CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
BAYER HEALTHCARE LLC

I. PREAMBLE

Bayer HealthCare LLC (Bayer) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, Bayer HealthCare LLC is entering into a Settlement Agreement with the United States. Bayer's agreement to this CIA is a condition precedent to the Settlement Agreement.

Prior to the Effective Date of this CIA (as defined below), Bayer established a compliance program (Compliance Program). Bayer shall continue its Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. Bayer may modify its Compliance Program, as appropriate, but, at a minimum, Bayer shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

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

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

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

1. "Arrangements" shall mean every arrangement or transaction that:

involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Bayer or any "Bayer Affiliate" (as defined in Section II.C.8) and any actual or potential source of referrals or sales of Government Reimbursed Products. The term "source" shall mean any distributor, wholesaler, supplier, physician or other health care provider, contractor, or agent, and the term "referrals or sales" shall be read to include referring, recommending, arranging for, ordering, prescribing, or purchasing of Government Reimbursed Products.

2. "Focus Arrangements" means every Arrangement that is between Bayer or any Bayer Affiliate and any actual source of Government Reimbursed Product referrals or sales and involves, directly or indirectly, the offer, payment, or provision of anything of value. Focus Arrangements include, but are not limited to, Bayer or Bayer Affiliate-sponsored (directly or indirectly) or Bayer or Bayer Affiliate-funded (directly or indirectly): speaker fees and speaker-related fees; honoraria; consultant fees, personal service arrangements, management or administrative arrangements; educational grants; charitable contributions; clinical or research grants; clinical or research agreements; advisory boards; continuing medical education sponsorships; marketing service fees; disease management services; reimbursement support programs; data purchasing arrangements; and any other Arrangement that involves payment to any individual or entity, including but not limited to any distributor, wholesaler, supplier, physician, or other health care provider pursuant to a fee for service agreement (such as an advertising agreement). Notwithstanding the foregoing provisions of Section II.C., the following shall not be considered Focus Arrangements: (1) bona fide employment Arrangements with sales representatives; (2) an Arrangement for the provision of "drug samples" (as

defined in 21 U.S.C. § 353(c)(1)), to a health care provider without charge to any patient or payer, for distribution to patients in accordance with the requirements set forth in the Prescription Drug Marketing Act of 1987; (3) an Arrangement for provision to a health care provider one time per calendar year of an item (such as an anatomical model for use in an examination room) designed primarily for the education of patients or health care providers valued at $100 or less, if the item does not have value to the health care provider outside of his or her professional responsibilities; (4) an Arrangement to provide an Accompanying Meal as defined below in Section II.C.11; (5) Carved-Out Bills of Sale (as defined below in Section II.C.12); and (6) Carved-Out Purchase Contracts (as defined below in Section II.C.13).

Nothing in this Section II.C affects the responsibility of Bayer or any Bayer Affiliate to comply with (or liability for noncompliance with) all applicable Federal health care program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)); the regulations and other guidance documents related to the Anti-Kickback Statute; the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and all applicable FDA requirements as they relate to Arrangements, including Focus Arrangements.

3. "Covered Persons" includes:

a. all owners of Bayer and any Bayer Affiliate who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading);

b. all officers, directors, and employees of Bayer or any Bayer Affiliate, except as carved out below in this Section II.C.3; and

c. all contractors, subcontractors, agents, and other persons who perform Promotional and Product Services Related Functions (as defined below in Section II.C.7) on behalf of Bayer or any Bayer Affiliate;

Notwithstanding the above, this term does not include: (1) part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year; (2) officers or employees of Bayer HealthCare LLC's Animal Health and Consumer Care Divisions so long as they do not (i) manufacture, market, distribute, sell, or promote Government Reimbursed Products; (ii) perform Promotional and Product Services Related Functions; or (iii) perform Government Pricing and Contracting Functions; (3) employees of "Bayer Affiliate Manufacturing-Only Entities," defined below in Section II.C.14; or (4) employees of Bayer or Bayer Affiliates who perform only manufacturing functions.

4. "Arrangements Covered Persons" includes each Covered Person involved with the initiation, negotiation, proposal, development, approval, implementation, management, oversight (including accounting functions), or review of Bayer's and Bayer Affiliates' Arrangements, as such term is defined in Section II.C.1.

5. "Third Party Educational Activity" shall mean any continuing medical education (CME), independent medical education (IME), disease awareness, or other scientific, educational, or professional program, meeting, or event sponsored by Bayer or any Bayer Affiliate, including but not limited to, sponsorship of symposia at medical conferences.

6. "Government Reimbursed Products" refers to all drugs, devices, and other items that are marketed, distributed, sold, or promoted by Bayer or Bayer Affiliates and reimbursed, in whole or in part, by Federal health care programs. This term includes products promoted by Bayer or a Bayer Affiliate regardless of whether Bayer or a Bayer Affiliate holds the New Drug Application.

7. The term "Promotional and Product Services Related Functions" includes: (a) the promotion, advertising, distribution, marketing, and sale of Government Reimbursed Products; and (b) the development or

dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products.

8. The term "Bayer Affiliate" shall mean any entity, other than Bayer HealthCare LLC, that is owned or controlled, directly or indirectly, by Bayer AG and (a) makes Government Reimbursed Products (as defined above in Section II.C.6); (b) performs Promotional and Product Services Related Functions (as defined above in Section II.C.7); or (c) performs Government Pricing and Contracting Functions (as defined below in Section II.C.10). Intendis, Inc. is a Bayer Affiliate and acknowledges same in a letter annexed hereto dated November 20, 2008 (hereinafter the Intendis Letter).

9. The term "Third Party Personnel" shall mean personnel of the entities with whom Bayer or any Bayer Affiliate has or may in the future enter into agreements to co-promote a Government Reimbursed Product or engage in joint promotional activities relating to such product. Bayer has represented that: (1) the Third Party Personnel are employed by other independent entities; (2) neither Bayer nor any Bayer Affiliate controls Third Party Personnel; and (3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements in this CIA. Bayer agrees to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.3, V.A.6, and V.B.5 related to Third Party Personnel who meet the definition of Covered Persons. Provided that Bayer complies with the requirements of Sections III.B.3, V.A.6, and V.B.5, Bayer shall not be required to fulfill the obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

10. The term "Government Pricing and Contracting Functions" shall mean the collection, calculation, verification, or reporting of information for purposes of the Medicaid Drug Rebate Program (codified at 42 U.S.C. § 1396r-8, et seq.), the Medicare Program (codified at 42 U.S.C. § 1395-1395hhh), the 340B Drug Pricing Program, codified at 42 U.S.C. § 256(b), or other government programs through which health care items or services may be purchased or reimbursed, in whole or in part, by the federal

government, and the Veterans Administration pricing program (the "VA Programs"), as set forth in the Federal Supply Schedule and the Veteran's Healthcare Act of 1992. This definition includes, but is not limited to, those individuals whose job responsibilities include the calculation and reporting of Average Sales Price, Average Manufacturer Price, Best Price, and all other price information reported and used in connection with reimbursement under the Federal health care programs described in this paragraph.

11. The term "Accompanying Meal" shall mean an occasional meal offered in connection with a presentation or discussion led by Bayer or Bayer Affiliate representatives made to or with health care providers concerning Bayer or Bayer Affiliate Government Reimbursed Products, where the presentation is made during the health care providers' working day, including mealtimes, and where the presentation provides scientific or educational value and the meal is: (a) modest as judged by local standards; (b) not part of an entertainment or recreational event; and (c) provided in a manner conducive to informational communication.

12. The term "Carved-Out Bill of Sale" shall mean a bill of sale that only identifies and reflects a transaction conducted pursuant to: (a) a Focus Arrangement that has been added to the Focus Arrangements Database; or (b) a "Carved-Out Purchase Contract," defined below. Any bill of sale not described in the foregoing sentence or which alters, in any way, a Focus Arrangement or a Carved-Out Purchase Contract is not a "Carved-Out Bill of Sale."

13. The term "Carved-Out Purchase Contract" shall mean a contract between Bayer or a Bayer Affiliate and a purchaser for the purchase of Government Reimbursed Products, where the only remuneration identified in and to be exchanged pursuant to the contract is a price for the Government Reimbursed Products to be paid by the purchaser in exchange for the Government Reimbursed Products provided to the purchaser. In addition to the price for the Government Reimbursed Products, a Carved-Out Purchase Contract may identify and require Bayer or a Bayer Affiliate to: (1) pay a bona fide GPO fee; and/or (2) deduct a prompt-pay discount from the purchase price or pay a prompt-pay rebate to the purchaser, where

the purchaser pays for the Government Reimbursed Products within a designated time period. Any contract not described in the foregoing Carved-Out Purchase Contract definition is not a Carved-Out Purchase Contract.

14. The term "Bayer Affiliate Manufacturing-Only Entities" shall mean Bayer Affiliates who: (a) make Government Reimbursed Products (as defined above in Section II.C.6); but do not (b) perform Promotional and Product Services Related Functions (as defined above in Section II.C.7); or (c) perform Government Pricing and Contracting Functions (as defined above in Section II.C.10).

III. CORPORATE INTEGRITY OBLIGATIONS

Prior to the Effective Date, Bayer implemented a Compliance Program. Bayer shall establish and maintain a Compliance Program throughout the term of this CIA that includes the following elements:

A. Compliance Responsibilities of Compliance Officer, Compliance Committee, the Board of Directors, and Management Certifications.

1. *Compliance Officer.* Prior to the Effective Date, Bayer appointed a Compliance Officer. Bayer shall maintain a Compliance Officer during the term of the CIA who meets the requirements of this Section III.A.1. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and FDA requirements. The Compliance Officer shall be a member of senior management of Bayer, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Bayer, and shall be authorized to report on such matters to the Board of Directors of Bayer at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Bayer and Bayer Affiliates as well as for any reporting obligations created under this CIA.

Bayer shall report to OIG, in writing, any changes in the identity or position description 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 CIA, within 15 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Bayer appointed a Compliance Committee. Bayer shall maintain its Compliance Committee during the term of the CIA that meets the requirements of this Section III.A.2. Bayer shall ensure that the Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives and managers of relevant departments, such as legal, sales and marketing, human resources, medical affairs or medical and clinical affairs, and audit). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall receive reports on compliance-related monitoring, audits, and investigations).

Bayer 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 CIA, within 15 days after such a change.

3. *Board of Directors.* The Board of Directors (Board) of Bayer shall retain ultimate responsibility for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board, or a Committee of the Board, shall, at a minimum, be responsible for the following:

a. The Board, or a Committee of the Board, shall meet at least quarterly to review and oversee Bayer's Compliance Program, including but not limited to the performance of the Compliance Officer and the Compliance Department.

b. To assist the Board with its responsibilities related to oversight of Bayer's Compliance Program, within 90 days of the Effective Date of this CIA, the Board shall retain three independent and objective individuals or entities with expertise in compliance with Federal health care program and FDA requirements (Compliance Expert Panel). The Board shall arrange for the performance of a review by the Compliance Expert Panel of the effectiveness of Bayer's Compliance Program (Compliance Program Review) for each Reporting Period of the CIA and shall review the results of the

Compliance Program Review as part of the review and assessment of Bayer's Compliance Program. The Compliance Expert Panel shall create a work plan for the Compliance Program Review and complete performance of the Compliance Program Review, and thereby assist the Board with its responsibilities for reviewing and assessing Bayer's Compliance Program. The Compliance Expert Panel shall perform the Compliance Program Review in a professionally independent and objective fashion, taking into account any other business relationships or engagements that may exist between the Compliance Expert Panel and Bayer. The Compliance Expert Panel will prepare a written report in connection with its review of Bayer's Compliance Program for each Reporting Period, to include, at a minimum, a description of the work plan upon which the Compliance Program Review was based, and recommendations made by the Compliance Expert Panel to Bayer's Board of Directors regarding Bayer's Compliance Program (Compliance Program Review Report). A copy of the Compliance Program Review Report shall annex a copy of the work plan and shall be provided to OIG in each Annual Report submitted by Bayer. The OIG's rights set forth in Section VII of this CIA shall apply to documentation and information related to the Compliance Program Review and individuals and entities that comprise the Compliance Expert Panel. The other applicable requirements relating to the Compliance Expert Panel are outlined in Appendix D to this CIA, which is incorporated by reference.

c. For each Reporting Period of the CIA, the Board shall adopt a resolution, signed by each individual member of the Board, summarizing its review and oversight of Bayer's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

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

"The Board of Directors has made a reasonable and due inquiry into the operations and effectiveness of Bayer's Compliance Program for the period _____, including the performance of the Compliance Officer, the Compliance Committee, and the Compliance Department. In connection with its inquiry, the Board of Directors has retained an independent and objective Compliance Expert Panel with expertise in compliance with the applicable Federal health care program and FDA requirements to support the Board of Directors' responsibilities. The Board of Directors has also arranged for the Compliance Expert Panel to perform a Compliance Program Review assessing the effectiveness of Bayer's Compliance Program and providing the Board of Directors with recommendations with respect to the Compliance Program. The Board of Directors has

reviewed the Compliance Program Review. Except as identified in Annex A to this resolution together with reasons for the decision not to adopt certain recommendations of the Compliance Expert Panel, the Board has adopted the recommendations of the Compliance Expert Panel set forth in the Compliance Program Review. Based on all of these steps, the Board has concluded that, to the best of its knowledge, Bayer has implemented an effective compliance program to meet the applicable Federal health care program requirements, FDA requirements, and the CIA obligations."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective compliance program at Bayer. In addition, if the Board decides not to adopt certain recommendations of the Compliance Expert Panel, the Board shall identify all recommendations it has decided not to adopt in an attachment to its resolution together with a written explanation of the reason(s) why it has decided not to adopt such recommendations.

Bayer shall report to OIG, in writing, on or before the Effective Date of this CIA, the names of the Board members. Bayer shall report to the OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such change.

4. *Management Accountability and Certifications*: Bayer represents that compliance is a component of each employee's performance objectives. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Bayer and Bayer Affiliate employees ("Certifying Employees") are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify in writing or electronically that the applicable area of authority, to the best of their knowledge, is compliant with applicable Federal health care program and FDA requirements, and the obligations of this CIA. The Certifying Employees include, at a minimum, all Bayer and Bayer Affiliate: presidents, chairpersons, chief executive officers; executive directors, vice presidents; and Chief Medical Officers, and directors of business units of Bayer or any Bayer Affiliate that perform pricing, sales, marketing, contracting, promotion, medical affairs, or medical information functions. Officers and employees of Bayer's Animal Health and Consumer Care Divisions shall not be Certifying Employees so long as they do not (i) manufacture, market, distribute, sell, or promote Government

Reimbursed Products; (ii) perform Promotional and Product Services Related Functions; or (iii) perform Government Pricing and Contracting Functions.

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

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

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

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Bayer developed, implemented, and distributed a Code of Conduct to certain of its employees. Within 90 days after the Effective Date, Bayer shall develop, implement, and distribute a written Code of Conduct that meets the requirements of this Section III.B to all Covered Persons. Bayer shall maintain a written Code of Conduct that meets the requirements of this Section III.B during the term of this CIA and make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. Bayer's commitment to full compliance with all applicable Federal health care program requirements and FDA requirements, including its commitment to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health care program and FDA requirements;

b. Bayer's requirement that all Covered Persons shall be expected to comply with all applicable Federal health care program requirements and FDA requirements and with Bayer's own Policies and Procedures as implemented pursuant to Section III.B.2 (including the requirements of this CIA);

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

d. the possible consequences to Bayer, Bayer Affiliates, and Covered Persons of failure to comply with Federal health care program and FDA requirements and with Bayer's own Policies and Procedures and the failure to report such noncompliance;

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

Within 90 days after the Effective Date, the Code of Conduct shall be distributed to each Covered Person, and each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by Bayer's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

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

2. *Policies and Procedures*. Prior to the Effective Date, Bayer implemented written Policies and Procedures regarding the operation of the Compliance Program and Bayer's compliance with Federal health care program and FDA requirements (Policies and Procedures). To the extent not already accomplished, within 90 days after the Effective Date, Bayer shall ensure that the Policies and Procedures address or shall continue to address:

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

b. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal health care program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)), the regulations and other guidance documents related to the Anti-Kickback Statute, and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733) and in accordance with all applicable FDA requirements;

c. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute), including but not limited to the Focus Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of Government Reimbursed Product referrals or sales;

d. consultant or other fee-for-service arrangements entered into with health care providers (HCPs) or health care institutions (HCIs) (including, but not limited to, speaker programs, speaker training programs, advisory boards, or any other financial relationship with an HCP or HCI) and all events and expenses relating to such engagements or Arrangements. These Policies and Procedures shall be designed to ensure that the Arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such Arrangements and events;

e. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be

designed to ensure that Bayer's and Bayer Affiliates' funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements;

f. funding of, or participation in, any Third Party Educational Activity as defined above in Section II.C.5. These Policies and Procedures shall be designed to ensure that Bayer's and Bayer Affiliates' funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements;

g. sponsorship or funding of research or related activities. These Policies and Procedures shall be designed to ensure that Bayer's and Bayer Affiliates' funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;

h. compensation (including salaries and bonuses) for Covered Persons who promote, sell, and market Government Reimbursed Products. These Policies and Procedures shall be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Bayer's and Bayer Affiliates'products; and

i. disciplinary policies and procedures for violations of Bayer's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

3. *Third Party Personnel.* Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Bayer shall send a letter to each entity employing Third Party Personnel. The letter (hereinafter the "Third Party Personnel Letter") shall outline Bayer's and Bayer Affiliates' obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. This letter shall include a description of Bayer's Compliance Program. Bayer shall attach a copy of its Code of Conduct to the Third Party Personnel Letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of Bayer's Code of Conduct and a description of Bayer's Compliance Program available to its Third Party Personnel; or (b) represent to Bayer that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel. The requirements set forth in the previous sentence shall be referred to as the "Third Party Personnel Procedure."

C. Training and Education.

1. *General Training.* Within 90 days after the Effective Date, Bayer shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Bayer's:

a. CIA requirements; and

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

Training programs may have different content to reflect the product and business practices of different organizations within Bayer and Bayer Affiliates, provided that training covers, at a minimum, the subjects in III.C.1.a and b. above. New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Arrangements Training.* Within 90 days after the Effective Date, each Arrangements Covered Person shall receive at least three hours of Arrangements Training, in addition to the General Training required above. Training programs may

have different content to reflect the products and business practices of different organizations within Bayer and Bayer Affiliates, provided that training covers, at a minimum, the subjects in III.C.2.a-e below. The Arrangements Training shall include a discussion of:

a. Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to this statute;

b. Bayer's policies, procedures, and other requirements relating to Arrangements, including but not limited to the Focus Arrangements Database, the internal Arrangements review and approval process, and the tracking of remuneration to and from sources of referrals or sales required by Section III.D of the CIA;

c. the personal obligation of each individual involved in the initiation, negotiation, proposal, development, approval, implementation, management, oversight (including accounting functions), or review of Arrangements to know the applicable legal requirements and Bayer's policies and procedures;

d. the legal sanctions under the Anti-Kickback Statute; and

e. examples of violations of the Anti-Kickback Statute.

New Arrangements Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 90 days after the Effective Date, whichever is later. An employee who has completed the Arrangements Training shall review a new Arrangements Covered Person's work until such time as the new Arrangements Covered Person completes his or her Arrangements Training.

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

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

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area of the training, including applicable Anti-Kickback Statute, Federal health care program, and FDA requirements.

5. *Update of Training.* Bayer shall review the training annually, and, where appropriate, update the training to reflect changes in Anti-Kickback Statute, Federal health care program, and FDA requirements, any issues discovered during internal audits, any review by an Independent Review Organization (as defined in Section III.E), the Arrangements Review, and any other relevant information.

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

D. Compliance with the Anti-Kickback Statute.

1. *Arrangements Procedures.* Within 120 days after the Effective Date, Bayer shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute or the regulations, directives, and guidance related to this statute (Arrangements Procedures). These procedures shall include the following:

a. creating and maintaining a database of all existing and new or renewed Focus Arrangements that shall contain the information specified in Appendix A (Focus Arrangements Database);

b. tracking remuneration to and from all parties to Focus Arrangements;

c. tracking service and activity logs (if applicable) or other documented proof of performance to ensure that parties to Focus Arrangements are performing the services required under the applicable Focus Arrangement(s);

d. establishing and implementing a written review and approval process for all Arrangements, including but not limited to a legal review of Focus Arrangements by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal controls, the purpose of which is to ensure that all new and existing or renewed Arrangements do not violate the Anti-Kickback Statute;

e. requiring the Compliance Officer to review the Focus Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide a report on the results of such review to the Compliance Committee; and

f. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events pursuant to Section III.I (Reporting) when appropriate.

2. *New or Renewed Focus Arrangements*. Prior to entering into new Focus Arrangements or renewing existing Focus Arrangements that are contractual in nature, in addition to complying with the Arrangements Procedures set forth above, Bayer shall comply with the following requirements (Focus Arrangements Requirements):

a. Ensure that each Focus Arrangement is set forth in writing and signed by Bayer or a Bayer Affiliate (as appropriate) and the other parties to the Arrangement;

b. (i) Include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with all applicable elements of Bayer's Compliance Program, including applicable training related to the Anti-Kickback Statute and provide each party to the Focus Arrangement with a copy of its

Code of Conduct and applicable Anti-Kickback Statute Policies and Procedures; or

(ii) Send each party to the Focus Arrangement a Third Party Personnel Letter (as defined in Section III.B.3 of this CIA) with a copy of Bayer's Code of Conduct and Anti-Kickback Statute Policies and Procedures attached; follow the Third Party Personnel Procedures set forth in Section III.B.3; and note in the Focus Arrangements Database receipt of the party's response to the Third Party Personnel Letter.

c. Include in the written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Focus Arrangement.

3. *Records Retention and Access*. Bayer shall retain and make available to OIG, upon request, the Focus Arrangements Database and all supporting documentation of the Focus Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Bayer shall engage an individual(s) or entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a review to assist Bayer in assessing its compliance with the obligations pursuant to Section III.D of this CIA (Focus Arrangements Review). The IRO engaged by Bayer to perform the Focus Arrangements Review shall have expertise with respect to the Anti-Kickback Statute and the regulations and other guidance documents related to this statute, and business or financial

arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute.

In addition, as more fully set forth in Appendix B to this CIA, incorporated herein by reference, Bayer shall engage an IRO to review up to two additional areas or practices of Bayer or a Bayer Affiliate (hereafter "Additional Items") identified by the OIG in its discretion (hereafter "Additional Items Reviews") as required by this Section III.E. and Appendix B.

Each IRO engaged by Bayer shall assess, along with Bayer and any Bayer Affiliate subject to the IRO review, whether it can perform the IRO review in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist. The engagement of the IRO for the Arrangements Review shall not be deemed to create an attorney-client relationship between Bayer or a Bayer Affiliate and the IRO. The other applicable requirements relating to the IRO(s) are outlined in Appendix C to this CIA, which is incorporated by reference.

b. *Frequency and Description of Reviews.*

Frequency of Focus Arrangements Reviews. The Focus Arrangements Reviews shall be performed annually and shall cover each of the Reporting Periods. An IRO shall perform all components of each annual Focus Arrangements Review.

Frequency of Additional Items Reviews. The Additional Items Reviews shall be performed during each Reporting Period for which the OIG requires performance of Additional Items Reviews in accordance with this Section III.E. and Appendix B.

c. *Retention of Records*. The IRO, Bayer, and Bayer Affiliates (as appropriate) shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft

reports (those exchanged between the IRO and Bayer) related to the reviews.

d. *Responsibilities and Liabilities*. Nothing in this Section III.E affects Bayer's or any Bayer Affiliate's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute.

2. *Focus Arrangements Review*. The IRO shall perform a review to assess whether Bayer is complying with the Arrangements Procedures and Focus Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA. The IRO shall randomly select a sample of 50 Focus Arrangements. The IRO shall assess whether Bayer has implemented the Arrangements Procedures and, for each selected Focus Arrangement, the IRO shall assess whether Bayer has complied with the Arrangements Procedures and Focus Arrangements Requirements specifically with respect to that Focus Arrangement. The IRO's assessment shall include, but is not limited to: (a) verifying that the Focus Arrangement is listed in the Focus Arrangements Database; (b) verifying that the Focus Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented; (c) verifying that the remuneration related to the Focus Arrangement is properly tracked; (d) verifying that the service and activity logs (if applicable) and/or other documented proof of performance is provided to and reviewed by Bayer or a Bayer Affiliate; (e) verifying that the Compliance Officer is reviewing the Focus Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to the Compliance Committee; (f) verifying that effective responses are being implemented when violations of the Anti-Kickback Statute are discovered; and (g) verifying that Bayer has met the requirements of Section III.D.2.

3. *Focus Arrangements Review Report*. The IRO shall prepare a report based upon the Focus Arrangements Review performed (Focus Arrangements Review Report). The Focus Arrangements Review Report shall include the IRO's findings with respect to: (a) whether Bayer has generally implemented the Arrangements Procedures described in Section III.D.1; and (b) specific findings as to whether Bayer has complied with the Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO. In addition, the

Focus Arrangements Review Report shall include any observations, findings and recommendations on possible improvements to Bayer's policies, procedures, and systems in place to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute.

4. *Validation Review.* In the event OIG has reason to believe that: (a) any IRO's Focus Arrangements Review fails to conform to the requirements of this CIA; (b) any IRO's Additional Items Review fails to conform to the requirements of the this CIA, including the governing Approved Additional Items Review Work Plan (as defined in Appendix B); or (c) any IRO's findings, Arrangements Reviews, or Additional Items Reviews results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether: (i) the applicable Arrangements Reviews complied with the requirements of the CIA; (ii) the applicable Additional Items Reviews complied with the requirements of this CIA, including the Approved Additional Items Review Work Plans; and/or (iii) the findings or Arrangements Reviews or Additional Item Reviews results are inaccurate (Validation Review). Bayer 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 Bayer's final Annual Report shall be initiated no later than one year after Bayer's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Bayer 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, Bayer may request a meeting with OIG to: (a) discuss the results of any Arrangements Review or Additional Items Review submissions or findings; (b) present any additional information to clarify the results of the Arrangements Review or Additional Items Review or to correct the inaccuracy of the Arrangements Review or Additional Items Review; and/or (c) propose alternatives to the proposed Validation Review. Bayer agrees to provide any additional information as may be requested by OIG under this Section III.E.4 in an expedited manner. OIG will attempt in good faith to resolve any Arrangements Review or Additional Items Review issues with Bayer 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.

5. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Bayer a certification or sworn affidavit that it has evaluated its professional independence and objectivity with respect to Bayer and Bayer Affiliates, as appropriate to

the nature of the engagement, with regard to the Arrangements Review or Additional Items Review and that it has concluded that it is, in fact, independent and objective.

F. Disclosure Program.

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

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

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

G. Ineligible Persons.

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

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

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).

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

a. Bayer shall screen all prospective and current Covered Persons against the Exclusion Lists prior to engagement of their services by Bayer or a Bayer Affiliate and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

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

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

Nothing in this Section affects the responsibility of (or liability for) Bayer and Bayer Affiliates to refrain (if applicable) from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Bayer understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Bayer and Bayer Affiliates 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 Bayer or Bayer Affiliates meet the requirements of this section III.G.

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

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

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Bayer shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Bayer conducted or brought by a governmental entity or its agents involving an allegation that Bayer or any Bayer Affiliate 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. Bayer shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

I. Reporting.

1. *Reportable Events.*

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

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 and/or applicable to any FDA requirements relating to the promotion of products for which penalties or exclusion may be authorized; or

ii. the filing of a bankruptcy petition by Bayer or any Bayer Affiliate.

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

b. *Reporting of Reportable Events.* If Bayer or a Bayer Affiliate determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, involving Bayer or a Bayer Affiliate, Bayer 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 and/or FDA authorities implicated;

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

iii. any further steps Bayer or a Bayer Affiliate plans to take to address the Reportable Event and prevent it from recurring.

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

J. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication between Bayer or any Bayer Affiliate and the FDA that materially discusses Bayer's, a Bayer Affiliate's, or a Covered Person's actual or potential unlawful or improper promotion of Bayer's or any Bayer Affiliate's products (including any improper dissemination of information about off-label indications), Bayer shall provide a copy of the report, correspondence, or communication to the OIG. Bayer shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Bayer or any Bayer Affiliate changes locations or closes a business unit or location that: (i) performs Promotional and Product Services Related Functions; or (ii) performs Government Pricing and Contracting Functions, Bayer shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Bayer or any Bayer Affiliate purchases or establishes a new business unit or location that: (i) performs Promotional and Product Services Related Functions; or (ii) performs Government Pricing and Contracting Functions, Bayer shall notify OIG no later than the date the sale is publicly disclosed. This notification shall include the address of

the new business unit or location, phone number, fax number, and Federal health care program provider or supplier number (if applicable), and the name and address of the contractor that issued each number (if applicable). Each new business unit or location and all Covered Persons at each business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Bayer or any Bayer Affiliate proposes to sell any or all of its or their business units or locations that: (i) perform Promotional and Product Services Related Functions; or (ii) perform Government Pricing and Contracting Functions, Bayer shall notify OIG of the proposed sale no later than the date the sale is publicly disclosed. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

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

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

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

3. the names and positions of the Certifying Employees required by Section III.A.4;

4. a copy of Bayer's Code of Conduct required by Section III.B.1;

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

6. (a) a copy of the Third Party Personnel Letter (including all attachments) required by Sections II.C.9, III.B.3, and III.D.2.b.ii, sent to each party employing Third

Party Personnel and parties to Focus Arrangements (as applicable); (b) a list of all existing co-promote or other joint promotion agreements; and (c) a description of the recipient entities' responses to the Bayer letter;

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

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

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

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

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

9. a description of the Focus Arrangements Database required by Section III.D.1.a;

10. a description of the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

11. the following information regarding the IRO(s) and each member of the Compliance Expert Panel: (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Bayer and the IRO, Bayer Affiliates and the IRO, Bayer and each Compliance Expert Panel member, and Bayer Affiliates and each Compliance Expert Panel member;

12. a certification from the IRO and each member of the Compliance Expert Panel regarding their professional independence and objectivity with respect to Bayer and Bayer Affiliates;

13. a description of the Disclosure Program required by Section III.F;

14. a description of the process by which Bayer fulfills the requirements of Section III.G regarding Ineligible Persons;

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

16. a list of all of: (a) Bayer's and Bayer Affiliates' locations (including locations and mailing addresses), excluding such information regarding Bayer Affiliate Manufacturing-Only Entities, the corresponding name under which each location is doing business, and the corresponding phone numbers and fax numbers; and (b) each Bayer or Bayer Affiliate 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 Bayer and Bayer Affiliates currently submit claims (if applicable);

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

18. the certifications required by Section V.C.

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

Each Annual Report shall include, at a minimum:

1. an explanation of any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; any change in the membership of the Compliance Committee or Certifying Employees described in Sections III.A.1, III.A.2, or III.A.4, and a copy of the Compliance Program Review Report described in Section III.A.3;

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in applicable requirements);

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

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

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

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

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

5. a copy of the Third Party Personnel Letter (including all attachments) required by Sections II.C.9, III.B.3, and III.D.2.b.ii, sent to each party employing Third Party Personnel and parties to Focus Arrangements (as applicable); (b) a list of all existing co-promote or other joint promotion agreements; and (c) a description of the recipient entities' response to the Bayer letter;

6. a description of any changes to the Focus Arrangements Database required by Section III.D.1.a;

7. a description of any changes to the Arrangements Procedures required by Section III.D.1;

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

9. Bayer's or any Bayer Affiliate's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

10. a summary and description of any and all current and prior engagements and agreements between Bayer and the IRO, Bayer Affiliates and the IRO, Bayer and each member of the Compliance Expert Panel, and Bayer Affiliates and each member of the Compliance Expert Panel, if different from what was submitted as part of the Implementation Report;

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

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

13. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; or (b) involve allegations of conduct that may involve illegal remunerations or inappropriate referrals in violation of the Anti-Kickback Statute;

14. any changes to the process by which Bayer fulfills the requirements of Section III.G regarding Ineligible Persons;

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

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

17. a summary describing any communication with the FDA required to have been reported pursuant to Section III.J. This summary shall include a description of the matter and the status of the matter;

18. a description of all changes to the most recently provided list of Bayer's and Bayer Affiliates' locations (including addresses) as required by Section V.A.16; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Bayer and/or any Bayer Affiliate currently submits claims (if applicable); and

19. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications.

1. Certifying Employees: In each Annual Report, Bayer shall include the certifications of Certifying Employees as required by Section III.A.4.

2. Compliance Officer: In each Implementation Report and annual Report, Bayer shall include the following individuals certification by the Compliance Officer:

a. 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;

b. to the best of his or her knowledge, Bayer has implemented procedures reasonably designed to ensure that all Arrangements do not violate the Anti-Kickback Statute, including the Arrangements Procedures required in Section III.D.1 of the CIA;

c. to the best of his or her knowledge, Bayer and Bayer Affiliates have fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 of the CIA;

d. to the best of his or her knowledge, except as otherwise described in the applicable report, Bayer and Bayer Affiliates are in compliance with the Federal

health care program requirements, FDA requirements, and the obligations of this CIA;

e. to the best of his or her knowledge, Bayer has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs; and

f. Bayer's: (i) Policies and Procedures, as referenced in Section III.B.2 above; (ii) templates for standardized contracts and other similar documents; and (iii) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be compliant with all applicable Federal health care program, Anti-Kickback Statute, and FDA requirements. If applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the documents reviewed and approximately when the review was completed. The documentation supporting the certification shall be available to OIG, upon request.

D. Designation of Information. Bayer 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. Bayer shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General

U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Bayer:

Lawrence P. Platkin
Vice President and Compliance Officer
Bayer HealthCare LLC
6 West Belt
Wayne, NJ 07470-6806
(973) 305-5439 - Phone
(973) 305-4451 – Fax
lawrence.platkin@bayer.com

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Bayer may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

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 Bayer's and Bayer Affiliates' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Bayer's locations for the purpose of verifying and evaluating: (a) Bayer's and Bayer Affiliates' compliance with the terms of this CIA; and (b) Bayer's and Bayer Affiliates' 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 Bayer or a Bayer Affiliate 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 Bayer's or Bayer Affiliates' 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. Bayer shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Bayer's and Bayer Affiliates' employees may elect to be interviewed with or without a representative of Bayer or the respective Bayer Affiliate present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

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

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

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

a. a Compliance Officer;

b. a Compliance Committee;

c. the Compliance Expert Panel and the Compliance Program Review;

d. the Board resolution;

e. a written Code of Conduct;

f. written Policies and Procedures;

g. the training of Covered Persons and Arrangements Covered Persons;

h. the Arrangements Procedures and/or Focus Arrangements Requirements described in Sections III.D.1 and III.D.2;

i. a Disclosure Program as required by Section III.F;

j. Ineligible Persons screening and removal requirements; and

k. notification of Government investigations or legal proceedings.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Bayer fails to engage a Compliance Expert Panel, as required by Section III.A.3 and Appendix 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 Bayer fails to engage an IRO, as required in Section III.E and Appendix C.

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 Bayer fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the

requirements of Section V by the deadlines for submission.

5. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Bayer fails to submit the Compliance Program Review Report, the annual Focus Arrangements Review Report, or the Additional Items Review Report (when required) in accordance with the requirements of Section III.E., Appendices A-B, and the Approved Additional Items Review Work Plan.

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

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

8. A Stipulated Penalty of $1,000 for each day Bayer fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Bayer stating the specific grounds for its determination that Bayer has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Bayer shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Bayer 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 1-7 of this Section.

B. Timely Written Requests for Extensions. Bayer may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Bayer fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Bayer 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 Bayer 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 Bayer of: (a) Bayer'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, Bayer 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 Bayer elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Bayer cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by 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 Bayer has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

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

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

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

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

d. a failure to engage and use an IRO in accordance with Section III.E.; or

e. a failure of the Board to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Bayer constitutes an independent basis for Bayer's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Bayer has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Bayer of: (a) Bayer'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.* Bayer 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. Bayer is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Bayer fails

to satisfy the requirements of Section X.D.3, OIG may exclude Bayer from participation in the Federal health care programs. OIG shall notify Bayer in writing of its determination to exclude Bayer (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 Bayer'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, Bayer 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 Bayer of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Bayer shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

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

appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

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

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

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Bayer had begun to take action to cure the material breach within that period; (ii) Bayer has pursued and is pursuing such action with due diligence; and (iii) Bayer provided to OIG within that period a reasonable timetable for curing the material breach and Bayer 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 Bayer, only after a DAB decision in favor of OIG. Bayer's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Bayer 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 Bayer 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. Bayer 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 Bayer, Bayer shall be reinstated effective on the date of the original exclusion.

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

XI. EFFECTIVE AND BINDING AGREEMENT

Bayer and OIG agree as follows:

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

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

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

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

E. This CIA and the Intendis Letter (described above in Section C.II.8) constitute the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA. Notwithstanding the foregoing statement, this CIA does not amend or otherwise affect the terms of the CIA Addendum between OIG and Bayer Corporation effective January 23, 2003 (the "Prior Bayer CIA"). The Prior Bayer CIA shall remain in effect and expire in accordance with its terms.

ON BEHALF OF BAYER

/Gary Balkema/

Gary Balkema
Chief Executive Officer
Bayer HealthCare LLC

11-21-09
DATE

/Scott Bass/

Scott Bass
Sidley & Austin, LLP
Counsel for Bayer HealthCare LLC

11/15/09
DATE

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

/Gregory E. Demske/

11/25/08

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

DATE

APPENDIX A

FOCUS ARRANGEMENTS DATABASE

Bayer shall create and maintain a Focus Arrangements Database to track all new and existing Focus Arrangements in order to ensure that each Focus Arrangement does not violate the Anti-Kickback Statute. The Focus Arrangements Database shall contain certain information to assist Bayer in evaluating whether each Focus Arrangement violates the Anti-Kickback Statute, including but not limited to the following:

1. Each party involved in the Focus Arrangement;

2. The type of Focus Arrangement (e.g., educational grant, speaker agreement, clinical research agreement, and other examples of Focus Arrangements identified in Section II.C.2 of the CIA);

3. The term of the Focus Arrangement, including the effective and expiration dates (if applicable) and any automatic renewal provisions;

4. The amount of compensation to be paid pursuant to the Focus Arrangement, the means by which compensation is paid, and verification of payments of amounts due pursuant to the Focus Arrangement;

5. The methodology for determining the compensation under the Focus Arrangement, including the methodology used to determine the fair market value of such compensation;

6. Whether the amount of compensation to be paid pursuant to the Focus Arrangement is determined based on the volume or value of referrals between the parties;

7. Whether each party has fulfilled the requirements of Section III.D.2 of the CIA, including a description of each response to Third Party Personnel Letters (defined in Section III.B.3 of the CIA) received by Bayer or any Bayer Affiliate from a party to a Focus Arrangement.

8. Whether services and/or items required to be provided pursuant to the Focus Arrangement have been provided; and

9. The name and title of the individual responsible for assessing whether the Focus Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor and the date the assessment was made.

APPENDIX B

ADDITIONAL ITEMS REVIEW

This Appendix contains the requirements relating to the Additional Items Reviews required by Section III.E of the CIA. The IRO(s) engaged to perform the Additional Items Reviews shall report on all aspects of each Additional Items Review in an Additional Items Review Report.

A. IRO Review of Additional Items

As set forth in Section III.E of the CIA and beginning with the second Reporting Period, the OIG, in its discretion, may identify up to two additional items per Reporting Period for an IRO to review (hereafter "Additional Items"). No later than 120 days prior to the end of the second through fifth Reporting Periods, the OIG shall notify Bayer of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Bayer shall submit an audit work plan to the OIG for approval, and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG (hereafter the "Approved Additional Items Review Work Plan").

To the extent that Bayer or Bayer Affiliates identify area(s) of potential risk through their risk assessment process and conduct internal audit(s) of the area(s), Bayer may propose to the OIG that such internal audit(s) of the identified risk area(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Bayer's or a Bayer Affiliate's internal audit work to be substituted for a portion of any Additional Items Review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Bayer's or a Bayer Affiliate's planned internal audit work, product portfolio, the results of the Arrangements Reviews, and Bayer's or a Bayer Affiliate's Promotional and Product Services Related Functions. If the OIG denies Bayer's request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Bayer shall engage the IRO to perform the Additional Items Review as outlined in the Approved Additional Items Review Work Plan and this Appendix B.

If the OIG agrees to permit certain of Bayer's or a Bayer Affiliate's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items Review, such internal work would be subject to verification by the IRO (Internal Work Verification Review). In such an instance, the OIG would provide additional details

about the scope of the Internal Work Verification Review to be conducted by the IRO. However, for purposes of any Internal Work Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Bayer or a Bayer Affiliate in its internal audits.

B. Additional Items Reviews Reports

For each Reporting Period during which the OIG requires an Additional Items Review, the IRO shall prepare a report based on its Additional Items Review(s). The report shall include the following:

a) for each Additional Item reviewed, a description of the review conducted;

b) for each Additional Item reviewed, the IRO's findings based on its review;

c) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Bayer's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and

d) for each Additional Item reviewed, recommendations, if any, for changes in Bayer's or a Bayer Affiliate's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

APPENDIX C

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

Each IRO engaged by Bayer shall possess the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. Each 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 a selected IRO, OIG will notify Bayer if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Bayer may continue to engage the IRO.

If Bayer 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, Bayer shall submit the information identified in Section V.A.11 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Bayer if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Bayer may continue to engage the IRO.

B. IRO Qualifications.

1. The IRO engaged to perform the Focus Arrangements Review shall assign individuals to conduct the Focus Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and have sufficient staff and resources to conduct the Focus Arrangements Reviews required by the CIA on a timely basis; and

2. The IRO(s) engaged to perform the Additional Items Review(s) shall assign individuals to conduct the Additional Items Review(s) who are knowledgeable about the Federal health care program requirements and FDA requirements that relate to the Additional Items Review(s) and have sufficient staff and resources to conduct the Additional Items Reviews required by the CIA, including Appendix B, on a timely basis.

C. IRO Responsibilities.

The IRO(s) shall:

1. perform each Focus Arrangements Review and Additional Items Review in accordance with the specific requirements of the CIA;

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

3. prepare timely, clear, well-written reports that include all the information required by Section III.E and Appendix B of the CIA.

D. IRO Independence and Objectivity.

The IRO(s) must perform each Arrangements Review and Additional Items Review in a professionally independent and objective fashion, taking into account any other business relationships or engagements that may exist between the IRO(s) and Bayer as well as the IRO(s) and Bayer Affiliates.

E. IRO Removal/Termination.

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

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

APPENDIX D

COMPLIANCE EXPERT PANEL

This Appendix contains the requirements relating to the Compliance Expert Panel required by Section III.A.3 of the CIA.

A. Compliance Expert Panel Engagement.

Each member of the Compliance Expert Panel engaged by Bayer shall possess the qualifications set forth in Paragraph B, below, to perform the responsibilities in Section III.A.3 of the CIA and Paragraph C below. Each member of the Compliance Expert Panel shall conduct the Compliance Program Review in a professionally independent and objective fashion, as set forth in Section III.A.3 of the CIA and Paragraph C below. Within 30 days after OIG receives written notice of the identity of a selected Compliance Expert Panel member, OIG will notify Bayer if the Compliance Expert Panel member is unacceptable. Absent notification from OIG that the Compliance Expert Panel member is unacceptable, Bayer may continue to engage the Compliance Expert Panel member.

If Bayer engages a new Compliance Expert Panel member during the term of the CIA, this Compliance Expert Panel member shall also meet the requirements of this Appendix and Section III.A.3 of the CIA. If a new Compliance Expert Panel member is engaged, Bayer shall submit the information identified in Section V.A.11 of the CIA to OIG within 30 days of engagement of the Compliance Expert Panel member. Within 30 days after OIG receives written notice of the identity of the selected Compliance Expert Panel member, OIG will notify Bayer if the Compliance Expert Panel member is unacceptable. Absent notification from OIG that the Compliance Expert Panel member is unacceptable, Bayer may continue to engage the Compliance Expert Panel member.

B. Compliance Expert Panel member Qualifications.

Each Compliance Expert Panel member engaged to perform the Compliance Program Review shall be knowledgeable in Federal health care program, FDA requirements, and the requirements of this CIA, and shall perform the Compliance Program Review on a timely basis.

C. Compliance Expert Panel member Responsibilities.

In addition to the responsibilities set forth in Section III.A.3, each Compliance Expert Panel member shall:

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

2. prepare timely, clear, well-written Compliance Program Review Reports (as defined in Section III.A.3.b of the CIA.

D. Compliance Expert Panel member Independence and Objectivity.

Each Compliance Expert Panel member must perform each Compliance Program Review Report in a professionally independent and objective fashion, taking into account any other business relationships or engagements that may exist between the Compliance Expert Panel member and Bayer as well as the Compliance Expert Panel member and Bayer Affiliates. Each Compliance Program Expert Panel member shall include the Compliance Program Review Report a certification or sworn affidavit that the Compliance Program Expert Panel member has evaluated his, her, or its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Compliance Program Review and has concluded that the Compliance Expert Panel member is, in fact, independent and objective.

E. Compliance Expert Panel member Removal/Termination.

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

2. *OIG Removal of Compliance Expert Panel member.* In the event OIG has reason to believe that any Compliance Expert Panel member 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 the responsibilities as described in Section III.A.3 of the CIA and Paragraph C above, OIG may, at its sole discretion, require Bayer to engage a new Compliance Expert Panel member in accordance with Paragraph A of this Appendix.

Prior to requiring Bayer to engage a new Compliance Expert Panel member, OIG shall notify Bayer 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, Bayer may request a meeting with OIG to discuss any aspect of the Compliance Expert Panel member's qualifications, independence or performance of his, her, or its responsibilities and to present additional information regarding these matters. Bayer 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 Compliance Expert Panel member with Bayer prior to requiring Bayer to terminate the Compliance Expert Panel member. However, the final determination as to whether or not to require Bayer to engage a new Compliance Expert Panel member shall be made at the sole discretion of OIG.