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

I. PREAMBLE

Effective July 29, 2004, Schering-Plough Corporation (Schering-Plough) entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) (hereinafter referred to as the "CIA"). Schering-Plough hereby enters into this Addendum to the CIA (Addendum). Contemporaneously with this CIA Addendum, Schering-Plough is entering into a Settlement Agreement with the United States. Schering-Plough is also prepared to enter into related settlement agreements with various states, and Schering-Plough's agreement to the CIA and this Addendum is a condition precedent to those agreements.

II. TERM AND SCOPE OF THE CIA AND ADDENDUM

A. All of the obligations assumed by Schering-Plough under the CIA shall continue for the time period set forth in the CIA. In addition, unless otherwise specifically revised by this Addendum or excepted, all of the provisions of the CIA shall be and hereby are incorporated into this Addendum. The obligations set forth in this Addendum shall remain in full force and effect during the period covered by the Addendum, with the following exceptions. The Average Sales Price-related review provisions (which are part of the Government Pricing and Medicaid Drug Rebate Engagement outlined in Section III.E and Attachment B to the CIA) and the Managed Care Expenditures Engagement requirements outlined in Section III.E and Attachment C shall remain in effect only through the five-year period of the CIA.

The period of the compliance obligations assumed by Schering-Plough under this Addendum shall be five years from the effective date of the Addendum, unless otherwise specified. The effective date shall be the date on which the final signatory of this Addendum executes the Addendum (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as an "Addendum Reporting Period." The Addendum Reporting Periods shall remain in effect until the expiration of the term of this Addendum.

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

B. The definitions of "Covered Persons" and "Relevant Covered Persons" set forth in the CIA shall apply for purposes of this Addendum. In addition, the marketing, sales, or other personnel of entities with which Schering-Plough has entered or may enter into joint venture agreements or agreements to co-market its products shall be known as "Third Party Personnel" for purposes of this Addendum. Schering-Plough has represented that: 1) the Third Party Personnel are employed by other pharmaceutical manufacturers; 2) Schering-Plough does not control the Third Party Personnel; and 3) it would be commercially impracticable to compel their compliance with the requirements set forth in this Addendum and the CIA.

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

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

2. The joint venture or co-marketing agreements referenced above in Section II.B.1 may require the entity contracting with Schering-Plough to make available to its Third Party Personnel a copy of Schering-Plough's Code of Conduct and a description of the Schering-Plough Compliance Program or the agreements may represent to Schering-Plough that the entity has and enforces a substantially comparable Code of Conduct and compliance program. If that is the case, each such agreement shall satisfy the requirements of Sections II.B.1(a) and (b) above.

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

III. CORPORATE INTEGRITY OBLIGATIONS

Throughout the term of this Addendum, Schering-Plough shall maintain a Compliance Program that includes all the elements specified in the CIA and in this Addendum:

A. Compliance Officer and Executive Management Team.

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

B. Written Standards.

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

C. Training and Education.

The terms of Section III.C of the CIA remain in effect and Schering-Plough shall continue its obligations under Section III.C through the term of this Addendum.

D. Average Sales Price Reporting Requirement.

The terms of Section III.D of the CIA (including the certification included as Attachment A to the CIA) remain in effect and Schering-Plough shall continue its obligations under those provisions through the term of this Addendum.

E. Engagement Procedures.

Except as otherwise specified below, the terms of Section III.E remain in effect and Schering-Plough shall continue its obligations under those provisions through the term of this Addendum. The reference in Section III.E.1.d of the CIA to retention of records for a period of "six years after the Effective Date" shall be read to mean "six years after the Effective Date of the Addendum."

With regard to the Government Pricing and Medicaid Drug Rebate Engagement discussed in Section III.E of the CIA and Attachment B, Schering-Plough shall continue to satisfy all requirements relating to the Engagement during the first three Addendum Reporting Periods. During the fourth and fifth Addendum Reporting Periods, Schering-Plough and/or the IRO shall perform the Reported Prices Procedures for Best Price portion of the Government Pricing and Medicaid Drug Rebate Transactions Engagement as set forth in Section III.B of Attachment B to the CIA, and the IRO and Schering-Plough shall submit reports about the Engagement in accordance with the requirements forth in Section III.E and Attachment B.

With regard to the Managed Care Expenditures Engagement, Schering-Plough shall continue to satisfy all requirements relating to this Engagement as set forth in Section III.E of the CIA and Attachment C thereto during the first three Addendum Reporting Periods.

The Promotional and Product Services Engagement referenced in Section III.E shall consist of two components, a Systems Review and a Transactions Review, and shall be performed in accordance with Section III.E and Attachment D, which is attached hereto and is incorporated by reference into this Addendum.

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

F. Disclosure Program.

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

G. Ineligible Persons.

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

H. Notification of Government Investigation or Legal Proceedings.

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

I. Reporting.

The terms of Section III.I of the CIA remain in effect and Schering-Plough shall continue its obligations under Section III.I through the term of this Addendum.

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

The terms of Section III.J of the CIA remain in effect and Schering-Plough shall continue its obligations under Section III.J through the term of this Addendum.

K. Schering-Plough Specialty Field Sales Force Promotion Monitoring Program.

Schering-Plough shall implement a Field Sales Force Promotion Monitoring Program that will consist of a formalized process designed to identify potential off-label promotional activities, by Schering-Plough's Specialty Field Sales Forces[1], through observations of the interactions of the Schering-Plough Field Force with Health Care Professionals (HCPs) by members of Schering-Plough's Global Compliance and Business Practices ("GCBP") group familiar with product labeling and appropriate product messages. During each Addendum Reporting Period, GCBP will conduct a minimum of 30 full-day, direct inspections and observations of the messages and materials delivered by Schering-Plough Specialty Field Sales Force Representatives to HCPs. (These inspections and observations shall be known as "Inspections.") Each Inspection day will consist of directly observing all meetings between Schering-Plough Specialty Field Sales Force Representatives and HCPs during that workday. The Inspections shall be scheduled throughout the Reporting Period, and shall be randomly selected by GCBP. The number of Inspections conducted for each Specialty Field Sales Force shall be proportional in number to the size of each Specialty Field Sales Force, and shall be conducted in all regions across the United States.

[1] SP Specialty Field Sales Forces are defined as Hepatitis/Virology, Oncology and Coronary Care Field Forces.

At the completion of each Inspection day, GCBP personnel shall complete an Inspection Report, which shall include: 1) the identity of the Specialty Field Sales Force Representative; 2) the identity of the GCBP professional; 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 Specialty Field Sales Force Representative.

In the event that a GCBP Inspection identifies potential off-label promotion, Schering-Plough shall investigate the incident consistent with Schering-Plough's established investigation protocol. If the investigation determines that there was off-label promotion by a Specialty Field Sales Force Representative, Schering-Plough shall notify the OIG pursuant to Section III.I of the CIA. As part of each Annual Report, Schering-Plough 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, Schering-Plough took as a result of such determinations. Schering-Plough shall make Inspection Reports for all other Inspections available to the OIG upon request.

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

Schering-Plough has in place, and shall continue to maintain, policies addressing the discussion and dissemination of information about non-FDA approved uses of products (off-label information). These policies provide, among other things, that Covered Persons may not directly or indirectly solicit, encourage, or promote unapproved uses of a product to HCPs. Schering-Plough's policies require that when Covered Persons receive inquiries about unapproved uses of products, Covered Persons shall direct such inquiries to headquarters personnel rather than responding to the inquiries themselves. Specifically, Schering-Plough has established a Global Drug Information Services (GDIS) unit to undertake various functions, including responding to requests for off-label information about Schering-Plough products.

Schering-Plough documents and records all inquiries submitted by field personnel to GDIS on behalf of customers, including requests relating to off-label information. On a quarterly basis, Schering-Plough 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, GDIS compiles and provides information to the GCBP group and others within Schering-Plough about all requests submitted to GDIS about Schering-Plough products. The request 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 therapy area, 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 GDIS requests for the top 10 requestors in the therapy area is reviewed by a compliance manager for each business unit. 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, Schering-Plough conducts a formal investigation of the situation and undertakes disciplinary action where appropriate.

Schering-Plough shall continue to conduct the quarterly Off-Label Inquiry Analyses, substantially in the form described in this Addendum, through the term of the 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, Schering-Plough shall submit to the OIG a description of the Off-Label Inquiry Analyses conducted during the Addendum Reporting Period and a summary of the findings of the Analyses.

M. Message Recall Monitoring Program.

Schering-Plough shall implement a Message Recall Monitoring Program designed to identify potential off-label promotional activities by Schering-Plough's Specialty Field Sales Forces through the analysis of commercially available, non-Schering-Plough studies generated by an independent entity concerning physician recall of the marketing messages delivered by those Sales Forces (Message Recall Studies) during the Addendum Reporting Period. During each Addendum Reporting Period, Schering-Plough shall obtain Message Recall Studies relating to two Schering-Plough products that have been selected by the OIG for that period (Covered Products). At its option, Schering may obtain other Message Recall Studies relating to the Covered Products or to other products. Schering-Plough shall analyze the results of all Message Recall Studies to determine whether they reveal any indicators of potential off-label promotional activities.

At the end of each Addendum Reporting Period, Schering-Plough shall complete a Message Recall Monitoring Report that shall consist of: 1) the initiation and completion dates of all Message Recall Studies conducted during that period; 2) the content and scope of those Message Recall Studies; 3) a description of any indicators of potential off-label promotional activities revealed by the Studies; and 4) a description of the action(s), if any, taken by Schering-Plough as a result of learning of such indicators. The Message Recall Monitoring Report shall be submitted to the OIG as part of each Annual Report.

Prior to the start of the Second Addendum Reporting Period and every Addendum Reporting Period thereafter, the OIG shall select up to two Schering-Plough products to be Covered Products for purposes of this Section III.M. The OIG shall notify Schering-Plough which Covered Products have been selected for each Addendum Reporting

Period. The Parties have already selected the Covered Products for the first Addendum Reporting Period.

IV. NEW BUSINESS UNITS OR LOCATIONS

The terms of Section IV of the CIA remain in effect and Schering-Plough shall continue its obligations under Section IV through the term of this Addendum.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Schering-Plough shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Addendum (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the information required by Section II.C of this Addendum;

2. the following information regarding the IRO(s) retained to perform the Promotional and Product Services Engagement: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between Schering-Plough and the IRO; and (d) the proposed start and completion dates of the Engagement; and

3. a certification from the IRO retained to perform the Promotional and Product Services Engagement regarding its professional independence and/or objectivity with respect to Schering-Plough.

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

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

1. the information required by Section II.C of this Addendum;

2. as required by Section III.K of this Addendum, a copy of Schering-Plough's 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, Schering-Plough took as a result of such determinations;

3. as required by Section III.L, a description of the Off-Label Inquiry Analyses conducted during the Addendum Reporting Period and a summary of the findings of the Analyses;

4. as required by Section III.M, the Message Recall Report pertaining to the Message Recall Studies conducted during the Addendum Reporting Period; and

5. a list and description of all actively promoted Schering-Plough products and, if available, information about the estimated relative usage (*e.g.*, the percentage) of those products for off-label uses.

The first Annual Report required by this section and the next Annual Report required by Section V of the CIA, shall be received by OIG no later than 150 days after the end of the first Addendum Reporting Period. Subsequent Annual Reports required by both this section and Section V of the CIA, shall be received by OIG no later than the anniversary date of the due date of the first Annual Report required by the Addendum.

C. Certifications. Sections V.C and V.D of the CIA remain in effect and Schering-Plough shall continue its obligations under those sections through the term of this Addendum.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

The terms of Section IX of the CIA remain in effect and Schering-Plough shall continue its obligations under Section IX through the term of this Addendum.

X. BREACH AND DEFAULT PROVISIONS

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

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

i. the Specialty Field Sales Force Promotion Monitoring Program; and

j. the Off-Label Inquiry Analysis; and

k. the Message Recall Monitoring Program.

In addition, the references to "Appendices B-C" in Sections X.A.2, X.A.4, and X.D.1.d of the CIA are amended to read "Appendices B-D."

XI. EFFECTIVE AND BINDING AGREEMENT

The terms of Section XI of the CIA remain in effect and Schering-Plough shall continue its obligations under Section XI through the term of this Addendum.

ON BEHALF OF SCHERING-PLOUGH CORPORATION

[redacted]

8/25/06

Brent Saunders
Senior Vice President
Global Compliance and Business Practices
Schering-Plough Corporation

DATE

[redacted]

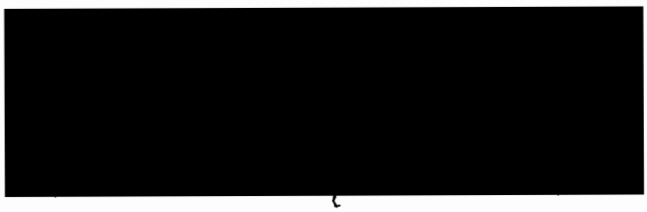
Paul E. Kalb, Esq.
Sidley Austin LLP

DATE

ON BEHALF OF SCHERING-PLOUGH CORPORATION

Brent Saunders
Senior Vice President
Global Compliance and Business Practices
Schering-Plough Corporation

DATE



8/25/06

Paul E. Kalb, Esq.
Sidley Austin LLP

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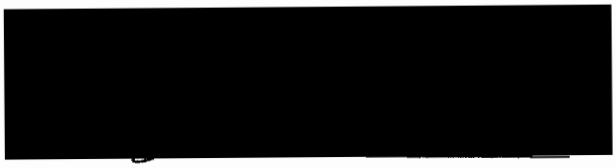
ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES



8/25/96

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

DATE

Attachment D to the Addendum to the CIA for Schering-Plough Corporation Promotional and Product Services Engagement

I. Promotional and Product Services Engagements - General Description

As specified more fully below, Schering-Plough Corporation (SP) shall retain an Independent Review Organization (IRO) to perform engagements to assist SP in assessing and evaluating its systems, processes, policies, and procedures related to sales, marketing, promotional, and product services activities (Promotional and Product Services Engagement). The Promotional and Product Services Engagement shall consist of two components – a systems engagement (the Promotional and Product Services Systems Engagement) and a transactions engagement (the Promotional and Product Services Transaction Engagement), as described more fully below. SP may engage, at its discretion, a single entity to perform both components of the Promotional and Product Services Engagement, provided that the entity has the necessary expertise and capabilities to perform both. SP may engage, at its discretion, the same entity that it engages to perform the engagements required by sections III.E.1.b.1-2 of the CIA.

The Promotional and Product Services Systems Engagement shall be a review of SP's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to sales, marketing, promotional, and product services activities. If there are no material changes in SP's applicable systems, processes, policies and procedures during the term of the Addendum, then the IRO shall only perform the Promotional and Product Services Systems Engagement for the second and fourth Addendum Reporting Periods. If SP materially changes its systems, processes, policies, and procedures relating to sales, marketing, promotional, and product services activities, then the IRO shall perform a Promotional and Product Services Systems Engagement covering the Addendum Reporting Period in which such changes were made in addition to conducting the Promotional and Product Services Systems Engagement for the second and fourth Addendum Reporting Periods. The additional Promotional and Product Services Systems Engagement shall consist of a description of the material changes, an assessment of whether the systems, processes, policies and practices already reviewed did not materially change, and an update on the systems, processes, policies, and procedures that materially changed.

The Promotional and Product Services Transactions Engagement shall be comprised of: 1) testing of samples of Control Documents, as defined

below in Section III.A.2; and 2) any additional engagement as defined below in Section III.A.4.

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

Consistent with Section III.E.1.c. of the CIA, after the third Addendum Reporting Period, the OIG may, at its discretion and upon request of SP, permit SP to perform the engagements described in this Attachment D, subject to verification by the IRO. In such an instance, the OIG will provide additional guidance about the exact scope of the IRO's verification review after consultation with SP. However, for purposes of the Promotional and Product Services Transactions Review, the IRO shall review at least 20% of the Sample Units reviewed by SP in its internal Promotional and Product Services Transactions Review (Validation Review). In addition, as part of the Validation Review, the IRO shall verify that SP followed the requirements set forth in Section III.E of the CIA and this Attachment D, and it shall report the results, Sample Unit by Sample Unit, of the Verification Review performed. The IRO's report shall identify any discrepancies between the IRO's findings and those of SP's internal review, and shall identify possible reasons for the discrepancies.

II. Promotional and Product Services Systems Engagement

A. Reviewed Policies and Practices

Consistent with Section I above, for at least the second and fourth Addendum Reporting Periods, the IRO, or SP pursuant to Section III.E.1.c of the CIA, shall review SP's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Practices"):

1) SP's systems, processes, policies, and procedures applicable to personnel in the Field Sales Force in connection with their handling of requests or inquiries they may receive relating to off-label uses of products;

2) SP's systems, processes, policies, and procedures applicable to Medical Science Liaisons (MSLs) in connection with their handling of requests or inquiries they may receive relating to off-label uses of products;

3) SP's systems, policies, processes, and procedures through which requests and inquiries directly from Health Care Professionals (HCPs) and/or through Field Sales Force personnel related to off-label uses of products are handled by Global Drug Information Services (GDIS) (*i.e.*, a review of the manner in which GDIS receives, tracks, and responds to such requests, including a review of the Schering-Plough Info Net which is used by GDIS to process unsolicited requests for medical information, the form and content of information disseminated by GDIS 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 MSLs 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 MSL personnel at such meetings or events;

4) SP's systems, processes, policies, and procedures relating to programs[1] initiated or facilitated by the Field Sales Force or Home Office Sales and Marketing. This shall include a review of systems, processes, policies, and procedures covering:

   i. The criteria used to determine the actual, bona fide and objective business need to hire an HCP for promotional programs. This business need should have a clearly stated purpose and objective;
   ii. The process and criteria used to identify and select particular HCPs for participation in the promotional programs, including the role played by the Field Sales Force in this process;
   iii. The processes and policies required to obtain a written agreement with an HCP for the applicable services to be rendered;
   iv. SP's processes for determining the Fair Market Value (FMV) for the compensation of HCPs and the rationale for any differentials in amounts paid to different HCPs;

[1] Those programs that may be initiated or facilitated by the Field Sales Force or Home Office Sales and Marketing are: Promotional Support (*e.g.*, exhibits and displays), Advisory Boards, Consulting Arrangements, Speaker Training, and Speaker Programs.

v. The processes and procedures for tracking or monitoring the services (and any work product) provided by the HCPs and ensuring that services are rendered prior to payment to a HCP;
vi. Whether and in what manner SP tracks or monitors the prescribing habits or product use of individuals or entities with whom it enters arrangements for promotional programs; and
vii. The budget funding source within SP for the payment for the promotional program;

5) SP's systems, processes, policies, and procedures relating to its internal system for tracking and approving promotional programs including: (i) the manner, processes, and systems through which information is inputted, maintained, and updated into the U.S. Customer Operations Support (USCOS[1]) system and other source systems; (ii) the controls and approval processes relating to promotional programs; and (iii) how SP verifies that all financial programs with HCPs are processed through USCOS, given that, with the exception of promotional support (*e.g.*, funding for exhibits and displays), USCOS does not serve as a mechanism for initiation or funding of programs for certain types of financial activities with HCPs, including advisory board arrangements;

6) SP's systems, processes, policies, and procedures relating to grants and sponsorships by SP. This review shall include a review of the following:
   i. the criteria used to determine whether and under what circumstances the funding will be provided;
   ii. the processes and procedures used to request and approve grants or sponsorships;
   iii. if the funding is used to support a particular event, SP's policies and procedures for requiring the recipient of the funding to disclose SP's financial support and any financial relationship SP may have with the participants in the event for which funding is provided;
   iv. the processes and procedures for determining the amount of the funding to be provided;
   v. the policies and procedures relating to the independence of any programs or events sponsored with funding by SP;

[2] USCOS is supported by multiple systems, through which it captures control documents related to promotional activities into a centralized repository. This customer data and documentation repository additionally collects, maintains and allows for the generation of reports of aggregate payments made to SP customers (*i.e.*, healthcare professionals, healthcare institutions, managed care organizations, *etc.*), as well as information from third-party vendors.

vi. whether and in what manner SP tracks or monitors the prescribing habits or product use of individuals or entities who receive grants or sponsorships from SP; and

vii. the budget funding source within SP for the payment for the grant or other financial support;

7) SP's systems, processes, policies, and procedures relating to funding or sponsorship of research agreements and/or grants (collectively "Research Activities") in the United States by the SP Global Medical Affairs Department (GMA). This review shall include a review of the following:

   i. the criteria used to determine whether and under what circumstances the funding will be provided for Research Activities;

   ii. the processes and procedures used to request and approve funding for Research Activities;

   iii. if the funding is used to support a particular project, SP's policies and procedures for requiring the recipient of the funding to disclose SP's financial support and any financial relationship SP may have with the participants in the project for which funding is provided;

   iv. the processes and procedures for determining the amount of the funding to be provided;

   v. the policies and procedures relating to the independence of any Research Activities sponsored with funding by SP;

   vi. whether and in what manner SP tracks or monitors the prescribing habits or product use of individuals or entities who receive funding for Research Activities from SP; and

   vii. the budget funding source within SP for the payment for the Research Activity funding;

8) SP's systems, processes, policies and procedures relating to the disciplinary actions that SP may impose in the event a Covered Person violates a SP policy or procedure regarding sales, marketing, promotional, and product services activities;

9) SP's systems, processes, policies and procedures for compensating (including with salaries and bonuses) employees in the Field Sales Force and the MSLs. This shall include a review of the policies that define the basis upon which compensation is determined and the extent to which compensation is based on product performance; and

10) SP's systems, processes, policies and procedures relating to the development of call plans utilized by SP's Specialty Field Sales Force. This shall include a review of the basis upon which specialties are included or excluded from the call plan based upon their potential on-label and off-label utilization of SP products promoted by the specific Specialty Field Sales Force.

B. Promotional and Product Services Systems Engagement Report

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

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

b) a description of SP's systems, processes, policies, and procedures with regard to items identified in Section II.A.1-10 above, including a description of SP's control and accountability systems (e.g., documentation and approval requirements and tracking mechanisms) and written policies regarding the Reviewed Policies and Practices;

c) a description of the manner in which control and accountability systems and the written policies relating to the Reviewed Policies and Practices are made known or disseminated within SP;

d) a description of the systems that support the USCOS department;

e) a description of the systems that support the GDIS department;

f) a general description of the disciplinary policies and procedures SP has established for failure to comply with its systems, processes, policies, and procedures relating to the Reviewed Policies and Practices;

g) a description of SP's compensation system (including salaries and bonuses) for employees in the Field Sales Force and MSLs, including a description of how and to what extent compensation is based on product performance. To the extent that SP may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

h) findings and supporting rationale regarding any weaknesses in SP's systems, processes, policies, and procedures relating to the Reviewed Policies and Practices, if any; and

i) recommendations to improve any systems, processes, policies or procedures relating to the Reviewed Policies and Practices, if any.

III. Promotional and Product Services Transactions Engagement

The IRO, or SP pursuant to Section III.E.1.c of the CIA, shall conduct a Promotional and Product Services Transactions Engagement for each of the five Addendum Reporting Periods. The Transactions Engagement shall include: 1) testing of samples of Promotional Activities Controls Documents as defined below; and 2) interviews with appropriate SP personnel, as necessary, to identify the root cause of any Material Errors.

A. Promotional Activities Transactional Engagement

1) Background on USCOS and Related Policies

SP has developed policies and procedures relating to promotional programs with HCPs that may be initiated by Field Sales Force and/or Home Office Sales and Marketing personnel. These policies are included in SP's "US Sales and Marketing Policy." SP has disseminated the US Sales and Marketing Policy to all field force and marketing personnel. In November of 2004, SP developed and implemented a USCOS spending repository, a system used to consolidate information related to promotional support, through which information and certain documentation relating to the financial programs initiated by personnel in the Field Sales Force and/or Marketing is tracked.

More specifically, the USCOS process is used to initiate and capture the following types of promotional programs (hereafter "Promotional Activities"):

a) Speaker Programs Handled by Vendor. Field Sales Force representatives initiate programs through a third party speaker program vendor. Two general types of speaker programs are performed: (i) lectures; and (ii) peer discussion in an office, hospital, or other location. Data feeds from third party

speaker program vendors are captured in the USCOS system at the individual and program level;

b) Speaker Training Programs. SP retains HCPs as promotional speakers who must be trained;

c) Advisory Boards and Consulting Arrangements. SP contracts with HCPs to obtain expert information (e.g., scientific/medical issues and marketing strategies);

d) Promotional Support. SP provides promotional support, consisting of funding for exhibits and display space, to Health Care Institutions and is charged a fee by these Health Care Institutions.

2) Description of Promotional Activities Control Documents

Promotional Activities Control Documents shall include all documents required by the US Sales and Marketing Policy or other relevant SP policy in connection with promotional programs initiated through USCOS. These documents include: contract initiation forms, business rationale forms, contracts, and documents and/or electronic records attesting that the event occurred.

3) Testing of Promotional Activities Control Documents

The IRO shall test the Control Documents associated with each of the following samples of Promotional Activities:

For Speaker Programs, the IRO shall test Control Documents associated with a random sample of 100 payments to Health Care Professionals (HCPs) from the population of Speaker Programs that were conducted during the relevant Reporting Period. For purposes of this Promotional and Product Services Transactions Engagement, "payments" refer to a completed event, within the Addendum Reporting Period, where the HCP or Health Care Institution (HCI) was paid or payment is in progress; and "conducted" refers to events with end dates that occur within the relevant Addendum Reporting Period.

For Speaker Training Programs, the IRO shall test Control Documents associated with a random sample of 30 payments to HCPs from the population of Speaker Training Programs that were conducted during the relevant Addendum Reporting Period.

For Consulting Arrangements, the IRO shall test Control Documents associated with a random sample of 11 payments to HCPs from the population of Consulting Arrangements that were conducted by SP Sales and Marketing during the relevant Addendum Reporting Period.

For Advisory Boards, the IRO shall test Control Documents associated with a random sample of 30 payments to HCPs from the population of Advisory Boards that were conducted by SP Sales and Marketing during the relevant Addendum Reporting Period.

For Promotional Support Programs, the IRO shall test Control Documents associated with a random sample of 30 payments to HCIs from the population of Promotional Support Programs that were conducted during the relevant Addendum Reporting Period.

The IRO shall test the Control Documents associated with each selected sample of Promotional Activities to evaluate the following:

a) for each Promotional Activity tested, whether all required Control Documents exist in accordance with SP's policies;
b) whether the Promotional Activities Control Documents were completed in accordance with the requirements set forth in SP's policies; and
c) whether the Promotional Activities Control Documents reflect that all required written approvals were obtained in accordance with SP's policies.

4) Identification of Material Errors and Additional Engagement

The IRO will find there to be a Material Error for a transaction and shall note such Material Errors, if any of the following is identified:

a) a Promotional Activities Control Document does not exist and through further inquiry the IRO is unable to determine that: (i) corrective action was initiated prior to the IRO review, or (ii) SP otherwise satisfied the overall objectives of its Promotional Activities Policies and Procedures;
b) information or data is omitted from key fields in the Promotional Activities Control Documents that prevents the IRO from testing compliance with SP's policies and procedures and the IRO cannot obtain this information or data from reviewing other Control Documentation; or

c) testing of all the Control Documents and any other relevant documentation associated with the sampled transaction indicates that SP's policies related to its Promotional Activities were not followed.

If a Promotional Activities Control Document does not exist or is misplaced but SP has initiated corrective action prior to IRO testing, or the IRO can otherwise determine that the overall objectives of the Promotional Activities Policies and Procedures were satisfied, the IRO shall not consider this to be a Material Error, but rather an exception and it shall be reported as such.

If the IRO finds Material Errors, it shall conduct an Additional Engagement to further review the expenditures or activities reflected in the erroneous Promotional Activities Control Documents in a manner designed 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 errors.

B. Promotional and Product Services Transactions Engagement Report

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

1. Elements to be Included:

a) Promotional and Product Services Transactions Engagement Objectives: A clear statement of the objectives intended to be achieved by each part of the testing;
b) Engagement Protocol: A detailed narrative description of the procedures performed and a description of each sampling unit and universe utilized in performing the procedures for each sample tested; and
c) Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the Promotional and Product Services Transactions Engagement.

2. Results to be Included:

The following results shall be included in the Promotional Activities Transaction Review Report:

a) a description of each type of sample unit tested, including the number of each type of sample units tested (*e.g.*, for the various types of speaker programs, speaker training programs, advisory boards, consulting arrangements, and promotional support) and an identification of the types of Control Documents reviewed for each type of sample unit;
b) for each sample unit, the IRO shall state its findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable SP policy; (iii) each Control Document reflects that SP's policies were followed in connection with the underlying activity reflected in the document (*e.g.*, all required approvals were obtained); and (iv) any disciplinary action that was taken in those instances in which SP policy was not followed;
c) for each sample unit tested, the IRO shall identify and describe all exceptions discovered. The IRO 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, as defined in section III.A.4 of this Attachment D, are discovered in the sample unit reviewed, the IRO shall describe the error and the Additional Engagement procedures it performed, and shall state its findings as to the root causes of the Material Errors;
e) the IRO's recommendations, if any, for changes in SP's systems, processes, policies, and procedures, in order to correct or address any weaknesses or deficiencies uncovered during the Transactions Review. The IRO shall provide findings and supporting rationale for any such recommendations.