its systems, processes,

policies, and practices relating to Promotional and Product Services Related Functions, the IRO shall perform a Promotional and Product Services Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods.

c. *Retention of Records*. The IRO and Merck shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those generated by Merck in connection with any internal audits and those exchanged between the IRO and Merck) related to the Reviews.

4. *IRO and Internal Audit Review Reports*. Merck (if applicable) and the IRO shall prepare a report (Report) for each Medicaid Drug Rebate Review and each Promotional and Product Services Review performed. Information to be included in each Report is described in Appendices A and B. As set forth in Section V below, these Reports shall be included in each Annual Report.

5. *Validation Review*. In the event OIG has reason to believe that: (a) any Review fails to conform to the requirements of this Unified CIA; or (b) the IRO's or Merck's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable Review complied with the requirements of the Unified CIA and/or the findings or Review results are accurate (Validation Review). Merck shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Merck's final Annual Report shall be initiated no later than one year after Merck's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Merck 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, Merck may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the applicable Review; and/or (c) propose alternatives to the proposed Validation Review. Merck agrees to 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 Review

issues with Merck 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.

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

E. Disclosure Program.

Prior to the Merck Effective Date, Merck established a multi-faceted Disclosure Program that enabled individuals to raise concerns related to any potential unethical or illegal behavior associated with Federal health care programs, or Merck's policies, procedures, or practices confidentially to the Office of Ethics. To the extent not already accomplished, during the Modification Period Merck shall revise its Disclosure Program to ensure that it includes concerns regarding FDA Requirements. Merck will publish this change. The Disclosure Program includes Merck's AdviceLine and Ombudsman Program, mechanisms that individuals can access and for which appropriate confidentiality is maintained. Merck's AdviceLine is a toll-free telephone line staffed by a third-party that is available 24 hours a day, seven days a week. Merck's Ombudsman Program is staffed by individuals in the Office of Ethics. Merck shall continue this Disclosure Program during the term of this Unified CIA. Merck publicizes, and shall continue to publicize, the existence of the Disclosure Program in the Code of Conduct, the Ethical Operating Standards, through training sessions, and by posting information in prominent common areas of Merck's headquarter facilities, on Merck's intranet sites, and on Merck's external website.

The Disclosure Program emphasizes confidentiality and a nonretribution, non-retaliation policy. Merck makes and shall continue to make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that it obtains all necessary information 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, Merck conducts and shall continue to conduct an internal review of the allegations set forth in the disclosure. Merck shall ensure that proper follow-up is conducted. Disclosures made through the AdviceLine and the Ombudsman Program are investigated, as appropriate, by a designee from the Office of Ethics, who then

determines the appropriate resolution in coordination with the appropriate parties, including the Compliance Officer or designee.

Merck maintains, and shall continue to maintain, a disclosure log, which includes 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. This disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

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

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

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

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

b. "Exclusion Lists" include:

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

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

c. "Screened Persons" include:

i. prospective and current owners of Merck (other than shareholders who: (1) have an ownership interest of

less than 5%; and (2) acquired the ownership interest through public trading);

ii. prospective and current officers and directors of Merck;

iii. all prospective and current U.S.-based employees of Merck; and

iv. all prospective and current U.S.-based contractors and agents of Merck who are Covered Persons.

2. *Screening Requirements.* Merck shall ensure that all Screened Persons are not Ineligible Persons, by implementing (as applicable) and maintaining the following screening requirements.

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

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

c. Merck represents that it has a policy in place that requires all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person, and Merck shall maintain such policy during the term of the Unified CIA.

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

3. *Removal Requirement.* If Merck has actual notice that a Screened Person has become an Ineligible Person, Merck shall remove such Screened Person from responsibility for, or involvement with, Merck's business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Screened Person is reinstated into participation in the Federal health care programs.

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

G. Notification of Government Investigation or Legal Proceedings.

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

H. Reporting.

1. *Reportable Events.*

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

i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative

laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any FDA requirement relating to the off-label promotion of Schering Legacy Products for which penalties or exclusion may be authorized through August 25, 2011; and

iii. the filing of a bankruptcy petition by Merck.

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

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

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

ii. a description of actions taken by Merck to correct the Reportable Event;

iii. any further actions Merck plans to take to address the Reportable Event and prevent it from recurring; and

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

2. Merck shall not be required to report any Reportable Event that is the subject of an ongoing investigation or legal

proceeding by a government entity or its agents previously disclosed under Section III.G above.

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

Within 30 days after the date of any written report, correspondence, or communication from Merck to the FDA in connection with Merck's or a Covered Person's promotion, discussion, or dissemination of information about off-label uses of Merck's products, Merck shall provide a copy of the report, correspondence, or communication to the OIG. Merck shall also provide written notice to the OIG with a description of the findings and/or results of the matter, if any. This requirement applies to matters occurring on or before the termination date of the Schering–Plough Addendum (August 25, 2011).

J. Schering Legacy Specialized Products Promotion Monitoring Program.

Between August 26, 2009 and August 25, 2010, and again between August 26, 2010 and August 25, 2011 (which are the Fourth and Fifth Reporting Periods under the Schering-Plough Addendum), Merck shall conduct a minimum of 30 full-day, direct inspections and observations of the messages and materials delivered by Merck Sales Representatives to Health Care Professionals (HCPs) regarding Schering Legacy Specialized Products. (These inspections and observations shall be known as "Inspections.") Each Inspection day will consist of directly observing all meetings between Merck Sales Representatives and HCPs during that workday. The Inspections shall be scheduled throughout the Reporting Period, and shall be randomly selected by Merck. The number of Inspections conducted for each Schering Legacy Specialized Product shall be proportional in number to the sales of each Schering Legacy Specialized Product, and shall be conducted in all regions across the United States.

At the completion of each Inspection day, Merck personnel shall complete an Inspection Report, which shall include: 1) the identity of the Sales Representative; 2) the identity of Merck personnel conducting the Inspection; 3) the date and duration of the Inspection; 4) the products promoted during the Inspection; and 5) identification of any potential off-label promotional activity by the Sales Representative.

In the event that a Merck Inspection identifies potential off-label promotion, Merck shall investigate the incident consistent with Merck's established investigation protocol. If the investigation determines that there was off-label promotion by a Sales Representative, Merck shall notify the OIG

pursuant to Section III.H of the Unified CIA. As part of each Annual Report, Merck shall provide the OIG with copies of the Inspection Reports in any instances in which it was determined that there was off-label promotion during the Inspections and a description of the action(s), if any, Merck took as a result of such determinations. Merck shall make Inspection Reports for all other Inspections available to the OIG upon request.

K. Monitoring and Review of Requests for Off-Label Information.

This subsection, and the various requirements that it imposes, applies only to the Schering Legacy Products.

To the extent not already accomplished, during the Modification Period, Merck shall develop policies addressing the discussion and dissemination of information about non-FDA approved uses of products (off-label information). These policies shall provide, among other things, that Covered Persons may not directly or indirectly solicit, encourage, or promote unapproved uses of a product to HCPs. Merck's policies shall require that when Covered Persons receive inquiries about unapproved uses of products, Covered Persons shall direct or cause to be directed such inquiries to GMIO personnel or Medical Science Specialists (MSSs), who are scientifically trained personnel who shall respond consistent with FDA regulations and guidance, rather than responding to the inquiries themselves.

Merck has allocated responsibility for responding to requests for off-label information about Government Reimbursed Products to Global Medical Affairs, which oversees GMIO and the MSSs. Merck documents and records all inquiries by field personnel to GMIO and MSSs on behalf of customers including requests relating to off-label information. On a quarterly basis, Merck conducts a field force submitted off-label inquiry analysis (Off-Label Inquiry Analysis) as described below.

In order to conduct its Off-Label Inquiry Analysis, GMIO compiles and provides information to the Global Compliance Organization and others within Merck all requests submitted to GMIO about Government Reimbursed Products. The requested information is separated by therapy area and/or product (e.g., Primary Care, Hepatitis, Temodar, Intron A, PEG Intron, etc.), and analyzed to identify those field personnel associated with the highest number of requests for information. For each product and/or therapeutic category, the requests and resulting responses from the 10 field personnel with the largest number of requests are further analyzed and reviewed to determine whether the requests are for off-

label information. In addition, all information related to the GMIO requests for the top 10 requestors in the product and/or therapy area is reviewed by a compliance manager. The compliance manager completes a summary detailing any findings. In the event that the analysis and review indicates that an individual may have inappropriately caused the dissemination of off-label information or engaged in off-label promotion, Merck shall conduct a formal investigation of the situation and undertakes disciplinary action where appropriate.

Merck shall continue to conduct the quarterly Off-Label Inquiry Analyses, substantially in the form described in this Section, through at least August 25, 2011 (the end of the Schering-Plough Addendum). If incidents of off-label promotion are discovered, the Compliance Officer shall implement effective responses, including disclosing Reportable Events pursuant to Section III.I (Reporting), as appropriate. As part of each Annual Report, Merck shall submit to the OIG a description of the Off-Label Inquiry Analyses conducted during the Reporting Period (or partial Reporting Period with respect to 2011) and a summary of the findings of the Analyses.

L. Average Sales Price Reporting Requirements.

1. *General Statement of Purpose and Intent.*

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

2. *Specific Reporting Requirements.*

a. A*verage Sales Price Defined.* For purposes of the Unified 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 has been or may be made by the Secretary of the Department of Health and Human Services, through the issuance of regulations, written directives, or guidance. Merck shall report the ASP by National Drug Code (NDC) for each Covered Schering Product.

b. *Reporting Obligations for Covered Schering Products.* For the Third Reporting Period and the Fourth Reporting Period through and including August 25, 2011, in addition to any reporting required by the MMA, within 30 days after the last day of each calendar quarter Merck shall report, in accordance with section III.L.2.a above, the ASP of each of the Covered Schering Products identified by NDC to: 1) the Medicaid programs of those States who have executed a state settlement agreement with Schering; 2) to First DataBank Inc.[1] solely for the purpose of reporting pricing information based on those ASPs to the Medicaid programs of those States that have executed a state settlement agreement; and 3) to the OIG.

c. *Certification Requirement.* A high managerial agent of Merck will certify that the ASPs reported are calculated in accordance with the requirements of the MMA. Said certifications shall be made in the form attached hereto as Appendix D, and shall include an acknowledgement that the ASPs reported will be filed with and used in the administration of the Medicare and Medicaid programs. Merck agrees that this certification by an appropriate employee or agent of Merck constitutes a certification by Merck.

d. *Documentation Retention.* Merck shall retain all supporting work papers and documentation relating to the methodology for calculating ASPs of its Covered Schering Products for six years after the Effective Date of the Schering Addendum, 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 VIII of this Unified CIA.

[1] If appropriate to reflect changes in the sources from which the State Medicaid programs receive their pricing information, Merck agrees that, upon the receipt of a written request from 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.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Unified Effective Date, Merck changes locations or sells, closes, purchases, or establishes a new business unit or location related to Covered Functions, Merck shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, any Federal health care program provider or supplier number, and the name and address of any corresponding contractor that issued the number. Each new business unit or location meeting criteria set forth in this Section IV shall be subject to all the requirements of this Unified CIA.

V. MODIFICATION AND ANNUAL REPORTS

A. Modification Report. Within 150 days after the Unified Effective Date, Merck shall submit a written certification to OIG summarizing the status of its implementation of the requirements of the Unified CIA (Modification Report) to the extent that the Unified CIA has imposed new requirements that have resulted in implementation of new processes, procedures, policies, and other changes, as detailed below. The Modification Report shall, at a minimum, include:

1. any changes in the composition of the Compliance Committee since the Second Annual Report, or any actions or change that would affect the Compliance Committee's ability to perform the duties necessary to satisfy the obligations set forth in Section III.A;

2. a copy of the Ethical Operating Standards required by Section III.B;

3. copies of all Policies and Guidance Documents regarding the requirements of Sections III.I, III.J, and III.K of the Unified CIA:

4. an index of the Policies and Guidance Documents required by Section III.B that were either previously not required under the Merck CIA or were revised to comply with the Unified CIA. (Copies of these Policies and Guidance Documents shall be available to the 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 format used for the training (e.g., live presentation, computer-based training, etc.), the length of sessions, and a schedule of live training sessions; and

b. the number of individuals required to participate in training and complete the Acknowledgements required by Section III.C.4, the percentage of individuals who completed the training and Acknowledgements, and an explanation for 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 changes in Merck's corporate and management structure as a result of the Merger, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

7. the certifications required by Section V.C for the Modification Period.

B. Annual Reports. Merck shall submit to OIG annually a report with respect to the status of, and findings regarding, Merck's compliance activities for each of the remaining three 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 and any change in the membership of the Compliance Committee described in Section III.A;

2. the number of individuals required to review Merck's Ethical Operating Standards and complete the Acknowledgement required by Section III.B.2, the percentage of individuals who have completed such Acknowledgement, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

3. a summary of any significant changes or amendments to the Ethical Operating Standards and/or Policies and Guidance Documents required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and an index of any compliance-related Policies and Guidance Documents not

previously identified in the Modification Report (if any). (Copies of these Policies and Guidance Documents shall be available to OIG upon request.);

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

5. to the extent not provided in the Modification Report, 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 format used for the training (e.g., live presentation, computer-based training, etc.), the length of sessions, and a schedule of live training sessions; and

b. the number of individuals required to participate in the training and complete the Acknowledgements required by Section III.C.4, the percentage of individuals who completed the training and Acknowledgements, and an explanation for any exceptions.

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

6. a complete copy of all Reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter;

7. Merck's response and corrective action plan(s) related to any issues raised in the reports prepared pursuant to Section III.D;

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

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

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

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

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

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

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

15. A copy of Merck's Inspection Reports in any instances in which it was determined that there was off-label promotion during the Inspection and a description of the action(a), if any, Merck took as a result of such determination;

16. A description of the Off-Label Inquiry Analyses conducted during the Third Reporting Period and through August 25, 2011, and a summary of the findings of the Analyses;

17. A list and description of all actively promoted Schering Legacy Products through August 25, 2011 and, if available, information about the estimated relative usage (e.g., the percentage) of those products for off-label uses;

18. a description of all changes to the most recently provided list of Merck's locations (including addresses) as required by Section V.A.9; 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 or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Merck currently submits claims (if applicable); and

19. the certifications required by Section V.C.

The first Annual Report under the Unified CIA shall be received by OIG no later than 106 days after the end of the third Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

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

1. he or she has reviewed the Unified CIA in its entirety, understands the requirements described within, and maintains a copy of the Unified CIA for reference;

2. to the best of his or her knowledge, except as otherwise described in the Modification Report or applicable Annual Report, Merck is in compliance with all of the requirements of this Unified CIA;

3. 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;

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

5. all of Merck's: (a) Policies and Procedures referenced in Section III.B.4 above; (b) templates for standardized contracts and other similar documents; (c) training materials used for purposes of Section III.C, above; and (d) promotional materials used in connection with Government Reimbursed Products and for Managed Care Functions have been reviewed by competent legal counsel and have been found to be in compliance with the applicable Federal health care program requirements and FDA requirements; and

6. Merck has provided to the OIG the Medicaid Drug Rebate certification as set forth in Appendix D covering the applicable Reporting Period(s) and such certification is true and correct in all respects.

D. Designation of Information. Merck 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. Merck 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 Unified CIA shall be submitted to the following entities:

OIG:

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

Merck:

Lauran S. D'Alessio, Vice President
Divisional Compliance Officer
Global Support and US Business Practices and
Compliance
Merck & Co., Inc.
WS 3B-65
One Merck Drive
Whitehouse Station, NJ 08889
Telephone: 908-423-4321
Facsimile: 908-735-1370

Unless otherwise specified, all notifications and reports required by this Unified CIA may be made by certified mail, overnight mail, hand delivery, or other means,

provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Merck's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Merck's locations for the purpose of verifying and evaluating: (a) Merck's compliance with the terms of this; and (b) Merck'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 Merck 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 Merck'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. Merck shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Merck's employees may elect to be interviewed with or without a representative of Merck present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Merck and OIG hereby agree that failure to comply with certain obligations as set forth in this Unified 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 Merck fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

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;

h. notification of Government investigations or legal proceedings;

i. the Schering Legacy Specialized Products Promotion Monitoring Program; and

j. the Off-Label Inquiry Analysis.

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 Merck fails to engage an IRO, as required in Section III.D and Appendices A-D.

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 Merck fails to submit the Modification 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 Merck fails to submit the annual Merck or IRO Review Report(s) in accordance with the requirements of Section III.D and Appendices A-D.

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

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

7. A Stipulated Penalty of $1,000 for each day Merck fails to comply fully and adequately with any obligation of this Unified CIA. OIG shall provide notice to Merck, stating the specific grounds for its determination that Merck has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Merck shall take to comply with the Unified CIA. (This Stipulated Penalty shall begin to accrue 10 days after Merck 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. Merck 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 Unified 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 Merck fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies any such 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 Merck 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 Merck 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 Merck of: (a) Merck's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Merck 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 Merck elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Merck 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 Unified CIA and shall be grounds for exclusion under Section X.D.

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

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 Merck has materially breached this Unified 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 Unified CIA.

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

a. a failure by Merck to report a Reportable Event, take corrective action, and make any appropriate refunds, as required in Section III.H;

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

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

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

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

a. Merck is in compliance with the obligations of the Unified 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) Merck has begun to take action to cure the material breach; (ii) Merck is pursuing such action with due diligence; and (iii) Merck has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Merck fails to satisfy the requirements of Section X.D.3, OIG may exclude Merck from participation in the Federal health care programs. OIG shall notify Merck in writing of its determination to exclude Merck (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 Merck'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, Merck 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 Merck of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Unified CIA, Merck 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 Unified CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Unified CIA shall be: (a) whether Merck was in full and timely compliance with the obligations of this Unified CIA for which OIG demands payment; and (b) the period of noncompliance. Merck 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 Unified CIA and orders Merck to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Merck 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 Unified CIA shall be:

a. whether Merck was in material breach of this Unified 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) Merck had begun to take action to cure the material breach within that period; (ii) Merck has pursued and is pursuing such action with due diligence; and (iii) Merck provided to OIG within that period a reasonable timetable for curing the material breach and Merck 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 Merck, only after a DAB decision in favor of OIG. Merck's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Merck 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 Merck 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. Merck 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 Merck, Merck 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 Unified CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this Unified CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

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

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

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

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

D. The undersigned Merck signatories represent and warrant that they are authorized to execute this Unified CIA. The undersigned OIG signatory represents that he is signing this Unified CIA in his official capacity and that he is authorized to execute this Unified CIA.

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

ON BEHALF OF MERCK & CO., INC.

/Lauran S. D'Alessio/ 7-14-2010

Lauran S. D'Alessio DATE
Vice President & Divisional Compliance Officer
Global Support/U.S. Business Practices & Compliance
Merck & Co., Inc.

_____ _____

Bruce Kuhlik DATE
Executive Vice President and General Counsel
Merck & Co., Inc.

ON BEHALF OF MERCK & CO., INC.

Lauran S. D'Alessio
Vice President & Divisional Compliance Officer
Global Support/U.S. Business Practices & Compliance
Merck & Co., Inc.

DATE

/Bruce Kuhlik/

8/2/2010

Bruce Kuhlik
Executive Vice President and General Counsel
Merck & Co., Inc.

DATE

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

/Gregory E. Demske/ 8/2/10

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

DATE

APPENDIX A TO UNIFIED CIA FOR MERCK & CO., INC.

MEDICAID DRUG REBATE REVIEW

I. Medicaid Drug Rebate Review – General Description

As specified more fully below, Merck shall retain an Independent Review Organization (IRO) to perform reviews to assist Merck in assessing and evaluating its compliance with the requirements for Average Manufacturer Price (AMP) and Best Price (BP) under the Medicaid Drug Rebate Program. In order to conduct the Medicaid Drug Rebate Review, the IRO shall review samples of transactions to assess whether Merck is calculating AMPs and BPs consistent with the requirements of the Medicaid Drug Rebate Program. The Medicaid Drug Rebate Review shall consist of two parts, the "AMP Reported Prices Procedures" and the "BP Reported Prices Procedures." The IRO shall conduct the Medicaid Drug Rebate Review annually.

II. Medicaid Drug Rebate Review

A. Party(ies) Conducting the Medicaid Drug Rebate Review

Merck annually conducts audits relating to Government Pricing and Contracting Functions, and Merck expects to continue such audits during the term of the CIA. At its option, Merck may provide a detailed description of its planned annual audits to the OIG 60 days prior to the beginning of each new Reporting Period. Merck may propose to the OIG that its planned internal audits be substituted for a portion of the Medicaid Drug Rebate Review outlined below in this Section II for the applicable Reporting Period.

If the OIG agrees to permit certain of Merck's internal audit work for a given Reporting Period to be substituted for a portion of the Medicaid Drug Rebate Review, such internal audit work would, at a minimum, be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional direction and specification about the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Merck in its internal audits and shall prepare a report based on its review.

The OIG retains sole discretion over whether to allow Merck's internal audit work to be substituted for a portion of the IRO's Medicaid Drug Rebate Review. In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Merck's planned internal audit work, the results of the Medicaid

Drug Rebate Review(s) during prior Reporting Period(s), and Merck's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Merck's request to permit Merck's internal audit work to be substituted for a portion of the Medicaid Drug Rebate Review in a given Reporting Period, Merck shall engage the IRO to perform the Review as outlined below in this Section II.

B. General Description and Definitions

For each Reporting Period, the IRO shall select and review a sample of transactions from a randomly selected quarter within that Reporting Period to determine whether Merck calculated and reported AMP and BP consistent with the requirements of the Medicaid Drug Rebate Program. The selected quarter shall be identified through the use of the OIG's Office of Audit Services Statistical Sampling Software known as "RAT-STATS" or through the use of another method of random sampling acceptable to the OIG.

For purposes of the AMP Reported Prices Review, the following definitions shall apply:

1. "Actual Transaction Types" are defined as those transactions that are finalized at the time of the sale. As of the Effective Date, Merck had two categories of Actual Transaction Types, namely direct sales and on-invoice discounts. Each of these categories shall be considered a universe of Actual Transaction Types from which the IRO shall draw samples as detailed below in Section II.C.1. Each Transaction within the Actual Transaction Types group shall be referred to as an "Actual Transaction." If, during the term of the CIA, Merck establishes additional categories of Actual Transaction Types, each of the new categories shall be considered an additional universe of transactions from which samples of Actual Transactions shall be selected for purposes of the AMP Reported Prices Procedures.

2. "Lagged Transaction Types" are defined as those transaction types that are processed on a lagged basis. As of the Effective Date, Merck had two categories of Lagged Transaction Types, namely indirect sales, and adjustments or discounts available on a lagged basis. Each of these categories shall be considered a universe of Lagged Transaction Types from which the IRO shall draw samples as detailed below in Sections II.C.1. Each Transaction within the Lagged Transaction Types group shall be referred to as a "Lagged Transaction." If, during the term of the CIA, Merck establishes additional categories of Lagged Transaction Types, each of those new categories shall be considered an additional universe of

transactions from which samples of Lagged Transactions shall be selected for purposes of the AMP Reported Prices Procedures.

The Actual Transaction Types and Lagged Transaction Types shall be referred to hereafter as "Transaction Types".

C. AMP Reported Prices Procedures

1. Identification and Review of Transaction Types.

For each Reporting Period, the IRO shall review a sample of transactions to determine whether Merck calculated and reported AMP in accordance with the requirements of the Medicaid Drug Rebate Program (AMP Reported Prices Procedures). The IRO shall conduct its AMP Reported Prices Procedures by selecting and testing samples from each universe of the applicable Transaction Types, as identified by Merck, for the selected quarter within the Reporting Period. The IRO shall test a discovery sample of 30 Transactions from each universe of Transaction Types for the selected quarter.

a) Actual Transactions

For each universe of Actual Transaction Types, the IRO shall randomly select a discovery sample and, with regard to the sample, shall determine:

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

ii) Whether Merck included or excluded each Actual Transaction in the AMP calculation in accordance with Medicaid Drug Rebate Program requirements.

b) Lagged Transactions

For each universe of Lagged Transaction Types, the IRO shall randomly select a discovery sample and, with regard to the sample, shall determine:

i) Whether the Lagged Transaction amounts were calculated in accordance with Merck's policies, procedures, and methodologies and (where applicable) the Medicaid Drug Rebate Program requirements, and were supported by

relevant commercial arrangements or other source documentation; and

ii) Whether the Lagged Transactions were included in or excluded from the AMP calculation in accordance with Medicaid Drug Rebate Program requirements.

2. Additional Investigation of Transactions

If any discovery sample defined in Section II.C.1 reveals a net dollar Error Rate of 5% or greater, Merck and the IRO shall hold an interim conference with the OIG to discuss the IRO's findings. The IRO shall present its findings, Merck shall present its management response, and the OIG shall review and consider the information provided by the IRO and Merck. Following consultations with Merck and the IRO, the OIG, in its discretion, shall determine whether an Additional Investigation shall be required. For any required Additional Investigation, the IRO shall review additional documentation and/or conduct additional interviews with appropriate personnel, as necessary, to identify the root cause of the net Error Rate.

Upon review of the discovery sample and any Additional Investigation, if warranted, for each universe of Transaction Types, the IRO shall report its findings to the OIG and Merck.

In its discretion, the OIG will determine whether the review of a statistically valid random sample of additional Transactions from the applicable universe shall be required and the size of that statistically valid random sample. The OIG shall base these determinations on discussions with the IRO and Merck, the results of the IRO's reviews of discovery samples, and the findings of any Additional Investigation that may have been deemed warranted.

The discovery samples (and additional samples that may be required) 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.

D. BP Reported Prices Procedures

For each Reporting Period, the IRO shall conduct BP Reported Prices Procedures to determine whether Merck calculated and reported BP in accordance with the requirements of the Medicaid Drug Rebate Program.

The BP Reported Prices Procedures shall consist of two parts:

1. Part One of BP Reported Prices Procedures

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

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

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

[1] For purposes of this Appendix A, "NDC" means a single dosage, form, and strength of a pharmaceutical product, without regard to package size (i.e., NDC 9).
[2] For purposes of this Section II.D, "volume of sales" means for the most recent quarter for which complete data is available: (i) net sales before government rebates; or (ii) for managed care and other similar entities, utilization.

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

2. Part Two of BP Reported Prices Procedures

Merck shall provide the IRO with the following information:

a) a listing of the ten Medicaid rebate eligible NDCs for which Merck paid the largest amount (i.e., total dollars) of Medicaid rebates during the Reporting Period; and

b) for each of the ten Medicaid rebate eligible NDCs selected, a listing of all unique prices paid to Merck for the product that were lower than the reported BP for the selected quarter.

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

3. Additional Investigations

If the BP Reported Prices Procedures reveal any prices that were not accurately reflected in Merck's systems and/or were not appropriately included in, or excluded from, Merck's BP determination in accordance with Medicaid Drug Rebate Program requirements, such prices shall be considered an error. The IRO shall conduct such Additional Investigation as may be necessary to

determine the root cause of the error. For example, the IRO may need to review additional documentation, conduct additional interviews with appropriate personnel, and/or review additional contracts to identify the root cause of the error.

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

In the event the IRO discovers more than one error for the quarter under review in Part One or Part Two of the BP Reported Prices Procedures, Merck and the IRO shall hold an interim conference with the OIG to discuss the IRO's findings. The IRO shall present its findings, Merck shall present its management response, and the OIG shall review and consider the information provided by the IRO and Merck. Following consultations with Merck and the IRO, the OIG, in its discretion, shall determine whether further review is warranted. Should the OIG determine that further review is warranted, the IRO shall randomly select and review a second sample as set forth below in this Section II.D.3, using the same seed number, and repeat Part One and/or Part Two of the BP Reported Prices Procedures (depending on whether one or both parts of the BP Reported Prices Procedures warranted an Additional Investigation).

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

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

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

E. Medicaid Drug Rebate Review Report

1. General Requirements

The IRO shall prepare a report annually based upon each Medicaid Drug Rebate Review performed. The report shall contain the following general elements pertaining to both the AMP Reported Prices Procedures and the BP Reported Prices Procedures:

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

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

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

The IRO shall also include the following information in each Medicaid Drug Rebate Review Report:

2. AMP Reported Prices Procedures

a) A description of Merck's methodology for calculating AMP as reported for purposes of the Medicaid Drug Rebate Program, including its methodology for determining which classes of trade and types of transactions are included or excluded for purposes of calculating AMP;

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

c) For each universe of Transaction Types tested, the IRO shall specify the net Error Rate discovered;

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

e) For each universe of Transaction Types for which the IRO conducted a review on a second statistically valid sample as discussed in Section II.C.2, the IRO shall explain its findings and describe supporting evidence; and

f) The IRO shall report any recommendations for changes to Merck's policies, procedures, and/or methodologies to correct or address any

weaknesses or deficiencies discovered during the AMP Reported Prices Procedures.

3. BP Reported Prices Procedures – Part One

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

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

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

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

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

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

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

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

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

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

4. BP Reported Prices Procedures – Part Two

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

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

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

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

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

APPENDIX B TO UNIFIED CIA FOR MERCK & CO., INC.

Promotional and Product Services Review

I. Promotional and Product Services Review, General Description

As specified more fully below, Merck shall retain an Independent Review Organization (IRO) to perform reviews to assist Merck in assessing and evaluating its systems, processes, policies, procedures, and practices related to Merck's Promotional and Product Services Related Functions (Promotional and Product Services Review). The Promotional and Product Services Review shall consist of two components - a systems review (the Promotional and Product Services Systems Review) and a transactions review (the Promotional and Product Services Transactions Review), as described more fully below. Merck may engage, at its discretion, a single IRO to perform both components of the Promotional and Product Services Review, provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Merck's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. If Merck materially changes its systems, processes, policies, and/or procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Promotional and Product Services Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether there were any material changes in other systems, processes, policies, and/or procedures previously reviewed and reported; and 3) a review of the systems, processes, policies, and procedures that materially changed. Subject to the provisions relating to internal audits by Merck as set forth in Section III.D.2 of the Unified CIA and Section III of this Appendix, the IRO shall conduct the Promotional and Product Services Transactions Review for each Reporting Period of the Unified CIA.

II. Promotional and Product Services Systems Review

A. Description of Reviewed Policies and Procedures

The Promotional and Product Services Systems Review shall be a review of Merck's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Promotional and Product Services Related Functions. Where practical, Merck personnel may

compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Merck pursuant to the preceding sentence.

In conducting the Promotional and Product Services Systems Review, the IRO shall review Merck's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1) Merck's systems, policies, processes, and procedures relating to the retention of health care practitioners (HCPs) or health care institutions (HCIs) as consultants in support of Promotional and Product Services Related Functions (e.g., including, but not limited to, for purposes of advisory boards, expert input forums, thought leader market research, speakers, or other fee-for-service arrangements.) This shall include a review of:

a) the criteria used to determine whether, how many, and under what circumstances (including the venue for the performance of any services) Merck will enter such consultant arrangements and the business rationale for entering consultant arrangements;

b) the processes and criteria used to identify and select HCPs and HCIs with whom Merck enters consultant arrangements, including the role played by sales representatives or field personnel in the process (if any). This includes a review of Merck's internal review and approval process for such arrangements, and the circumstances under which there may be exceptions to the process;

c) the processes and policies required to obtain a written agreement with an HCP for the applicable services to be rendered;

d) Merck's systems, policies, processes, and procedures for tracking or monitoring the services provided or the work performed under consultant arrangements (including the receipt of the work product received from the HCPs or HCIs, if any);

e) Merck's policies and procedures related to any requirement that the HCPs or HCIs (or their agents) disclose the existence of their consultant arrangements with Merck and any financial relationship the HCP or HCI has with Merck;

f) Merck's systems, policies, processes, and procedures for ensuring and verifying that the work product received from the HCPs or HCIs is used by the Company;

g) Merck's processes for establishing the amounts paid to HCPs or HCIs under consultant arrangements and the reasons or justifications for any differentials in the amounts paid to different HCPs and HCIs;

h) the criteria used to determine under what circumstances meals, travel, lodging, entertainment, gifts, and/or other items or reimbursements are provided to the HCPs or HCIs in connection with the consultant arrangements, and Merck's policies for establishing the amounts paid or reimbursed for such items;

i) Merck's systems, policies, processes, and procedures relating to whether (if at all) and in what manner Merck tracks or monitors the prescribing habits or product use of individuals or entities with whom it enters consulting arrangements; and

j) the budget funding source within Merck (e.g., department or division) for the consulting arrangements;

2) Merck's systems, policies, processes, and procedures relating to Merck's Medical Forums (MMFs) (which are medical education programs facilitated by speakers under contract with Merck) (including peer discussion group, lecture, symposium, E-Medical Forum (eMF) and Physician Facilitated Interaction activities). This review shall include a review of the following items:

a) the processes and procedures used to approve the funding or sponsorship of any MMF activity;

b) the criteria used to determine whether and under what circumstances the funding or sponsorship will be provided;

c) the processes and criteria used to select participants (including the speakers/moderators/facilitators of the MMFs and attendees at the MMFs), including the role played by sales representatives or field personnel in the processes (if any), and the circumstances under which there may be exceptions to the processes;

d) Merck's policies and procedures relating to any requirements that speakers/moderators/facilitators of MMFs disclose Merck's funding or sponsorship and any financial relationship Merck may have with the speaker/moderator/facilitator;

e) Merck's policies or procedures for determining and memorializing the amounts paid to speakers/moderators/facilitators and the purpose or justifications for the amounts paid, including any differentials in amounts paid to different speakers/moderators/facilitators;

f) Merck's policies and procedures relating to the limitations on the number of times in a calendar year that a speaker/moderator/facilitator may be used for an MMF or other Merck-sponsored activity;

g) Merck's policies and procedures relating to the content and nature (e.g., promotional, non-promotional) of any MMFs;

h) the criteria used to determine under what circumstances meals, travel, lodging, gifts, and/or other items or reimbursements are provided in connection with the MMFs, and Merck's policies for establishing the amounts paid or reimbursed for such items;

i) Merck's systems, policies, processes, and procedures relating to whether (if at all, for each type of individual or entity) and in what manner Merck tracks or monitors the prescribing habits or product use of individuals or entities participating in the MMFs (either as attendees or as speakers/moderators/facilitators); and

j) the budget funding source within Merck (e.g., department or division) from which the funding for MMFs are provided;

3) Merck's systems, policies, processes, and procedures relating to funding of, sponsorship of, or participation in field-based-employee (FBE) facilitated meetings (including, but not limited to, in-office and out-of-office facilitated meetings, business and other meetings over meals, displays over meals, and external journal clubs) and field directed exhibits/displays (collectively "FBE Activities"). This review shall include a review of the following items:

a) the processes and procedures used to approve the funding or sponsorship of, or participation in, FBE Activities;
b) the criteria used to determine whether and under what circumstances Merck will fund, sponsor, or otherwise participate in FBE Activities;
c) the processes and criteria used to select recipients of the funding for the FBE Activities, including the role played by field personnel or sales representatives in the processes, and the circumstances under which there may be exceptions to the processes;
d) Merck's policies and procedures relating to any requirement that Merck or the recipient of the FBE Activity funding or sponsorship disclose Merck's funding and any financial relationship Merck may have with the recipient;
e) Merck's policies or procedures for determining and memorializing the amounts paid in connection with the FBE Activities and the purpose or justifications for the amounts paid;
f) the criteria used to determine under what circumstances meals, gifts, and/or other items or reimbursements are provided in connection with the FBE Activities, and Merck's policies for establishing the amounts paid or reimbursed for such items;
g) Merck's systems, policies, processes, and procedures relating to whether (if at all) and in what manner Merck tracks or monitors the prescribing habits or product use of individuals or entities receiving the FBE Activities funding or sponsorship; and
h) the budget funding source within Merck (e.g., department or division) for the Research Activities;

4) Merck's systems, policies, processes, and procedures relating to grants administered by Merck's Academic Affairs department (including, but not limited to, CE/CME Grants, Patient Advocacy Group Grants, and Professional Society Grants.) This review shall include a review of the following items:

a) the processes and procedures used to approve grants;
b) the criteria used to determine whether and under what circumstances Merck will provide grants;

c) the processes and criteria used to select grant recipients, including the role played by field personnel or sales representatives in the processes (if any), and the circumstances under which there may be exceptions to the processes;

d) Merck's policies and procedures relating to any requirement that the grant recipient (or the recipient's agent) disclose the grant and any financial relationship Merck may have with the recipient;

e) Merck's policies or procedures for determining and memorializing the grant amounts and the purpose or justifications for the amounts paid;

f) Merck's policies and procedures relating to the independence of any programs funded through the grants;

g) Merck's policies and procedures relating to the content and nature (e.g., promotional, non-promotional) of any programs funded through grants;

h) Merck's systems, policies, processes, and procedures relating to whether (if at all) and in what manner Merck tracks or monitors the prescribing habits or product use of individuals or entities receiving the grants; and

i) the budget funding source within Merck (e.g., department or division) for the grants;

5) Merck's systems, processes, policies, and procedures applicable to Sales Representatives in connection with their handling of requests or inquiries they may receive relating to off-label uses of products;

6) Merck's systems, processes, policies, and procedures applicable to GMIO employees and Medical Science Specialists (MSSs) in connection with their handling of requests or inquiries they may receive relating to off-label uses of products;

7) Merck's systems, policies, processes, and procedures through which requests and inquiries directly from Health Care Professionals (HCPs) and/or through Sales Representatives related to off-label uses of products are handled by Merck (*i.e.*, a review of the manner in which Merck receives, tracks, and responds to such requests, including the form and content of information disseminated by GMIO in response to such requests, and the internal review process for the information disseminated). The IRO shall also review the policies and procedures that apply when MSSs

accompany or participate with sales representatives in meetings or events with physicians or other HCPs (including detailing visits), if any, and the role of the MSS personnel at such meetings or events;

8) Merck's systems, policies, processes, and procedures for tracking expenditures (individual and aggregate) associated with the Reviewed Policies and Procedures referenced in Sections II.A.1-4, above;

9) Merck's policies, processes, and procedures relating to disciplinary actions that Merck may undertake in the event a Covered Person violates a Merck policy or procedure relating to Promotional and Product Services Related Functions;

10) Merck's systems, polices, processes, and procedures relating to compensation arrangements (including salaries and bonuses) for Relevant Covered Persons engaged in Promotional and Product Services Related Functions, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not motivate such individuals to engage in such Functions in an improper manner. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance;

11) Merck's systems, processes, policies, and procedures relating to the development of call plans involving Schering Legacy Products. This shall include a review of the basis upon which specialties are included ore excluded from the call plan based upon their potential on-label and off-label utilization of Schering Legacy Products.

B. Promotional and Product Services Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

1) a description of the documentation (including policies) reviewed and any personnel interviewed;

2) a detailed description of Merck's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-11 above, including a general description of Merck's control and accountability systems (*e.g.,* documentation and approval requirements, tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-11 above are made known or disseminated within Merck;

4) a description of Merck's systems, policies, processes, and procedures for tracking any expenditures associated with the Reviewed Policies and Procedures referenced in Sections II.A.1-4, above;

5) a general description of Merck's disciplinary measures applicable for a failure to comply with its policies and procedures relating to Promotional and Product Services Related Functions;

6) a detailed description of Merck's compensation system (including salaries and bonuses) for Relevant Covered Persons engaged in Promotional and Product Services Related Functions, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Merck may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

7) findings and supporting rationale regarding any weaknesses in Merck's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

8) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

III. Promotional and Product Services Transaction Review

Merck annually conducts audits relating to Promotional and Product Services Related Functions, and Merck expects to continue such audits during the term of the CIA. At its option, Merck may provide a detailed description of its planned annual audits to the OIG 60 days prior to the beginning of each new Reporting Period. Merck may propose to the OIG that its planned internal audits be substituted for a portion of the Promotional and Product Services Transactions Review outlined below in this Section III for the applicable Reporting Period.

If the OIG agrees to permit certain of Merck's internal audit work for a given Reporting Period to be substituted for a portion of the Promotional and Product Services Transaction Review, such internal audit work would, at a minimum, be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional direction and specification about the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Merck in its internal audits and shall prepare a report based on its review.

The OIG retains sole discretion over whether to allow Merck's internal audit work to be substituted for a portion of the Promotional and Product Services Transactions Review. In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Merck's planned internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Merck's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Merck's request to permit Merck's internal audit work to be substituted for a portion of the Promotional and Product Services Review in a given Reporting Period, Merck shall engage the IRO to perform the Review as outlined below in this Section III.

A. Promotional and Product Services Transactions Review

1) Background on Policies and Merck Activities

Merck has developed policies and procedures relating to programs and activities with HCPs and others that may be initiated by its field-based employees or by its headquarters personnel.

The activities initiated and handled by headquarters personnel include consulting activities and grants. These programs are initiated and handled by Merck's Marketing department and Merck's Academic Affairs department, respectively. More specifically, Merck's Marketing department initiates consultant activities including: Advisory Boards, Thought Leader Market Research activities, and Expert Input Forums. These activities shall be referred to collectively as "Consulting Activities."

Merck's Academic Affairs department evaluates and administers all CE/CME grants, Patient Advocacy Group Grants, and Professional Society Grants. These activities shall be referred to collectively known as "Grants".

The activities primarily initiated and handled by field based-employees U.S. Pharma fall into three general categories: facilitated meetings, field directed exhibits/displays, and speaker-facilitated programs (also known as Merck Medical Forums (MMFs).) Facilitated meetings are informal meetings that provide a setting for clinical and/or product discussions with a small group of HCPs that are facilitated by Merck field-based employees. MMFs include peer discussion groups, lectures, physician facilitated interactions, symposium, and eMedical forums. Certain Merck headquarters personnel are also involved with MMF activities. The facilitated meetings, field directed exhibits/displays, and MMFs shall be referred to collectively as "Field Activities".

For purposes of the Promotional and Product Services Transactions Review, Consulting Activities, Grants, and Field Activities shall each be a universe from which samples of activities shall be drawn and reviewed by the IRO. Consulting Activities, Grants, and Field Activities shall be referred to collectively as "Reviewed Activities".

2) Description of Reviewed Activities Control Documents and Selection of Samples for Review

"Control Documents" shall be defined to include all documents or electronic records (collectively "documents") associated with each set of Reviewed Activities. These documents include, but are not limited to, all documents submitted by sales representatives or headquarters personnel to request approval for the Reviewed Activity; business rationale or justification forms; written contracts relating to the Reviewed Activity; all documents relating to the occurrence of the Reviewed Activity (*e.g.*, attendance rosters, receipts); and all documents reflecting any work product generated in connection with the Reviewed Activity.

For each Transactions Review, the IRO shall review a total of 90 distinct Reviewed Activities that occurred during the relevant Reporting Period with the exception of the Third Reporting Period of the Unified CIA. During the Third Reporting Period the IRO shall review a total of 120 distinct Reviewed Activities. The Third Annual Report sample shall include the Schering-Plough Addendum activities as of August 26, 2009. For the period beginning on August 26, 2009 up to Unified CIA Effective Date, the Schering Addendum activities shall be measured against the requirements of the Schering-Plough Addendum, and the Merck activities shall be

measured against the requirements of the Merck Legacy CIA. For the period beginning on the Unified CIA Effective Date, all activities shall be measured against the requirements of this Unified CIA.

For each Reporting Period, the OIG, in its discretion, shall identify the number and type(s) of Reviewed Activities from each of the three universes (Consulting Activities, Grants, and Field Activities) to be reviewed by the IRO. For example, the OIG may determine that for a particular Reporting Period, the IRO's review shall include 30 Grants, and that the Grants-related review shall encompass 15 CME/CE Grants and 15 Professional Society Grants.

In order to aid the OIG in making its determinations about the number and types of Reviewed Activities, no later than 120 days prior to the start of each Reporting Period, Merck shall provide the OIG with certain information. Specifically, Merck shall provide information about the estimated number of each type of Reviewed Activities that occurred (or will occur) during the preceding Reporting Period and the amount of spending associated with each type of Reviewed Activity. The OIG shall make its determination about the number and types of Reviewed Activities to be reviewed from each of the three universes after reviewing the information provided by Merck and after consultation with Merck.

After making its determinations, the OIG shall notify Merck about the number and type(s) of Reviewed Activities that shall be reviewed from each of the three universes as part of the Transactions Review. Based on the OIG's determinations, the IRO shall randomly select the appropriate number of occurrences of each specified type of Reviewed Activities from the three universes. The IRO shall review all Control Documents associated with the selected sample of Reviewed Activities.

For each sampled Reviewed Activity, the IRO shall review the associated Control Documents to evaluate the following:

a) Whether all required Control Documents exist in appropriate files in accordance with Merck's policies and procedures;

b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Merck's policies and procedures; and

c) Whether the Control Documents reflect that Merck's policies and procedures were followed in connection with the underlying activities (*e.g.*, all required written approvals for the activity were obtained in accordance with Merck's policies.)

3) Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

a) All required Control Documents relating to a Reviewed Activity do not exist and:
   i. no corrective action was initiated prior to the selection of the Reviewed Activities by the OIG; or
   ii. the IRO cannot confirm that Merck otherwise followed its policies and procedures relating to the Reviewed Activity.

b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Merck's policies and procedures and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Merck initiated corrective action prior to the sample selection of the Reviewed Activities by the IRO, or if a Control Document does not exist but the IRO can determine that Merck otherwise followed its policies and procedures with regard to the Reviewed Activity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Reviewed Activities associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

B. Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Promotional and Product Services Transactions Review. The report shall include the following:

1) General Elements to Be Included in Report

a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;

b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and

c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Promotional and Product Services Transactions Review.

2) Results to be Included in Report

The following results shall be included in each Promotional and Product Services Review Report:

a) a description of each type of sample unit reviewed for each Reviewed Activity, including the number of each type of sample units reviewed (*e.g.*, Control Documents associated with each of the various types of Reviewed Activities) and an identification of the types of Control Documents reviewed for each type of sample unit;

b) for each sample unit, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed and archived in accordance with all of the requirements set forth in the applicable Merck policies and procedures; (iii) each Control Document reflects that Merck's policies and procedures were followed in connection with the underlying activity reflected in the document (*e.g.*, all required approvals were obtained); and (iv) any disciplinary action was undertaken in those instances in which Merck policies and procedures were not followed;

c) for each sample unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the IRO review, including a description of the circumstances requiring corrective action and the nature of the corrective action;

d) if any Material Errors are discovered in the sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error; and

e) recommendations, if any, for changes in Merck's systems, processes, policies, and procedures to correct or address any weaknesses or deficiencies uncovered during the Transactions Review. The report shall include findings and supporting rationale for all such recommendations.

APPENDIX C TO UNIFIED CIA FOR MERCK & CO., INC.

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

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

If Merck engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Merck shall submit the information identified in Section V.A.6 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Merck if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Merck may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Medicaid Drug Rebate Reviews and the Promotional and Product Services Reviews who have expertise in all applicable Federal health care program requirements relating to Government Pricing and Contracting Functions and Promotional and Product Services Related Functions and in the general requirements of the Federal health care program(s) under which Merck's products are reimbursed;

2. assign individuals to the Medicaid Drug Rebate Review and the Promotional and Product Services Review who are knowledgeable about appropriate techniques required for the Reviews, including assigning individuals who are knowledgeable about appropriate statistical sampling techniques to design and select samples for the Transaction Reviews; and

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

C. IRO Responsibilities.

The IRO shall:

1. perform each Medicaid Drug Rebate Review and Promotional and Product Services Review in accordance with the specific requirements of the CIA, including Appendices A-B, as applicable;

2. follow all applicable Federal health care program requirements in making assessments in each Medicaid Drug Rebate Review and Promotional and Product Services Review;

3. if in doubt of the application of a particular Federal health care program policy or regulation, request clarification from the appropriate authority (e.g., CMS);

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

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

D. IRO Independence and Objectivity.

The IRO must perform each Medicaid Drug Rebate Review and Promotional and Product Services Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Merck.

E. IRO Removal/Termination.

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

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

Prior to requiring Merck to engage a new IRO, OIG shall notify Merck of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Merck may request a meeting with OIG to

discuss any aspect of the IRO's qualifications, independence, or performance of its responsibilities and to present additional information regarding these matters. Merck shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Merck prior to requiring Merck to terminate the IRO. However, the final determination as to whether or not to require Merck to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX D TO UNIFIED CIA FOR MERCK & CO., INC.

Certification

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

1) Merck has in place policies and procedures describing in all material respects its methods for collecting, 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 Merck's obligations under the Medicaid Drug Rebate Program;

3) Merck's Medicaid Rebate Policies and Procedures were followed in all material respects in connection with the calculation of Average Manufacturer Price (AMP) and Best Price (BP) for Merck's products for each of the below-listed four quarters: [specifically identify the applicable quarters]; and

In accordance with Section III.M of the CIA, Average Sales Prices (ASPs) for the Products listed on Attachment 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 any other price reporting entity as specified in the Unified CIA); and 3) to the OIG. The ASPs reported were calculated in accordance with the definition of and requirements relating to the ASP set forth in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). I understand that the ASPs 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. I hereby certify that the Statements made in connection with the ASPs, the AMPs, and BPs reported to CMS in the above-listed quarters were calculated accurately and all information and statements made in

connection with the submission of AMPs and BPs and in this Certification are true, complete, and current and are made in good faith.

_____

Signature

_____

Name of CEO, CFO, or other appropriate individual consistent with 42 C.F.R. § 447.510(e)

_____

Date

APPENDIX E TO UNIFIED CIA FOR MERCK & CO., INC.

List of Schering Products for Which Average Sales Prices Are Reported.

The products on this list shall be defined as "Covered Schering Products" for the purposes of the requirements of Section III.L and Appendix D of the Unified CIA.

1. All products that were Schering products (including the products of Schering subsidiaries) for which Schering reported Average Sales Prices to the Centers for Medicare & Medicaid Services as of the Effective Date of the Schering-Plough CIA.
2. Clarinex
3. Claritin
4. Isosorbide Mononitritate
5. Clotrimazole and Betamethoasone Dipropionate Crème
6. Ribavirin
7. Sucralfate Tablets
8. Clotrimazole Crème
9. Augmented Betamethasone Dipropoinate Ointment
10. Potassium Chloride
11. Avelox
12. Cipro
13. Levitra
14. Adalat
15. Dome-Paste
16. Biltricide