

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ALLERGAN, INC.

I. PREAMBLE

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

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

II. TERM AND SCOPE OF THE CIA

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

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

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

1. "Covered Persons" includes:

a. all owners of Allergan and any Allergan Affiliate (as defined below) 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 Allergan or any Allergan Affiliate, who are: 1) based in the United States, or 2) based outside the United States and who have responsibilities relating to Promotional Functions or Product Related Functions, except as carved out below in this Section II.C.1; and

c. all contractors, subcontractors, agents, and other persons who perform Promotional Functions or Product Related Functions in the United States on behalf of Allergan or any Allergan Affiliate.

Notwithstanding the above, the term "Covered Persons" does not include: (i) employees, contractors, subcontractors, agents or other personnel of Allergan, or any Allergan Affiliate, who perform only manufacturing or building and facilities functions (i.e., facilities maintenance, grounds maintenance, and food services functions), so long as such personnel do not have responsibilities relating to Promotional Functions or Product Related Functions; and (ii) part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. “Relevant Covered Persons” includes all Covered Persons whose job responsibilities relate to Promotional Functions or Product Related Functions.
3. “Government Reimbursed Products” refers to all Allergan human pharmaceutical products promoted or sold by Allergan or any Allergan Affiliate in the United States or pursuant to contracts with the United States that are reimbursed by Federal health care programs.
4. The term “Promotional Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation, or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to any applicable review committees.
5. The term “Product Related Functions” includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal health care program and/or FDA requirements and distributed to healthcare professionals (HCPs) and healthcare institutions (HCIs) about Government Reimbursed Products, including those functions relating to any applicable review committees and Allergan’s Medical Affairs Department (Medical Affairs); (b) contracting with HCPs in the United States to conduct post-marketing clinical trials and other post-marketing studies (including Investigator-Initiated Trials (IITs)) relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products in government-listed compendia (such as DrugDex or other compendia of information about Government Reimbursed Products).
6. The term “Third Party Personnel” shall mean personnel who perform Promotional Functions or Product Related Functions who are employees of entities with whom Allergan or any Allergan Affiliate has or may in the future (during the term of this CIA) enter into agreements to co-

promote a Government Reimbursed Product in the United States. Allergan has represented that: 1) Third Party Personnel are employed by entities other than Allergan or any Allergan Affiliate; 2) neither Allergan nor any Allergan Affiliate controls the Third Party Personnel; and (3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Allergan agrees that Allergan and Allergan Affiliates shall 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.2, V.A.7 and V.B.7. Provided that Allergan complies with the requirements of Sections III.B.2, V.A.7 and V.B.7, Allergan shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

7. The term “Third Party Educational Activity” shall mean any continuing medical education (CME), or other scientific, educational, or professional program, meeting, or event supported conducted by a third party in the U.S. and supported by Allergan, or an Allergan Affiliate, including but not limited to, sponsorship of symposia at medical conferences.
8. The term “Allergan Affiliate” shall mean any entity that is controlled, directly or indirectly, through ownership or otherwise, by Allergan and whose employees or contractors perform Promotional Functions or Product Related Functions. The term Allergan Affiliates includes, but is not limited to, the following entities: Allergan USA Inc., Allergan Sales LLC, and Pacific Communications.

III. CORPORATE INTEGRITY OBLIGATIONS

Allergan shall establish and maintain a Compliance Program throughout the term of this CIA that includes the following elements:

A. Compliance Responsibilities of Certain Allergan Employees and the Board.

1. *Chief Compliance Officer.* Prior to the Effective Date, Allergan appointed a Chief Compliance Officer and Allergan shall maintain a Chief Compliance Officer during the term of the CIA. During the term of the CIA, the Chief Compliance Officer shall be authorized to oversee compliance with regard to Allergan's U.S. operations, with Federal health care program and FDA requirements, and with the requirements of this CIA. The Chief 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 Chief Compliance Officer shall be a member of senior management of Allergan, shall report directly to the Chief Executive Officer of Allergan, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Allergan or a Committee of the Board of Directors of Allergan (the term "Board" shall mean such Board of Directors or Committee thereof), and shall be authorized to report on such matters to the Chief Executive Officer of Allergan and the Board at any time. The Chief Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The Chief Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Allergan as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Chief Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Allergan shall report to OIG, in writing, any change in the identity of the Chief Compliance Officer, or any actions or changes that would affect the Chief Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after the change.

2. *U.S. Compliance Committee.* Prior to the Effective Date, Allergan established a Compliance Committee that addressed U.S. compliance issues, and Allergan shall maintain a U.S. Compliance Committee during the term of this CIA. The U.S. Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments). The Chief Compliance Officer shall chair the U.S. Compliance Committee, and the U.S. Compliance Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities under the CIA (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of

internal and external audits and investigations). The U.S. Compliance Committee shall meet at least quarterly.

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

3. *Board Compliance Obligations.* The Board of Allergan shall be responsible 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 shall, at a minimum, be responsible for the following:

- a. The Board shall meet at least quarterly to review and oversee Allergan's Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities of the Chief Compliance Officer and other compliance personnel.
- b. For each Reporting Period, the Board shall adopt a resolution, and the resolution shall be signed by each individual member of the Board, summarizing its review and oversight of matters relating to Allergan's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board of Directors [or a Committee of the Board] has made a reasonable inquiry into the operations of Allergan's Compliance Program for the period ____, including but not limited to evaluating its effectiveness and receiving updates about the activities of its Chief Compliance Officer and other compliance personnel. Based on its inquiry, the Board [or the Committee] has concluded that, to the best of its knowledge, Allergan has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

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 assure implementation by Allergan of an effective Compliance Program at Allergan.

Allergan shall report to OIG, in writing, any changes in the composition of the Board, 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 a change.

4. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Allergan 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 Allergan component is compliant with Federal health care program requirements, FDA requirements, and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following individuals from Allergan: Chief Executive Officer; President; Corporate Vice President, North America; Corporate Vice President, Allergan Medical; Corporate Vice President, Global Marketing; Vice President, Medical Affairs; Vice President, Managed Markets; and the Vice Presidents of U.S. Dermatology Sales and Marketing; U.S. Managed Markets; U.S. Eye Care Sales and Marketing; U.S. Neurosciences Sales and Marketing; U.S. Commercial Operations; Health Sales and Marketing; Facial Aesthetics Sales and Marketing; Breast Aesthetics Sales and Marketing; and Global Strategic Marketing.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

“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 monitoring and oversight of 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 department or functional area] of Allergan 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 provide a written explanation of the reasons why he or she is unable to provide make the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Allergan developed, implemented, and distributed a written Code of Conduct to all Covered Persons who are employees. Allergan shall make the promotion of, and adherence to, the Code of Conduct a condition of employment of all Covered Persons who are employees.

The Code of Conduct sets forth and shall continue to set forth, at a minimum, the following:

- a. Allergan's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health program requirements and FDA requirements;
- b. Allergan's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with Allergan's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. Allergan's requirement that all of Allergan's Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by Allergan, suspected violations by Allergan or persons acting on behalf of Allergan of any Federal health care program and FDA requirements or of Allergan's own Policies and Procedures; and
- d. the right of individuals to use the Disclosure Program described in Section III.E, and Allergan's commitment to nonretaliation and to

maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished within the last 150 days, within 120 days after the Effective Date, the Code of Conduct shall be distributed to each Covered Person and each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Allergan'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 120 days after the Effective Date, whichever is later.

Allergan 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 by the Corporate Compliance Department. 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. *Third Party Personnel.* Within 150 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Allergan and/or the Allergan Affiliate shall send a letter to each entity employing Third Party Personnel. The letter shall outline Allergan's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of Allergan's Compliance Program. Allergan and/or the Allergan Affiliate shall attach a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of Allergan's Code of Conduct and a description of Allergan's Compliance Program available to its Third Party Personnel; or (b) represent to Allergan and/or the Allergan Affiliate that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* Prior to the Effective Date, Allergan implemented written Policies and Procedures regarding the operation of the Compliance Program and Allergan's compliance with Federal health care program and FDA requirements (Policies and Procedures). To the extent not already accomplished, within

150 days after the Effective Date, Allergan 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 Functions, including sponsorships, in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);
- c. appropriate ways to conduct Product Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);
- d. appropriate ways to conduct Promotional Functions in compliance with all applicable FDA requirements;
- e. appropriate ways to conduct Product Related Functions in compliance with all applicable FDA requirements;
- f. appropriate ways to provide reimbursement support services in compliance with all applicable Federal health care program requirements. The Policies and Procedures shall be designed to ensure that Allergan's provision of reimbursement support services complies with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require appropriate qualified Allergan legal and other personnel to review Allergan's policies, procedures, and practices relating to the provision of reimbursement support services (including the compliance controls relating to the provision of such services) on at least an annual basis. If Allergan determines, through its review, that its policies, procedures, and/or practices relating to

reimbursement support services are not in compliance with applicable Federal health care program and FDA requirements, Allergan shall modify its policies, procedures, and/or practices to ensure compliance with all applicable Federal health care program and FDA requirements;

- g. the materials and information that may be distributed by Allergan sales representatives about Allergan's Government Reimbursed Products and the manner in which Allergan sales representatives respond to requests for information about non-FDA approved (or "off-label") uses of Allergan's Government Reimbursed Products. As of the Effective Date, Allergan's Policies and Procedures required that sales representatives refer all requests for information about off-label uses of Allergan's Government Reimbursed Products to Medical Affairs;
- h. the materials and information that may be distributed by Medical Affairs and the mechanisms through, and manner in which, Medical Affairs receives and responds to requests for information submitted by sales representatives about off-label uses of Allergan's Government Reimbursed Products; the form and content of information disseminated by Allergan in response to such requests; and the internal review process for the information disseminated. These Policies and Procedures shall also require that distribution of any reprints of medical journal articles must be consistent with applicable FDA requirements;

The Policies and Procedures shall include a requirement that Medical Information (a subdivision of Medical Affairs) develop database(s) to track all requests for information about Allergan's Government Reimbursed Products to Medical Information. This database shall be referred to as the "Inquiries Database." The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Allergan's products: 1) date of Inquiry; 2) form of Inquiry (*e.g.*, fax, phone, etc.); 3) name of the requesting health care professional (HCP) or health care institution (HCI) in

accordance with applicable privacy laws; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Allergan (including a record of the materials provided to the HCP or HCI in response to the request); and 6) the name of the Allergan representative who called on or interacted with the HCP or HCI, if known;

- i. the manner and circumstances under which medical personnel from Medical Affairs participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to unsolicited requests about off-label indications of Allergan's Government Reimbursed Products;
- j. the development, implementation, and review of plans for calling on and distributing samples to HCPs and HCIs (Call Plans), for sales representatives who promote Government Reimbursed Products. For each Government Reimbursed Product, the Policies and Procedures shall require that Allergan review the Call Plans for the product and the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the Call Plans. The Policies and Procedures shall also require that Allergan modify the Call Plans as necessary to ensure that Allergan is promoting its Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The Call Plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;
- k. the development, implementation, and review of policies for the distribution of samples of Allergan's Government Reimbursed Products. This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may

receive samples from Allergan. The Policies and Procedures shall also require that Allergan modify the sample distribution policy as necessary to ensure that Allergan is promoting its products in a manner that complies with all applicable Federal health care program and FDA requirements;

- l. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, and ad hoc advisory activities, and any other financial engagement or arrangement 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 and Procedures shall include requirements about the content and circumstances of such arrangements and events;
- m. programs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings and experience-based learning activities, if any. These Policies and Procedures shall be designed to ensure that the programs 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;
- n. sponsorship or funding of charitable contributions. These Policies and Procedures shall be designed to ensure that Allergan's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- o. funding of grants (including educational grants) to HCPs and HCIs. These Policies and Procedures shall be designed to ensure that Allergan's funding complies with all applicable Federal health care program and FDA requirements;

- p. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.7 above. These Policies and Procedures shall be designed to ensure that Allergan's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements.

The Policies and Procedures shall require that: 1) Allergan disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with subsection III.B.3.p.5 below, any financial relationships with faculty, speakers, or organizers at such Activity; 2) as a condition of funding, the third party shall agree to disclose Allergan's financial support of the Third Party Educational Activity and any financial relationships that Allergan might have with faculty, speakers, or organizers at such Activity; 3) any faculty, speakers, or organizers at the Third Party Educational Activity disclose any financial relationship with the applicable Allergan entity; 4) the Third Party Educational Activity have an educational focus; 5) the content, organization, and operation of the Third Party Educational Activity be independent of Allergan's control; 6) Allergan or the Allergan Affiliate support only Third Party Educational Activity that is non-promotional in tone/nature; and 7) Allergan's or any Allergan Affiliate's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Third Party Educational Activity that is fair, balanced, accurate and not misleading;

- q. review of all promotional and written materials and information intended to be disseminated outside Allergan by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Allergan's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information comply with all applicable Federal

health care program and FDA requirements. The Policies and Procedures shall require that: 1) applicable review committees review all promotional materials prior to the distribution or use of such materials; and 2) deviations from the standard review committee practices and protocols (including timetables for the review of materials) shall be documented and referred for appropriate follow-up;

- r. compensation (including through salaries, bonuses, and contests) for Relevant Covered Persons who are sales representatives. These Policies and Procedures shall: 1) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Allergan's Government Reimbursed Products; and 2) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate the off-label promotion of Allergan Government Reimbursed Products;
- s. the submission of information about any Government Reimbursed Product to any compendia such as DrugDex or other published source of information used in connection with the determination of coverage by a Federal health care program for the Product ("Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (*e.g.*, any changes based on Allergan's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia.) The Policies and Procedures shall include a requirement that Allergan conduct an annual review of all arrangements, processing fees, or other payments or financial support (if any) provided by the company to any Compendia. Allergan U.S. compliance personnel shall be involved in this review;
- t. the sponsorship of post-marketing clinical trials or other post-marketing studies (including IITs) including the decision to provide financial or other support for such studies; the manner in

which support is provided; and support for publication of information about such studies, including the publication of information about the trial outcomes and results and the uses made of publications relating to such studies;

- u. authorship of any articles or other publications about Government Reimbursed Products or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all relationships between the author and Allergan or any Allergan Affiliate, the identification of all authors or contributors (including professional writers) associated with a given publication, and the scope and breadth of research results made available to each author or contributor; and
- v. disciplinary policies and procedures for violations of Allergan's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 150 days after the Effective Date, the relevant portions of the Policies and Procedures shall be 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), Allergan 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.

C. Training and Education.

1. *General Training.* Within 150 days after the Effective Date, Allergan shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain Allergan's:

- a. CIA requirements; and

b. Compliance Program, including the Code of Conduct.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 150 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. Specific Training.

Within 150 days after the Effective Date, each Relevant Covered Person engaged in Promotional Functions and/or Product Related Functions shall receive at least three hours of Specific Training applicable to their specific job functions in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Promotional Functions and/or Product Related Functions;
- b. all applicable FDA requirements relating to Promotional Functions and/or Product Related Functions;
- c. all Allergan Policies and Procedures and other requirements applicable to Promotional Functions and/or Product Related Functions;
- d. the personal obligation of each individual involved in Promotional Functions and/or Product Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and

f. examples of proper and improper practices related to Promotional Functions and/or Product Related Functions.

New Relevant Covered Persons shall receive the applicable training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 150 days after the Effective Date, whichever is later.

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

3. *Board of Directors Member Training.* Within 150 days after the Effective Date, Allergan shall provide at least one hour of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of Board of Director members and corporate governance.

New members of the Board of Directors shall receive the Board of Directors member training described above within 30 days after becoming a member or within 150 days after the Effective Date, whichever is later.

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

5. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area of the training, including applicable Federal health care program and FDA requirements. The training and education required under this Section III.C may be provided by supervisory employees, knowledgeable staff, Allergan trainers, and/or outside consultant trainers selected by Allergan.

6. *Update of Training.* Allergan shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements or FDA requirements, any issues discovered during any internal audits or any IRO Review, and any other relevant information.

7. *Computer-based Training.* Allergan may provide the training required under this CIA through appropriate computer-based training approaches. If Allergan 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 Covered Persons receiving such training.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Allergan shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews required by this CIA to assist Allergan in assessing and evaluating its Promotional Functions and its Product Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by Allergan shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with Allergan, whether it can perform the engagement 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 IRO(s) shall conduct two types of reviews that assess Allergan’s systems, processes, policies, procedures, and practices relating to Promotional Functions and to Product Related Functions (collectively, “IRO Reviews”).

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the IRO Reviews shall consist of two components: a Systems Review and a Transactions Review. The Systems Review shall assess Allergan’s systems, processes, policies, and procedures relating to Promotional Functions and Product

Related Functions. If there are no material changes in Allergan's relevant systems, processes, policies, and procedures, the IRO Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If Allergan materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendix B.

The Promotional and Product Services Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.

In addition, each Transactions Review shall also include a review of up to three additional areas or practices of Allergan identified by the OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with Allergan and may consider internal audit work conducted by Allergan, Allergan's Government Reimbursed Product portfolio, the nature and scope of Allergan's promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Appendix B, Allergan may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow Allergan's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify Allergan of the nature and scope of the IRO review for each of the Additional Items not later than 150 days prior

to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Allergan 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.

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

2. *IRO Review Reports.* The IRO(s) shall prepare a report (or reports) based upon each Review performed (IRO Review Report). The information and content to be included in the IRO Review Report is described in Appendix B, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any IRO Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Allergan 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 Allergan's final Annual Report shall be initiated no later than one year after Allergan's final submission (as described in Section II) is received by OIG.

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

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

E. Disclosure Program. Allergan currently has a disclosure program that Allergan represents is designed to facilitate communications relating to compliance with Federal health care program and FDA requirements and Allergan's policies (the "Disclosure Program"). During the term of the CIA, Allergan shall maintain a Disclosure Program that includes a mechanism (a toll-free compliance telephone line and/or on-line electronic reporting) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Allergan'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. Allergan shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Chief Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Chief 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, Allergan shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

F. Ineligible Persons.

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

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the scope 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.* Allergan shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

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

b. Allergan shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

c. Allergan 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) Allergan to (if applicable) refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Allergan understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Allergan 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 Allergan meets the requirements of Section III.F.

3. *Removal Requirement.* If Allergan has actual notice that a Covered Person has become an Ineligible Person, Allergan shall remove such Covered Person from responsibility for, or involvement with, Allergan's business operations related to the Federal health care programs and shall remove such Covered Person 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 Allergan has actual notice that a Covered Person is charged with a criminal offense that falls within the scope 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, Allergan 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 the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings. Within 30 days after discovery by Allergan, Allergan shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that Allergan 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. Allergan shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reportable Events.

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

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any FDA requirements relating to the promotion of Government Reimbursed Products (including an FDA Warning Letter issued to Allergan or any Allergan Affiliate);
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or
- d. the filing of a bankruptcy petition by Allergan.

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

2. *Reporting of Reportable Events.* If Allergan determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Allergan 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 Allergan's actions taken to correct the Reportable Event; and
- iii. any further steps Allergan 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.

Allergan shall not be required to report as a Reportable Event any matter previously disclosed under Section III.G, above.

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

J. Field Force Monitoring and Review Efforts.

To the extent not already accomplished, within 120 days after the Effective Date, Allergan shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor sales representatives' interactions with HCPs and HCIs relating to Government Reimbursed Products. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales representatives' interactions with HCPs relating to Government Reimbursed Products and to identify potential off-

label promotional activities relating to such products. As described in more detail below, the FFMP shall include: 1) a Speaker Monitoring Program; 2) direct field observations (Observations) of sales representatives; and 3) the monitoring and review of other records relating to sales representatives' interactions with HCPs and HCIs (Records Reviews).

Allergan represents that, prior to the Effective Date, it developed and implemented a comprehensive system for streamlining business and compliance processes. This system is referred to as the Business Execution Automated Compliance Navigator (BEACON). BEACON is used to manage consultant arrangements with HCPs, Advisory Boards, Speaker Programs, and provision of educational items, meals, and expenses. In addition to the data entered by individual users, BEACON interfaces with some of Allergan's other systems, including the system through which promotional materials are reviewed and approved and the system through which expenses are tracked.

Allergan represents that in BEACON, consulting arrangements are managed through annual operating plans (discussed further below), entry of requests for individual events, including completion of a form addressing details and the business need for the event, and review and approval of those requests. BEACON includes controls that identifies when a proposed event or arrangement does not comply with Allergan's policies and procedures and notifies the Corporate Compliance Department of that issue for additional review and approval. BEACON requires that documentation of the event and any expenses incurred be uploaded to the system and verified by the responsible employee. If all requirements are met, BEACON approves payments to HCPs and tracks aggregate payments.

As it applies to certain processes, BEACON is described further below.

1. *Speaker Program Activities.* With regard to speaker programs relating to Government Reimbursed Products, Allergan shall maintain processes to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements that the speaker may only use Allergan approved materials and may not directly or indirectly promote the product for off-label uses). Allergan shall maintain a centralized electronic system (BEACON) through which all such speaker programs are administered. BEACON shall establish controls regarding eligibility and qualifications of speakers and venues for the programs and require that speakers are paid according to a centrally managed rate structure determined based on a

fair-market value analysis conducted by Allergan. Allergan shall continue to maintain a comprehensive list of speaker program attendees through BEACON. In addition, through BEACON, Allergan shall track and review the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs relating to Government Reimbursed Products conducted during each Reporting Period. Allergan shall require, through BEACON, certified evaluations by sales representatives or other Allergan personnel regarding whether a speaker program complied with Allergan requirements, and in the event of non-compliance, Allergan shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

To the extent not already accomplished, Allergan shall institute a Speaker Monitoring Program under which Allergan compliance or management personnel or outside personnel acting on behalf of Allergan shall attend 75 speaker programs relating to Government Reimbursed Products during each Reporting Period and conduct live monitoring of the programs (Speaker Monitoring Program). The programs subject to the Speaker Monitoring Program shall be selected both on a risk-based targeting approach and on a sampling approach. For each program reviewed, personnel conducting the Speaker Monitoring Program shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and Allergan representative activities during the program to assess whether the programs were conducted in a manner consistent with Allergan's Policies and Procedures. Allergan shall maintain the controls around speaker programs as described above, and shall conduct its Speaker Monitoring Program as described above throughout the term of the CIA.

2. *Observations.* As a component of the FFMP, Allergan compliance personnel shall conduct observations of sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with applicable legal requirements and with Allergan's Policies and Procedures. These observations shall be full day ride-alongs with sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. The Observations shall be scheduled throughout the year, selected by Allergan compliance personnel both on a risk-based targeting approach and on a sampling approach, include each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each Observation, Allergan compliance personnel shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Allergan compliance personnel;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Allergan policy; and
- 6) the identification of any potential off-label promotional activity or other improper conduct by the sales representative.

Allergan U.S. compliance personnel shall conduct at least 30 Observations during each Reporting Period.

3. *Records Reviews.* As a component of the FFMP, Allergan shall also review various types of records to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations. For each Reporting Period, Allergan shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products and a sampling of the representatives promoting those products in every separate region. The OIG shall have the discretion to identify the three Government Reimbursed Products to be reviewed for each Reporting Period. The OIG will select the products based on information about Allergan's products provided by Allergan, upon request by the OIG no later than 60 days prior to the beginning of the Reporting Period, and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed within the first 30 days of the Reporting Period, Allergan shall select the three products to be reviewed.

For the first Reporting Period, the Records Reviews shall include the monitoring and review of: 1) records in BEACON relating to sales representatives' interactions with HCPs and HCIs relating to promotional speaker program activities, meals and expenses, and advisory boards; 2) requests for medical information; 3) sales representatives' call notes; 4) sales representatives' e-mails; and 5) recorded results of the Observations of sales representatives.

For the second and subsequent Reporting Periods, the Records Reviews shall include the monitoring and review of: 1) records in BEACON relating to sales representatives' interactions with HCPs and HCIs; 2) requests for medical information; 3) message recall studies or any other similar records in Allergan's possession purporting to

reflect the details of sales representatives' interactions with HCPs and HCIs; 4) sales representative call notes; 5) sales representatives' e-mails and any electronic records; and 6) recorded results of the Observations of sales representatives and other notes or information from the sales representatives' managers relating to interactions between the sales representatives and HCPs and HCIs pertaining to the Government Reimbursed Product at issue.

4. *Reporting and Follow-up.* Personnel conducting the Speaker Monitoring Program, Observations, and Records Reviews shall have access to all relevant records and information necessary to assess potential or actual compliance violations. Results from the FFMP monitoring, including the identification of potential violations of policies and/or legal requirements, shall be compiled and reported to the Corporate Compliance Department for review and follow-up as appropriate. In the event that a potential violation of Allergan's Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during any aspect of the FFMP, Allergan shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during a Speaker Monitoring Program, Observation and/or Records Review and any corrective action shall be recorded in the files of the Corporate Compliance Department.

Allergan shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, Allergan also shall provide the OIG with copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Allergan took as a result of such determinations. Allergan shall make the Observation reports for all other Observations available to the OIG upon request.

K. Monitoring of Non-Promotional Activities.

To the extent not already accomplished, within 150 days after the Effective Date Allergan shall develop and implement a monitoring program for the following types of

activities: 1) consultant arrangements; 2) research-related activities; 3) publication activities; and 4) medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program.

1. *Consultant Arrangement Activities.* To the extent that Allergan engages U.S.-based HCPs for services that relate to Promotional Functions or to Product Related Functions, other than for speaker programs or research-related functions (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs shall be referred to herein as Consultants. Allergan shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultants. Allergan shall continue to maintain a centralized electronic system through BEACON where all such Consultant arrangements are administered. BEACON shall establish controls regarding eligibility and qualifications of Consultants and requires that Consultants are paid according to a rate structure based on fair market value. Allergan shall maintain a comprehensive list of Consultants through BEACON. In addition, through BEACON, Allergan shall track and review the aggregate amount paid to each Consultant in connection with Consultant arrangements relating to Government Reimbursed Products conducted during each Reporting Period.

To the extent not already accomplished, within 150 days after the Effective Date, Allergan shall establish a process to develop annual operating plans that identify the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the following year. Such annual operating plans shall include a needs assessment (or business rationale form) to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs or HCIs to be engaged, the agenda for the proposed meeting and a description of the proposed work to be done and type of work product to be generated). Any deviations from the Consultant operating plans shall be documented in the needs assessment form (or business rationale form) and shall be subject to review and approval by Allergan compliance personnel. The annual operating plans shall also identify the budgeted amounts to be spent on Consultant-related activities. Allergan's compliance personnel shall be involved in the review and approval of such operating plans, including any subsequent modification of an approved plan. The purpose of this review shall be to

ensure that Consultant arrangements and related events are used for legitimate purposes in accordance with applicable Allergan Policies and Procedures.

To the extent not already accomplished, within 150 days after the Effective Date, Allergan shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, Allergan received the work product generated by the Consultant.

Within 150 days after the Effective Date, Allergan shall establish a Consultant Monitoring Program through which it shall conduct live monitoring for each Reporting Period (Consultant Program Observations) of at least 30 Consultant arrangements with HCPs. The Consultant Program Observations shall include live monitoring of at least 10 advisory board programs and monitoring of 20 other professional services agreements with HCPs. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a sampling approach. Allergan compliance personnel conducting the Consultant Program Observations shall review needs assessment documents, consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Allergan's Policies and Procedures. Results from the Consultant Program Observations, including the identification of potential violations of policies, shall be compiled and reported to the Corporate Compliance Department for review and follow-up, as appropriate.

2. *Research-Related Activities.* To the extent that Allergan or any Allergan Affiliate (hereafter in this Section III.K.2, collectively "Allergan") provides funding or other support to U.S.-based HCPs or HCIs to conduct Phase IV post-marketing studies or IITs, such HCPs and HCIs shall be referred to collectively as "Researchers". Allergan shall require all Researchers to enter written agreements describing the scope of the research or other work to be performed, the fees to be paid, and compliance obligations for the Researchers. Researchers shall be paid based on a fair-market value analysis conducted by Allergan. This fair-market value analysis shall be incorporated into guidelines that are used in the review, approval, and funding of Researchers' activities. Documentation of such review, approval, and funding activities shall be maintained by Allergan Medical Affairs.

To the extent not already accomplished, within 150 days after the Effective Date, Allergan shall establish an annual budgeting plan for Researchers that identifies the business or scientific need for, and the estimated numbers of, the various Researcher engagements and activities to occur during the year. Allergan Medical Affairs personnel, in consultation with compliance personnel, shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Research arrangements and related events are used for legitimate purposes in accordance with Allergan Policies and Procedures.

To the extent not already accomplished, within 150 days after the Effective Date, Allergan shall establish a process to ensure that each Researcher has submitted a needs assessment to justify the retention of the Researcher prior to the provision of funding or other support to the Researcher. The needs assessment shall identify the business or scientific need for the information to be provided by the Researcher and provide specific details about the research arrangement (including, for example, information about the numbers and qualifications of the HCPs or HCIs to be engaged, a description of the proposed research to be done (including the research protocol) and type of work product to be generated).

To the extent not already accomplished, within 150 days after the Effective Date, Allergan shall amend its policies and procedures in a manner designed to ensure that each Researcher performed the work for which the Researcher was provided funding or other support.

Within 150 days after the Effective Date, Allergan shall establish a Researcher Monitoring Program through which it shall conduct monitoring for each Reporting Period of at least 20 Researcher arrangements with HCPs or HCIs. The Researcher Monitoring Program shall review Researcher arrangements both on a risk-based targeting approach and on a sampling approach. Allergan compliance personnel conducting the Researcher Monitoring Program shall review needs assessment documents, proposal and/or protocol documents, approval documents, contracts, and payments in order to assess whether the programs and arrangements were supported by Allergan and performed by the Researchers in a manner consistent with Allergan's Policies and Procedures. Results from the Researcher Monitoring Program, including identification of potential violations of policies, shall be compiled and reported to the Corporate Compliance Department for review and follow-up as appropriate.

3. *Publication Activities.* To the extent that Allergan engages U.S.-based HCPs or HCIs to produce articles or other publications relating to Phase IV post-marketing studies or IITs relating to Government Reimbursed Products (collectively “Publication Activities”) such HCPs or HCIs shall be referred to as Authors. Allergan shall require all Authors to enter written agreements describing the scope of work to be performed, the fees to be paid in connection with the Publication Activities, and compliance obligations of the Authors. Authors shall be paid based on a fair-market value analysis conducted by Allergan. This fair-market value analysis shall be incorporated into guidelines that are used in the review, approval, and funding of Publication Activities. Documentation of such review, approval, and funding activities shall be maintained by Allergan Medical Affairs.

To the extent not already accomplished, within 150 days after the Effective Date, Allergan shall establish a process to develop annual plans that identify the business needs for and the estimated numbers of various Publication Activities (Publications Plans). The annual Publications Plan shall also identify the budgeted amounts to be spent on Publication Activities. Allergan’s Medical Affairs personnel, in consultation with the Corporate Compliance Department personnel, shall be involved in the review and approval of such annual Publications Plans, including any modification of an approved plan. The purpose of this review shall be to ensure that Publication Activities and related events are used for legitimate purposes in accordance with Allergan Policies and Procedures.

To the extent not already accomplished, within 150 days after the Effective Date, Allergan shall establish a needs assessment process for Publication Activities. This process shall ensure that a needs assessment has been completed prior to the retention of an Author for a Publication Activity. The needs assessment shall provide specific details about Publication Activities to be performed (including a description of the proposed work to be done, type of work product to be generated, and the purpose for the work).

Within 150 days after the Effective Date, Allergan shall establish a Publication Monitoring Program through which it shall conduct monitoring for each Reporting Period of at least 25 U.S.-sponsored Publication Activities. The Publication Monitoring Program shall select publications for review both on a risk-based targeting approach and on a sampling approach. Allergan compliance personnel conducting the Publication Monitoring Program shall review needs assessment documents, proposal documents, approval documents, contracts, payments and materials relating to the Publication

Activities (including work product resulting from the Activities), in order to assess whether the activities were conducted in a manner consistent with Allergan's Policies and Procedures. Results from the Publication Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Corporate Compliance Department for review and follow-up as appropriate.

4. *Medical Education Grant Activities.* Allergan represents that it has established a Medical Education Department within its Medical Affairs Department as the exclusive mechanism through which requestors may seek or be awarded grants for independent medical education activities.

Allergan represents that its sales and marketing departments have no involvement in, or influence over, the review and approval of medical education grants. Grant requests shall be submitted through an on-line process and requests are processed in accordance with standardized criteria developed by the Medical Education Department. Allergan shall continue the medical education grant process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at least 60 days prior to the implementation of any new system subsequent to the Effective Date.

To the extent not already accomplished, within 150 days after the Effective Date, Allergan shall establish a Grants Monitoring Program through which it shall conduct monitoring for each Reporting Period of at least 30 medical education grants. The Grants Monitoring Program shall select grants for review both on a risk-based targeting approach and on a sampling approach. Allergan compliance personnel conducting the Grants Monitoring Program shall review proposal documents (including grant requests), approval documents, contracts, payments, and materials relating to the Medical Education Department's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities are conducted in a manner consistent with Allergan's Policies and Procedures. Results from the Grant Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Corporate Compliance Department for review and follow-up as appropriate.

5. *Follow Up Reviews and Reporting.* In the event that a potential violation of Allergan's Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during any aspect

of the Non-Promotional Monitoring Program, Allergan shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during any Non-Promotional Monitoring Program referenced above, and any corrective action, shall be recorded in the files of the Corporate Compliance Department.

Allergan shall include a summary of the Non-Promotional Monitoring Program and the results of the Non-Promotional Monitoring Program as part of each Annual Report. As part of each Annual Report, Allergan also shall provide the OIG with descriptions of any instances identified through the Non-Promotional Monitoring Program in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated Allergan's requirements or Policies and Procedures, and a description of the action(s) that Allergan took as a result of such determinations. Allergan shall make the documents relating to the Non-Promotional Monitoring Program available to the OIG upon request.

L. Notice to Health Care Providers and Entities. Within 90 days after the Effective Date, Allergan shall send, by first class mail, postage prepaid and return receipt requested, a notice containing the language set forth below to all HCPs and HCIs that Allergan currently details. This notice shall be dated and shall be signed by Allergan's President. The body of the letter shall state the following:

As you may be aware, Allergan recently entered into a global civil, criminal and administrative settlement with the United States and individual states in connection with the promotion and use of one of its products. This letter provides you with additional information about the settlement, explains Allergan's commitments going forward, and provides you with access to information about those commitments.

In general terms, the Government alleged that Allergan unlawfully promoted the drug Botox for certain uses not approved by the Food & Drug Administration (FDA). To resolve these matters, Allergan pled guilty to a misdemeanor criminal violation of the Federal Food, Drug & Cosmetic Act (FDCA), settled certain civil claims, and agreed to pay \$600 million to the Federal Government and State Medicaid programs. More information about this settlement may be found at the

following: **[Allergan shall include a link to the USAO, and Allergan websites in the letter.]**

As part of the federal settlement, Allergan also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, Allergan agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by Allergan's representatives to Allergan's Corporate Compliance Department or the FDA.

Please call or email Allergan at **1-800-TBD** or **[Allergan shall insert website address in the letter]** if you have questions about the settlement referenced above or to report any instances in which you believe that a Allergan representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any such instances to the FDA's Division of Drug Marketing, Advertising, and Communications at 301-796-1200. You should direct medical questions or concerns about the products to **[insert name and telephone number for contact line]**.

The Chief Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The disclosure log shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, Allergan shall provide to the OIG a summary of the calls and messages received.

M. Reporting of Physician Payments.

1. Reporting of Payment Information.

(i) Phase I Reporting: On or before April 30, 2011, Allergan shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities (as defined below) who or which received Phase I Payments (as defined below) directly or indirectly from Allergan during the last two quarters of 2010 and the aggregate value of such Phase I Payments.

On or before August 31, 2011, Allergan shall also post on its website a listing of updated information about all Phase I Payments provided during the first two quarters of 2011. Each Phase I report shall be easily accessible and readily searchable.

(ii) Phase II Reporting: On or before November 30, 2011, Allergan shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities (as defined below) who or which received Phase II Payments (as defined below) directly or indirectly from Allergan during the third quarter of 2011 and the aggregate value of such Phase II Payments. After the November 30, 2011 posting, 60 days after the end of each subsequent calendar quarter, Allergan shall also post on its website a listing of updated information about all Phase II payments provided during the preceding quarter(s) in each calendar year.

In addition, beginning on February 29, 2012, and 60 days after the end of each subsequent calendar year, Allergan shall post on its website a report of the cumulative value of the Phase II Payments provided to all U.S.-based physicians and Related Entities directly or indirectly from Allergan during the prior applicable calendar year. Each quarterly and annual Phase II report shall be easily accessible and readily searchable. The commencement of Phase II reporting will terminate the obligations of Phase I reporting.

2. Definitions and Miscellaneous Provisions

(i) Each listing made pursuant to this Section III.M shall include a complete list of all individual physicians and Related Entities to whom or to which Allergan directly or indirectly made Payments in the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or the name of the Related Entity. The Payment amounts in the lists shall be reported in \$10,000 increments (e.g., \$0 - \$10,000; \$10,001- \$20,000; etc.) For each physician, the applicable listing shall include the following information: i) physician's full name; ii) name of any Related Entities (if applicable); iii) city and state that the physician or

Related Entity has provided to Allergan for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding six-month period or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

Allergan shall continue to make each annual listing and the most recent quarterly listing of Payments available on its website at least throughout the term of this CIA. Allergan shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual and/or quarterly listings of Payments. Nothing in this Section III.M affects the responsibility of Allergan to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entities.

(ii) For purposes of this Section III.M, the term “Phase I Payments” is defined to include all payments or transfers of value (whether in cash or in kind) made by Allergan to physicians and/or to Related Entities related to meals, speaker programs, or advisory boards conducted by Sales, Marketing, or Medical Affairs.

(iii) For purposes of Section III.M.1, “Phase II Payments” is defined to include all “payments or transfers of value” as that term is defined in §1128G(e)(10) under Section 6002 of the Patient Protection and Affordable Care Act (Public Law 111-148) (Affordable Care Act) and any regulations promulgated thereunder. The term Payments include, by way of example, the types of payments or transfers of value enumerated in §1128G(a)(1)(A)(vi) of the Affordable Care Act. The term includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom Allergan would otherwise report a Payment if made directly to the physician. The term Payments also includes any payments or transfers of value made, directly by Allergan or by a vendor retained by Allergan to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

(iv) The term “Payments” does not include transfers of value or other items that are not included or are excluded from the definition of “payment” as set forth in § 1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder.

(v) For purposes of this Section III.M, the term “Related Entity” is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

N. Other Transparency/Disclosure Initiatives.

Within 120 days after the Effective Date of this CIA, and thereafter on a bi-annual basis, Allergan shall post on its company website the following information with respect to both medical education grants and charitable contributions to U.S.-based HCIs: 1) the recipient organization’s name; 2) a brief description of the program for which the grant or charitable contribution was requested; and 3) the amount of the grant or charitable contribution. Allergan shall continue to post (and provide updates to) the above-described information about medical education grants and charitable contributions to U.S.-based HCIs throughout the term of this CIA. Allergan shall notify the OIG in writing at least 60 days prior to any change in the substance of its policies regarding the funding of medical education grants and charitable contributions to U.S.-based HCIs or posting of the above-referenced information relating to such funding.

Allergan represents that it requires all U.S.-based Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Allergan that may be externally imposed on the Consultants based on their affiliation with formulary or Pharmacy & Therapeutics committees or committees associated with the development of treatment protocols or standards. Allergan shall continue this requirement throughout the term of this CIA. Within 120 days after the Effective Date, Allergan shall amend its policies relating to Consultants to explicitly state Allergan’s requirement about full disclosure by Consultants consistent with the requirements of any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any amendment to its contracts with Consultants and in any new contracts with Consultants entered into after 120 days following the Effective Date, Allergan shall include an explicit requirement that the Consultants fully comply with applicable disclosure requirements and disclose their relationship with Allergan as required pursuant to their affiliation with any HCI, medical committee, or other medical or scientific organization.

Allergan represents that it expects all Authors of biomedical manuscripts to fully comply with the International Committee of Medical Journal Editors (ICMJE) criteria regarding authorship and disclosure of their relationship with Allergan and to disclose any

potential conflicts of interest, including any financial or personal relationships that might be perceived to bias their work. Within 120 days after the Effective Date, Allergan shall amend its policies relating to Authors to explicitly state Allergan's requirement about full disclosure by Authors consistent with the requirements of any HCI, medical committee or other medical or scientific organization with which the Authors are affiliated. In addition, for any amendments to its contracts with Authors and in any new contracts with Authors entered into after 120 days following the Effective Date, Allergan shall include an explicit requirement that Authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, any potential conflicts of interest, including their financial or personal relationship with Allergan, the names of any individuals who have provided editorial support for any manuscript or other publication, and all funding sources for the study or publication.

Allergan represents that for all applicable clinical trials (as defined by 42 U.S.C. §282(j)) where Allergan is a sponsor, it registers and reports the results on the National Institutes of Health (NIH) sponsored website (www.clinicaltrials.gov) or requires that another responsible party (as defined by 42 U.S.C. § 282(j)) register and report the results on the NIH website. Allergan shall continue to comply with Federal health care program requirements, FDA requirements, or other applicable requirements relating to the reporting of clinical study information throughout the term of this CIA. In addition, if there is a change in Federal health care program requirements, FDA requirements, or other applicable requirements relating to the reporting of clinical study information, Allergan shall fully comply with such requirements.

Allergan represents that it posts information on its company website about postmarketing commitments (PMCs). The Allergan website (www.allergan.com) provides access to general information about the PMC process, including study descriptions and information about the nature and status of FDA PMCs. Allergan shall continue to post the above-described information about PMCs on its website throughout the term of this CIA.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Allergan changes locations or closes a business unit or location related to Promotional Functions or Product Related Functions, Allergan 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, Allergan purchases or establishes a new business unit or location related to Promotional Functions or Product Related Functions, Allergan shall notify OIG no later than five days after the date that the purchase or establishment is publicly disclosed by Allergan. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider or supplier number (if applicable), and the name and address of the contractor that issued each number (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Allergan proposes to sell any or all of its business units or locations related to Promotional Functions or Product Related Functions that are subject to this CIA, Allergan shall notify OIG of the proposed sale no later than 5 days after the date the sale is publicly disclosed by Allergan. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 180 days after the Effective Date, Allergan 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 Chief Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Chief Compliance Officer may have;

2. the names and positions of the members of the U.S. Compliance Committee required by Section III.A.2;
3. the names of the members of the full Board of Directors and any Committee of the Board with responsibility for compliance as referenced in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of Allergan's Code of Conduct required by Section III.B.1;
6. the number of Covered Persons required to complete the Code of Conduct certification required by Section III.B.1, the percentage of Covered Persons who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
7. a) a copy of the letter (including all attachments) required by Section II.C.6 and III.B.2 sent to each party employing Third Party Personnel; b) a list of all such existing co-promotion and other applicable agreements; and c) a description of the entities' response to Allergan's letter;
8. a summary of all Policies and Procedures required by Section III.B.3 (a copy of such Policies and Procedures shall be made available to OIG upon request);
9. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
 - b. the number of Covered Persons required to be trained, percentage of Covered Persons actually trained, and an explanation of any exceptions.

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

10. the following information regarding the IRO(s): (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 Allergan and the IRO;

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

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

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

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

15. a certification by the Chief Compliance Officer that the notice required by Section III.L was mailed to each HCP and HCI, the number of HCPs and HCIs that received a copy of the notice, a sample copy of the notice required by Section III.L, and a summary of the calls or messages received in response to the notice;

16. a list of all of Allergan's U.S. locations (including locations and mailing addresses); the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

17. a description of Allergan's 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.2.

B. Annual Reports. Allergan shall submit to OIG annually a report with respect to the status of, and findings regarding, Allergan's 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 Chief Compliance Officer and any change in the membership of the U.S. Compliance Committee, the Board, or the group of Certifying Employees described in Sections III.A.2-4;
2. a complete copy of all reports prepared pursuant to Section III.A.3,
3. Allergan's response and action plans(s) related to any issues raised by the reports prepared pursuant to Section III.A.3;
4. a copy of the resolution by the Board required by Section III.A.3;
5. 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);
6. the number of Covered Persons required to complete the Code of Conduct certification required by Section III.B.1, the percentage of Covered Persons who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
7. a) a copy of the letter (including all attachments) required by Section II.C.6 and III.B.2 sent to each party employing Third Party Personnel; b) a list of all such existing co-promotion and other applicable agreements; and c) a description of the entities' response to Allergan's letter;
8. the following information regarding each type of training required by Section III.C:

- a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and
- b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, 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 complete copy of all reports prepared pursuant to Section III.D;
10. Allergan's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;
11. a summary and description of any and all current and prior engagements and agreements between Allergan and the IRO, if different from what was submitted as part of the Implementation Report;
12. a certification from the IRO regarding its professional independence and objectivity with respect to Allergan;
13. a summary of the disclosures in the disclosure log required by Section III.E that relate to the Government Reimbursed Products or to Federal health care programs;
14. any changes to the process by which Allergan fulfills the requirements of Section III.F regarding Ineligible Persons;
15. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by Allergan in response to the screening and removal obligations set forth in Section III.F;
16. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a

description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

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

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

19. a summary of the FFMP and the results of the FFMP required by Section III.J, including copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Allergan took as a result of such determinations;

20. a summary of the Non-Promotional Monitoring Program and the results of the program described in Section III.K, including detailed description of any identified instances in which it was determined that the activities violated Allergan's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) Allergan took as a result of such determinations;

21. a summary of the calls and messages received in response to the notice required by Section III.L and the disposition of those calls and messages;

22. a certification from the Chief Compliance Officer that, if required under Section III.M and to the best of his/her knowledge, information regarding Payments has been posted on Allergan's website as required by Section III.M;

23. a description of all changes to the most recently provided list of Allergan's locations (including addresses) as required by Section V.A.16; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers; and

24. a description of any additional, updated, supplemental or changed information submitted to any Compendia in accordance with Section III.B.3.r; and a description of all arrangements, processing fees, and other payments or financial support

(if any) with or made to any Compendia evaluated during the annual review described in Section III.B.3.t; and

25. the certifications required by Section V.C.

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

C. Certifications. The following certifications shall be included in the Implementation Report and Annual Reports:

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

2. Chief Compliance Officer: In the Implementation Report and Annual Reports, Allergan shall include the following individual 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, except as otherwise described in the applicable report, Allergan is in compliance with the Federal health care program and FDA requirements and the obligations of the CIA;

c. he or she has verified with appropriate personnel that Allergan's: 1) Policies and Procedures as referenced in Section III.B.3 above; 2) templates for standardized contracts and other similar documents; 3) the training materials used for purposes of Section III.C; and 4) Allergan's reimbursement support services policies, procedures, and practices (as referenced in Section III.B.3.f) all have been reviewed by competent legal counsel and/or legal personnel working at their direction and have been found to be in compliance with all applicable Federal health care program and FDA requirements. If the 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 and/or legal personnel working at their direction.

The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request;

d. he or she has verified with appropriate personnel that, except as otherwise described in the applicable report, Allergan's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Allergan have been reviewed by competent regulatory, medical, and/or legal personnel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns are properly addressed and are elevated when appropriate, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the 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 regulatory, medical, and/or legal personnel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

e. he or she has verified with appropriate personnel that Allergan's Call Plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.j) and, for each product the Call Plans were found to be consistent with Allergan's policy objectives as referenced above in Section III.B.3.j.

D. Designation of Information. Allergan 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. Allergan 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:

Corporate Integrity Agreement
Allergan, Inc.

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

Allergan: Chief Compliance Officer
Allergan, Inc.
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623
Telephone: 714.246.4500
Facsimile: 714.246.4971

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, Allergan 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 Allergan's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Allergan's locations for the purpose of verifying and evaluating: (a) Allergan's compliance with the terms of this CIA; and (b) Allergan's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Allergan 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 Allergan's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Allergan shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Allergan's employees may elect to be interviewed with or without a representative of Allergan present.

VIII. DOCUMENT AND RECORD RETENTION

Allergan 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 Allergan prior to any release by OIG of information submitted by Allergan pursuant to its obligations under this CIA and identified upon submission by Allergan as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Allergan shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Allergan is expected to fully and timely comply with all of its CIA obligations. The breach and default remedies available to the OIG under this Section X do not preempt or limit any actions that individual States may take against Allergan under applicable legal authorities or under any applicable settlement agreement or consent decree between the State and Allergan.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Allergan 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 Allergan fails to establish, implement, or accomplish any of the following obligations as described in Section III:

- a. a Chief Compliance Officer;
- b. a U.S. Compliance Committee;
- c. the resolution from the Board;
- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons and Relevant Covered Persons;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings;
- j. notification of written communications with FDA as required by Section III.I;
- k. a program for FFMP as required by Section III.J;
- l. a program for Non-Promotional Monitoring Activities as required by Section III.K;
- m. notification to HCPs and HCIs as required by Section III.L;
- n. posting of any Payments as required by Section III.M;
- o. the reporting of any Reportable Event.

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

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

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Allergan fails to submit the annual IRO Review Report(s) in accordance with the requirements of Section III.D and Appendices A-B.

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

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

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

B. Timely Written Requests for Extensions. Allergan 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 Allergan 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 Allergan 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 Allergan 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 Allergan of: (a) Allergan'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, Allergan 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 Allergan elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Allergan 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 Allergan 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 repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- c. 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 Allergan constitutes an independent basis for Allergan's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Allergan has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Allergan of: (a) Allergan'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.* Allergan 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. Allergan 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) Allergan has begun to take action to cure the material breach; (ii) Allergan is pursuing such action with due diligence; and (iii) Allergan has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Allergan fails to satisfy the requirements of Section X.D.3, OIG may exclude Allergan from participation in the Federal health care programs. OIG shall notify Allergan in writing of

its determination to exclude Allergan (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 Allergan’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, Allergan 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 Allergan 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, Allergan 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 Allergan was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Allergan 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 Allergan to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Allergan 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 Allergan 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) Allergan had begun to take action to cure the material breach within that period; (ii) Allergan has pursued and is pursuing such action with due diligence; and (iii) Allergan provided to OIG within that period a reasonable timetable for curing the material breach and Allergan 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 Allergan, only after a DAB decision in favor of OIG. Allergan's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Allergan 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 Allergan 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. Allergan 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 Allergan, Allergan 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

Allergan and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Allergan;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;
- D. The undersigned Allergan 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; and
- E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF ALLERGAN, INC.



Rose-Karen Swanson
Chief Compliance Officer
Allergan, Inc.

8/30/10

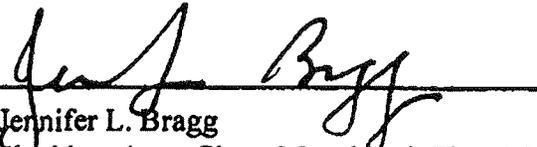
Date



John T. Bentivoglio
Skadden, Arps, Slate, Meagher & Flom LLP
Counsel for Allergan, Inc.

8/30/10

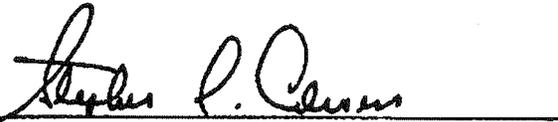
Date



Jennifer L. Bragg
Skadden, Arps, Slate, Meagher & Flom LLP
Counsel for Allergan, Inc.

8/30/10

Date



Stephen S. Cowen
King & Spalding LLP
Counsel for Allergan, Inc.

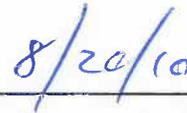
8/30/10

Date

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



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



DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

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

If Allergan 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, Allergan shall submit the information identified in Section V.A.10 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 Allergan if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Allergan may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional Functions and to Product Related Functions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Allergan's Government Reimbursed Products are reimbursed;
2. assign individuals to design and select the samples for the Transaction Reviews who are knowledgeable about the appropriate statistical sampling techniques; and
3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each IRO Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;
3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy, or regulation, request clarification from the appropriate authority (e.g., CMS or FDA);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the IRO Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Allergan.

E. IRO Removal/Termination.

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

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

Prior to requiring Allergan to engage a new IRO, OIG shall notify Allergan 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, Allergan 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. Allergan

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

Appendix B to CIA Promotional and Product Related Review

I. Promotional and Product Related Review, General Description

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

If there are no material changes in Allergan's systems, processes, policies, and procedures relating to Promotional and Product Related Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Allergan materially changes its systems, processes, policies, and procedures relating to Promotional and Product Related Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) described in Section III.D.1.b of the CIA shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

II. IRO Systems Review

A. Description of Reviewed Policies and Procedures

The Promotional and Product Related Systems Review shall be a review of Allergan's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Promotional and Product Related Functions. Where practical, Allergan personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Allergan pursuant to the preceding sentence.

Specifically, the IRO shall review Allergan’s systems, processes, policies, and procedures associated with the following (hereafter “Reviewed Policies and Procedures”):

1) Allergan’s systems, policies, processes, and procedures applicable to the manner in which Allergan sales representatives handle and submit requests or inquiries to Medical Affairs relating to information about the uses of products (including non-FDA-approved (i.e., off-label) uses) and the dissemination of materials relating to off-label uses of products. This review includes:

- a) the manner in which Allergan sales representatives handle and submit or generate requests for information about off-label uses of products to Medical Information (including through the Information Request Management System (IRMS));
- b) the manner in which Medical Information personnel handle and respond to requests for information about off-label uses (including tracking the requests and using the materials provided in response to the request);
- c) the form and content of information and materials related to Products disseminated to physicians, pharmacists, or other health care professionals (collectively “HCPs”) or health care institutions (HCIs) by Allergan;
- d) Allergan's systems, processes, and procedures (including the Inquiries Database) used to track requests for information about off-label uses of products and responses to those requests;
- e) the manner in which Allergan collects and supports information reported in any systems used to track and respond to requests for product information, including the Inquiries Database;
- f) the processes and procedures by which Medical Information and Allergan’s Corporate Compliance Department or their designees monitor and identify situations in which it appears that improper off-label promotion may have occurred; and
- g) Allergan's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;

2) Allergan’s systems, processes, policies and procedures applicable to the manner and circumstances under which personnel from Medical Affairs (e.g., Regional Scientific Services, or RSS) interact with or participate in meetings or events with HCPs or HCIs (either alone or with sales

representatives) and the role of the medical personnel at such meetings or events, including the manner in which they handle responses to unsolicited requests about off-label indications of Products. This includes any Medical Affairs Monitoring Plan designed to monitor the activities of the RSMs;

3) Allergan's systems, policies, processes, and procedures relating to Allergan's internal review and approval of information and materials related to products disseminated to HCPs or HCIs by Allergan;

4) Allergan's systems, processes, policies, and procedures relating to incentive compensation for Relevant Covered Persons who are sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Allergan's products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Allergan establishes different systems, processes, policies, or procedures relating to compensation for different products, the IRO shall review each type of compensation arrangement separately;

5) Allergan's systems, processes, policies, and procedures relating to the development and review of Call Plans (as defined in Section III.B.3.j of the CIA). This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the Call Plans based on, among other factors, expected utilization of products for FDA-approved uses or non-FDA-approved uses;

6) Allergan's systems, processes, policies, and procedures relating to sample distribution. This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Allergan (including, separately, from Allergan sales representatives and other Allergan personnel or components). It shall also include a review of whether samples of Products are distributed by Allergan through sales representatives or are distributed from a central location and the rationale for the manner of distribution;

7) Allergan's systems (including any centralized electronic system), processes, policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;

8) Allergan's systems, processes, policies, and procedures relating to non-speaker related consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, presentations, consultant task force meetings, advisory boards, preceptorships, mentorships (if any), and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;

9) Allergan's systems, processes, policies and procedures relating to the submission of information about any product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the Product ("Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information, (e.g., any changes based on Allergan's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia.) The review shall also assess Allergan's processes relating to its annual review of all arrangement, processing fees, or other payments or financial support (if any) provided by the company to any Compendia;

10) Allergan's systems, processes, policies, and procedures relating to investigator-initiated trials (IITs) including the decision to provide financial or other support for those studies; the manner in which support is provided for the IITs; and support for publication of the information about those studies, including publication of information about the trial outcomes and results and the uses made of publications relating to those studies;

11) Allergan's systems, processes, policies and procedures relating to authorship or any articles or other publications about products or therapeutic areas or disease states that may be treated with products, including, but not limited to, the disclosure of any and all relationships between the author and Allergan, the identification of all authors or contributors (including professional writer, if any) associated with a given publication, and the scope and breadth of research results made available to each author or contributor; and

12) Allergan's systems, processes, policies, and procedures relating to the provision of reimbursement support services, including the controls around the provision of such services; the manner in which Allergan provides reimbursement support services; the frequency with which Allergan provides such services; and the determination about which HCPs or HCIs will be eligible to receive such services. The review shall also assess

Allergan's processes relating to its annual review of reimbursement support services as referenced in Section III.B.3.f of the CIA.

B. IRO Systems Review Report

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

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of Allergan's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-12 above, including a general description of Allergan's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
- 3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-12 above are made known or disseminated within Allergan;
- 4) a detailed description of any system(s) used to track and respond to requests for information about Allergan's products (including the Inquiries Database);
- 5) a detailed description of Allergan's incentive compensation system for Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Allergan may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;
- 6) findings and supporting rationale regarding any weaknesses in Allergan's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
- 7) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

III. IRO Transaction Review

As described more fully below in Sections III.A-E, the Transactions Review shall include: (1) a review of a sample of Inquiries reflected in the Inquiries Database; (2) a review of Allergan's Call Plans and Allergan's Call Plan review process; (3) a review of Sampling Events as defined below in Section III.C; (4) a review of records relating to a sample of the Payments that are reported by Allergan pursuant to Section III.M of the CIA; and (5) a review of up to three additional items identified by the OIG in accordance with Section III.D.1.b of the CIA (hereafter "Additional Items".) The IRO shall report on all aspects of its reviews in the Promotional and Product Related Transactions Review Reports.

A. Review of Inquiries and Inquiries Database

1) Description of Inquiries Database

As set forth in Section III.B.3.h of the CIA, Allergan shall establish a database (Inquiries Database) to track information relating to all requests for information received by Allergan about its products (Inquiries). Allergan shall record in the Inquiries Database the following information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, medical information request form); 3) name of requesting HCP or HCI; 4) nature and topic of request including exact language of the Inquiry (if made in writing); 5) nature/form of the response from Allergan (including a record of any materials provided in response to the request); and 6) the name of the Allergan representative who called upon or interacted with the HCP or HCI, if known.

2) Internal Review of Inquiries Database

On a semi-annual basis, the Chief Compliance Officer, or a designee, shall review the Inquiries Database and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters (Inquiry Report). The Chief Compliance Officer shall review the Inquiry Reports to assess whether the information contained in the report suggests that improper off-label promotion may have occurred in connection with any Inquiry(ies). If the Chief Compliance Officer, in consultation with other appropriate Allergan personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, the Chief Compliance Officer shall initiate a follow-up review of the Inquiry (Off-Label Review), make specific findings based on his/her Off-Label Review, and take all appropriate responsive action (including

disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.H of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of 50 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. Forty of the Inquiries reviewed by the IRO shall be Inquiries for which Allergan conducted an Off-Label Review, and the other 10 shall be Inquiries for which Allergan did not conduct an Off-Label Review. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section III.A.1 is reflected in the Inquiries Database for each reviewed Inquiry; and
- b) For each Inquiry for which the Chief Compliance Officer conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Chief Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by Allergan based on the Off-Label Review findings.

B. IRO Review of Allergan's Call Plans and Call Plan Review Process

The IRO shall conduct a review and assessment of Allergan's review of its Call Plans as set forth in Section III.B.3.j of the CIA. Allergan shall provide the IRO with: i) a list of products promoted by Allergan during the Reporting Period; ii) information about the FDA-approved uses for each Allergan product; and iii) the Call Plans for each product. Allergan shall also provide the IRO with information about the reviews of Call Plans that Allergan conducted during the Reporting Period and any modifications to the Call Plans made as a result of Allergan's reviews.

For each Call Plan, the IRO shall select a sample of 50 of the HCPs and HCIs included on the Call Plan. For each Call Plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by Allergan in conducting its review and/or modification of the Call Plan in order to determine whether Allergan followed its criteria and Policies and Procedures in reviewing and modifying the Call Plan.

The IRO shall note any instances in which it appears that the sampled HCPs and HCIs on a particular Call Plan are inconsistent with Allergan's criteria relating to the Call

Plan and/or Allergan's Policies and Procedures. The IRO shall also note any instances in which it appears that Allergan failed to follow its criteria or Policies and Procedures.

C. IRO Review of the Distribution of Samples of Allergan Products

The IRO shall conduct a review and assessment of the distribution of samples of Allergan products to HCPs and HCIs. Allergan shall provide the IRO with: i) a list of products for which Allergan distributed samples during the Reporting Period; ii) information about the FDA-approved uses for each Allergan product; and iii) information about Allergan's policies and procedures relating to the distribution of samples of each type of product, including Allergan's Call Plan showing which particular medical specialties or types of clinical practices are eligible to receive samples. Allergan shall also provide the IRO with information about the reviews of Call Plans that Allergan conducted during the Reporting Period and any modifications to the plans made as a result of Allergan's reviews.

For each product for which Allergan distributed samples during the Reporting Period, the IRO shall randomly select a sample of 30 separate instances in which Allergan provided samples of the product to HCPs or HCIs. Each such instance shall be known as a "Sampling Event."

For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP or HCI. The reviewed materials shall include materials about the following: 1) the quantity, dosage, and form of the Allergan product provided to the HCP or HCI; 2) the identity and type of medical specialty or clinical practice of the HCP or HCI; 3) which individual Allergan sales representative or department (e.g., medical services) provided the sample to the HCP or HCI; 4) the manner and mechanism through which the sample was requested (e.g., sample request form, letter or call to Medical Information department); and 5) the manner and mechanism through which the request was fulfilled (e.g., sales representative distribution or direct shipment.)

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the product approved by the FDA and whether the sample was distributed by a Allergan representative in a manner consistent with Allergan's sample distribution policy for the product(s) provided during the Sampling Event. To the extent that a sample was provided to an HCP or HCI by an Allergan representative other than a sales representative, the IRO shall contact the HCP or HCI by letter. The letter shall request that the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (e.g.,

conversations with a Allergan sales representative, conversation with a representative of Allergan’s Medical Information department, independent research or knowledge of the HCP or HCI, etc.)

For each Sampling Event, the IRO shall compare the medical specialty and type of clinical practice of the HCPs and HCIs that received the sample with uses of the product approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the product approved by the FDA. For each such situation, the IRO shall note the process followed by Allergan in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. The IRO shall also note any instances in which it appears that Allergan failed to follow its Call Plan for the product(s) provided during the Sampling Event.

D. IRO Review of Physician Payment Listings

1. Information Contained in Physician Payment Listings

As set forth in Section III.M of the CIA, in phases, Allergan shall post quarterly and annual listings of physicians and Related Entities who received Payments, as defined in the CIA, directly or indirectly from Allergan. For purposes of the IRO review as set forth in this Section III.D, each annual listing shall be referred to as the “Physician Payment Listing” or “Listing.” For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) full name; ii) name of Related Entity (if applicable); iii) city and state of the physician’s practice or the Related Entity; and iv) the aggregate value of the Payment(s) in the preceding year.

For purposes of this IRO review, the term “Control Documents” shall include all documents or electronic records associated with each Payment reflected in the Physician Payments Listing for the sampled physician and/or Related Entity. For example, the term “Control Documents” includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by sales representatives or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

2. Selection of Sample for Review

For each Reporting Period, the OIG shall have the discretion to identify up to 50 physicians or Related Entities from the applicable Physician Payment Listing that will be

subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the physicians and/or Related Entities subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 physicians and/or Related Entities to be included in the review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in Listing identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

3. IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Allergan's policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the value of the Payment(s) reflected in the Control Documents; and
- d) Whether the Control Documents reflect that Allergan's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with Allergan's policies.)

4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:
 - i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
 - ii. the IRO cannot confirm that Allergan otherwise followed its policies and procedures relating to the entry in the

Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or

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

If a Control Document does not exist, but Allergan has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that Allergan otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

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

E. IRO Review of Additional Items

As set forth in Section III.D.1.b of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items".) No later than 150 days prior to the end of the applicable Reporting Period, the OIG shall notify Allergan 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 Allergan 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. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Allergan's systems, processes, policies, and procedures based on its review of each Additional Item.)

Allergan may propose to the OIG that its internal audit(s) and/or reviews conducted as part of the Field Force Monitoring Program (FFMP) described in Section III.J of the CIA or the Non-Promotional Monitoring Program described in Section III.K of the CIA be 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 Allergan's internal audit work and monitoring activities to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Allergan's planned monitoring activities and internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Allergan's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Allergan's request to permit its monitoring activities or internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Allergan shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of Allergan's monitoring activities or 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 (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Allergan in its internal audits.

F. Promotional and Product Related Transactions Review Report

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

- 1) General Elements to Be Included in Report
 - a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
 - b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
 - c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Promotional and Product Related Transactions Review.
- 2) Results to be Included in Report

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

(Relating to the Review of Inquiries)

- a) in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (e.g., the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;
- b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the Inquiries Database;
- c) for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the Inquiries Database; and (ii) for each Inquiry for which an Off-Label Review was conducted, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Chief Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by Allergan as a result of the Chief Compliance Officer's findings;
- d) the findings and supporting rationale regarding any weaknesses in Allergan's systems, processes, policies, procedures, and practices relating to the Inquiries, and the Inquiries Database, if any;
- e) recommendations for improvement in Allergan's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

(Relating to the Call Plan Reviews)

- f) a list of the products promoted by Allergan during the Reporting Period and a summary of the FDA-approved uses for such products;
- g) for such Allergan products: i) a description of the criteria used by Allergan in developing or reviewing the Call Plans and for including or excluding specified types of HCPs or HCIs from the Call Plans; ii) a description of the review conducted by Allergan of the Call Plans and an indication of whether Allergan reviewed the Call Plans as required by Section III.B.3.j of the CIA; iii) a description of all

instances for each Call Plan in which it appears that the HCPs and HCIs included on the Call Plan are inconsistent with Allergan's criteria relating to the Call Plan and/or Allergan's Policies and Procedures; and iv) a description of all instances in which it appears that Allergan failed to follow its criteria or Policies and Procedures relating to Call Plans or the review of the Call Plans;

- h) the findings and supporting rationale regarding any weaknesses in Allergan's systems, processes, policies, procedures, and practices relating to Allergan's Call Plans or the review of the Call Plans, if any;
- i) recommendations, if any, for changes in Allergan's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to Call Plans or the review of the Call Plans;

(Relating to the Sampling Event Reviews)

- j) for each Allergan product distributed during the Reporting Period: i) a description of the Call Plan (including whether sales representatives may provide samples of the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice a sales representative may provide samples); ii) a detailed description of any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the product approved by the FDA. This description shall include a description of the process followed by Allergan in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iii) a detailed description of any instances in which it appears that Allergan failed to follow its Call Plan for the product(s) provided during the Sampling Event;
- k) the findings and supporting rationale regarding any weaknesses in Allergan's systems, processes, policies, procedures, and practices relating to Allergan's distribution of samples of Allergan products, if any;
- l) recommendations, if any, for changes in Allergan's systems, processes, policies, procedures, and practices that would correct or

address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples;

(Relating to the Physician Payment Listing Reviews)

- m) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;
- n) for each sampled physician or Related Entity, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable Allergan policy; (iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that Allergan's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (v) any corrective action or disciplinary action was undertaken in those instances in which Allergan policies were not followed;
- o) for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;
- p) if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Additional Items)

- q) for each Additional Item reviewed, a description of the review conducted;
- r) for each Additional Item reviewed, the IRO's findings based on its review;

- s) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Allergan's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
- t) for each Additional Item reviewed, recommendations, if any, for changes in Allergan's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.