

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

**I. PREAMBLE**

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

Aegerion represents that, prior to the Effective Date (as defined below), it implemented a compliance program that includes the following elements with regard to its business operations in the United States: a compliance officer, a compliance committee, training and education, policies and procedures, a hotline for reporting compliance issues, and monitoring and auditing activities (the "Compliance Program"). Aegerion shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Aegerion may modify its Compliance Program as appropriate but, at a minimum, Aegerion shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

## **II. TERM AND SCOPE OF THE CIA**

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

B. Sections VII, X, and XI shall expire no later than 120 days after OIG=s receipt of: (1) Aegerion's final Annual Report; or (2) any additional materials submitted by Aegerion 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 Aegerion who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading) and all directors of Aegerion and Novelon Therapeutics Inc.;
- b. all officers and employees of Aegerion and all officers and employees of Novelon Therapeutics Inc. and Novelon Services USA, Inc. who are engaged in or who supervise personnel who are engaged in Covered Functions (as defined below in Section II.C.7); and
- c. all contractors, subcontractors, agents, and other persons (including contract sales personnel) who perform any of the Covered Functions on behalf of Aegerion, and in that capacity either: (i) interact directly with healthcare professionals (HCPs), healthcare institutions (HCIs), Payors (as defined below in Section II.C.6) or consumers; or (ii)

perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by an Aegerion employee who is a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term Covered Persons does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours during a Reporting Period, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the Reporting Period.

2. "Relevant Covered Persons" includes all Covered Persons who engage in any of the Covered Functions and all individuals who supervise Covered Persons who engage in any of the Covered Functions.

3. "Government Reimbursed Products" refers to all Aegerion products that are: (a) marketed or sold by Aegerion in the United States (or pursuant to contracts with the United States) and (b) 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 Aegerion's review and approval processes for promotional materials and any applicable review committee(s).

5. The term "Product Related Functions" includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to HCPs, HCIs, and Payors about Government Reimbursed Products, including those functions relating to any applicable review committees and those functions relating to Medical Affairs; (b) contracting with HCPs licensed to practice medicine in the United States or with U.S. HCIs, including for the purposes of conducting post-marketing clinical trials; Investigator-Initiated Studies (IISs) about Government Reimbursed Products, and any

other types of post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; (d) to the extent applicable to Aegerion, activities related to the submission of information about Government Reimbursed Products to compendia (such as Drugdex or other compendia of information about Government Reimbursed Products); and (e) activities relating to the provision of instructions or advice to HCPs and HCIs regarding the preparation or submission of claims, statements of medical necessity, or other related documents or information in order to obtain coverage or reimbursement for Government Reimbursed Products.

6. The term "Payor Related Functions" refers to Promotional Functions and Product Related Functions as they relate to interactions (including contracting functions) between Aegerion and entities that provide a drug health benefit program for Government Reimbursed Products, including but not limited to government payors (e.g., Medicaid and Medicare) or individuals or entities under contract with or acting on behalf of government payors (such as PBMs) and commercial health plans (collectively referred to as "Payors"). Payor Related Functions also includes interactions with Payors related to formulary placement, contracting, and rebate activities involving Government Reimbursed Products, including those involving supplemental rebate agreements, and other types of rebate agreements.

7. The term "Covered Functions" refers to "Promotional Functions," "Product Related Functions," and/or "Payor Related Functions" collectively.

8. The term "Third Party Educational Activity" shall mean any scientific, educational, or professional program, meeting, or event for HCPs that are intended to be independent of Aegerion's control or influence conducted by a third party and supported by Aegerion, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

Aegerion shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations.

1. *Compliance Officer.* Within 90 days after the Effective Date, Aegerion shall appoint an individual to serve as its Vice President Ethics and Compliance (Compliance Officer). Aegerion shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. The Compliance Officer shall be an employee and a member of senior management of Aegerion and shall report directly to the President of Aegerion. The Compliance Officer shall also report to the Global Chief Compliance Officer who, in turn, reports to the Chief Executive Officer of Novilion Therapeutics Inc. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Novilion Therapeutics Inc. or a committee thereof (hereafter "Board") and shall be authorized to report on such matters to the Board at any time. Written documentation of the Compliance Officer's reports to the Board shall be made available to OIG upon request.

The Compliance Officer shall not be, or be subordinate to, the General Counsel or the Chief Financial and Administration Officer of Novilion Therapeutics Inc. or the Vice President Corporate Counsel of Aegerion. The Compliance Officer shall not have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Aegerion, Novilion Therapeutics Inc., or Novilion Services USA, Inc. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Aegerion as well as for any reporting obligations created under this CIA. Any job responsibilities of the Compliance Officer unrelated to compliance shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee.* Within 90 days after the Effective Date, Aegerion shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., executives or heads of relevant departments who have knowledge and oversight of compliance matters within such departments, such as sales, marketing, legal, medical affairs, regulatory affairs, clinical, human resources, finance, technical operations, and quality). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Aegerion's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Board of Directors Compliance Obligations.* The Board 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 must include independent (i.e., non-executive) members.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee Aegerion's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the Compliance Program and in support of making the resolution below during each Reporting Period; and

- c. for each Reporting Period of the CIA, adopting a resolution, signed by each individual member of the Board, summarizing its review and oversight of Aegerion'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 has made a reasonable inquiry into the operations of Aegerion's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Aegerion has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Aegerion.

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

4. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Aegerion officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Aegerion business unit is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: (i) the following officers or employees of Novelion Therapeutics Inc., by virtue of Novelion Therapeutics Inc.'s contractual service obligations to Aegerion: the Global Chief Compliance Officer; the Chief Commercial

Officer; the Head of Research & Development; and the Chief Financial and Administration Officer; and (ii) the following officers or employees of Aegerion: the President & Chief Accounting Officer; the Senior Vice President of Technical Operations; the Senior Vice President of Medical Affairs; the President of Commercial U.S.; the Senior Vice President of Regulatory; the Vice President of Clinical Development; and the Senior Vice President of Global Market Access, Patient Advocacy and REMS; and (iii) to the extent that an Aegerion business unit performs Covered Functions and is not covered by the certifications of one of the above-listed individuals, such other Aegerion executives, vice presidents, or leaders of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit engaged in Covered Functions.

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 [insert name of department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the \_\_\_\_\_ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Aegerion policies, and I have taken steps to promote such compliance. To the best of my knowledge, the \_\_\_\_\_ [insert name of department or functional area] of Aegerion is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 120 days after the Effective Date, Aegerion shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the

certification required by this section (e.g., reports that must be reviewed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

**B. Written Standards.**

Within 120 days after the Effective Date, Aegerion shall implement written policies and procedures regarding the operation of its Compliance Program, including the Compliance Program requirements outlined in this CIA and Aegerion's compliance with Federal health care program and FDA requirements (Policies and Procedures). Throughout the term of this CIA, Aegerion shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element in evaluating the performance of all employees who are Covered Persons.

At a minimum, the Policies and Procedures shall address the following:

- a. appropriate ways to conduct Promotional Functions in compliance with all: (i) 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); and (ii) all applicable FDA requirements;
- b. appropriate ways to conduct Product Related Functions in compliance with: (i) 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); and (ii) all applicable FDA requirements;
- c. appropriate ways to conduct Payor Related Functions in compliance with all: (i) applicable Federal health care program, requirements, including but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§

3729-3733); (ii) applicable FDA requirements; and (iii) other applicable requirements, including state laws;

- d. the materials and information that may be distributed by Aegerion sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which Aegerion sales representatives respond to requests for information about non-FDA approved uses of Government Reimbursed Products. These Policies and Procedures shall require that sales representatives: (i) not engage (directly or indirectly) in promotion of Government Reimbursed Products for non-approved uses (i.e., sales representatives shall not promote the products for usages, dosages, length of treatment, or patient populations other than those in, or consistent with, the FDA-approved label); (ii) use only materials that have been reviewed and approved consistent with Policies and Procedures; and (iii) refer all requests for information about for non-approved uses of Government Reimbursed Products to the Medical Affairs department;
- e. 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 from an HCP or another individual or entity about the use of Government Reimbursed Products for non-approved uses; the form and content of information disseminated by Aegerion in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Aegerion develop a database for use by Medical Affairs (Inquiries Database) to track all requests for information about Government Reimbursed Products made to Medical Affairs. The Inquiries Database shall include the following

items of information for each unique inquiry (Inquiry) received for information about Government Reimbursed Products: (i) date of Inquiry; (ii) form of Inquiry (e.g., fax, phone, etc.); (iii) name of the requesting HCP, HCI, or other individual or entity; (iv) nature and topic of request (including exact language of the Inquiry if made in writing); (v) an evaluation of whether the Inquiry relates to information about a non-approved use of a product; (vi) nature/form of the response from Aegerion (including a record of the materials provided to the HCP or HCI in response to the request); and (vii) the name of the Aegerion representative who called on or interacted with the HCP, customer, or HCI, if known;

- f. the manner and circumstances under which Aegerion Medical Science Liaisons (MSLs) interact with or participate in meetings or events with HCPs, HCIs, or Payors (either alone or with Aegerion sales representatives) and the role of the MSLs at such meetings or events, as well as how they handle responses to requests for information about uses of Government Reimbursed Products for non-approved uses. These Policies and Procedures shall require that MSLs not engage (directly or indirectly) in the promotion of Government Reimbursed Products for non-approved uses;
- g. the materials and information that may be distributed or made available by Aegerion through social media and/or direct-to-consumer advertising. These Policies and Procedures shall be designed to ensure that Aegerion's activities in this area and the information distributed or made available comply with all applicable Federal health care program and FDA requirements, and have been reviewed and approved by the applicable review committee(s) of Aegerion before they are posted or disseminated;

- h. the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other Aegerion representatives who promote and sell Government Reimbursed Products. For each Government Reimbursed Product, the Policies and Procedures shall require that Aegerion 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 Aegerion modify the call plans as necessary to ensure that Aegerion is promoting 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;
- i. the development, implementation, and review of all plans for the distribution of samples of, or coupons or vouchers for, Government Reimbursed Products (Sample Distribution Plans). 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, coupons, or vouchers from Aegerion (including, separately, from sales representatives, from Medical Affairs, or through other channels). The Policies and Procedures shall also require that Aegerion modify the Sample Distribution Plans as necessary to ensure that Aegerion is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;
- j. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker

programs (if applicable), speaker training programs, presentations, consultant task force meetings, advisory boards, 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;

- k. programs by HCPs to educate sales representatives (if applicable), including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities. 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;
- l. sponsorship or funding of Grants (as defined below in Section III.M.3). These Policies and Procedures shall be designed to ensure that Aegerion's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- m. arrangements and interactions with (including donation funding of, sponsorship, or contributions to) independent third-party patient assistance programs (Independent Charity PAPs). These Policies and Procedures shall be designed to ensure that Aegerion's arrangements and donation funding

comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall also be designed to ensure that Aegerion's arrangements, interactions, and funding comply with all guidance issued by the OIG relating to the support and funding of patient assistance programs (OIG Guidance), including but not limited to the OIG's Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005) and OIG's Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014);

- n. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.8 above. These Policies and Procedures shall be designed to ensure that the Third Party Educational Activity has a genuine educational purpose and function, appropriate disclosures of Aegerion's funding or participation are made, and that Aegerion's funding or participation satisfies all applicable Federal health care program and FDA requirements;
- o. review of promotional, reimbursement, and disease state materials and information intended to be disseminated in the United States 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 Aegerion'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: (i) applicable review committees review all promotional materials prior to the distribution or use of such materials; (ii) the copy review and approval process ensure that FDA communications relevant

to the product are considered and appropriately reflected in promotional materials; and (iii) deviations from the standard review committee practices and protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;

- p. compensation (including through salaries, bonuses, or other means) for sales representatives or their direct managers. These Policies and Procedures shall: (i) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Aegerion's Government Reimbursed Products; and (ii) include mechanisms, where appropriate, to exclude from incentive (variable) compensation sales that indicate improper promotion of Government Reimbursed Products has occurred;
- q. if applicable to Aegerion, 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 (hereafter "Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (including any changes based on Aegerion's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results);
- r. sponsorship or other support of post-marketing clinical trials and all other post-marketing studies of Government Reimbursed Products and support of IISs conducted by U.S.-based HCIs or U.S.-licensed HCPs (collectively, "Research"), including the decision to provide financial or other support

for such Research; the manner in which Research support is provided; the publication of information about the Research (including the publication of information about the Research results and trial outcomes); and uses made of publications relating to Research;

- s. authorship of journal 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 financial relationships between the author and Aegerion or other potential conflicts of interest that might bias the author's work; 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
- t. disciplinary policies and procedures for violations of Aegerion's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

The Policies and Procedures shall be made available to all Covered Persons.

At least annually (and more frequently, if appropriate), Aegerion shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education.

1. *Training Plan.* Within 90 days after the Effective Date, Aegerion shall develop a written plan (Training Plan) that outlines the steps Aegerion will take to

ensure that: (a) all Covered Persons receive adequate training regarding Aegerion's CIA requirements and Compliance Program; and (b) all Relevant Covered Persons receive adequate training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions and (ii) all Aegerion Policies and Procedures and other requirements applicable to Covered Functions.

The Training Plan shall include information regarding the following: (i) training topics; (ii) the categories of Covered Persons and Relevant Covered Persons required to attend each training session; (iii) the length of the training; (iv) the schedule for training; and (v) the format of the training. Aegerion shall furnish training to its Covered Persons and Relevant Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 120 days after the Effective Date, Aegerion shall provide at least two hours of training to each member of the Board. This training shall address Aegerion's CIA requirements and Compliance Program, the corporate governance responsibilities of Board members, and the responsibilities of Board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of OIG's guidance on Board member responsibilities.

New members of the Board shall receive the Board Member Training described above within 30 days after becoming a Board member or within 120 days after the Effective Date, whichever is later.

3. *Training Records.* Aegerion shall make available to OIG, upon request, training materials and records verifying that Covered Persons and Relevant Covered Persons and Board members have timely received the training required under this section.

D. Risk Assessment and Mitigation Process.

Within 120 days after the Effective Date, Aegerion shall implement a centralized annual risk assessment and mitigation process (RAMP) as further described in this Section III.D and Appendix B. The RAMP shall require compliance, legal and business unit leaders, at least annually, to evaluate and identify risks associated with Aegerion's participation in Federal health care programs and the risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products. Based on the outcomes of the risk-identification component of the RAMP, Aegerion legal, compliance and other personnel shall centrally develop and implement specific plans designed to mitigate or reduce the identified risks. The risk mitigation plans shall be developed annually and a plan shall be developed for each Government Reimbursed Product. Aegerion shall implement the risk mitigation plans and shall track the implementation of the mitigation plans. The RAMP shall be reviewed by the IRO, and the IRO review of the process is described in more detail in Appendix B. Aegerion shall maintain the RAMP for the duration of the CIA.

E. Review Procedures.

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Aegerion shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Aegerion in assessing and evaluating its Covered Functions and its RAMP. More specifically, the IRO(s) shall conduct reviews that assess Aegerion's systems, processes, policies, procedures, and practices relating to the Covered Functions and the RAMP (collectively, "IRO Reviews"). The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

- b. *Retention of Records.* The IRO and Aegerion shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Aegerion) related to the IRO Reviews.

2. *System, Transaction, and Additional Items Reviews.* As set forth more fully in Appendix B, the IRO Reviews shall consist of two components: Systems Reviews and Transactions Reviews. The Systems Reviews shall assess Aegerion's systems, processes, policies, and procedures relating to the Covered Functions and RAMP. If there are no material changes in Aegerion's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the second and fourth Reporting Periods. If Aegerion 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 second and fourth Reporting Periods, as set forth more fully in Appendix B.

The Transactions Reviews 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, as set forth in Appendix B, each Transactions Review shall also include a review of up to three additional areas or practices of Aegerion identified by 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, OIG will consult with Aegerion and may consider internal audit and monitoring work conducted by Aegerion, the Government Reimbursed Product portfolio, the nature and scope of Aegerion's promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Appendix B, Aegerion may propose to 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. OIG retains sole discretion over whether, and in what manner, to allow Aegerion's internal audit and

monitoring work to be substituted for any portion of the Additional Items review conducted by the IRO.

OIG shall notify Aegerion of the nature and scope of the IRO review for each of the Additional Items not later than 120 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or Aegerion shall submit an audit work plan to OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by OIG.

3. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO Review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendices A-B.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Aegerion a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A. The IRO's certification shall include a summary of all current and prior engagements between Aegerion and the IRO.

F. Disclosure Program.

Within 90 days after the Effective Date, Aegerion shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Aegerion's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Aegerion shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Aegerion's Covered Persons shall be expected to report

suspected violations of any Federal health care program and/or FDA requirements to the Compliance Officer or other appropriate individuals designated by Aegerion.

Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all 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, Aegerion shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log which includes a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The Compliance Officer (or designee) shall record each disclosure in the disclosure log within two business days of receipt of the disclosure.

G. Ineligible Persons.

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

- a. an "Ineligible Person" shall include an individual or entity who:
  - i. is currently excluded from participation in the Federal health care 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.
- b. "Exclusion List" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at

<http://www.oig.hhs.gov>);

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

- a. Aegerion shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Aegerion shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a quarterly basis thereafter.
- c. Aegerion shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

3. *Removal Requirement.* If Aegerion has actual notice that a Covered Person has become an Ineligible Person, Aegerion shall remove such Covered Person from responsibility for, or involvement with, Aegerion's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation is paid in whole or part, directly or indirectly, by any Federal health care

program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If Aegerion 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, Aegerion 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, or the accuracy of any claims submitted to any Federal health care program.

H. Employee and Executive Incentive Compensation Restriction Program and Executive Financial Recoupment Program.

Aegerion agrees to develop and maintain throughout the term of the CIA policies and procedures for sales personnel (including sales representatives, sales managers, rare disease partners, and sales trainers) that shall: (1) be designed to ensure that financial incentives do not improperly motivate sales personnel to engage in improper promotion, sales, or marketing of Aegerion's products; (2) include mechanisms, where appropriate, to exclude from incentive (variable) compensation any sales under circumstances indicating that improper promotion of Aegerion's products may have occurred; and (3) provide for the internal review and analysis of all variable compensation prior to payment (Variable Compensation Program). The specific terms and conditions of the Variable Compensation Program are described in Appendix C to this CIA.

Aegerion agrees to establish and maintain throughout the term of this CIA a financial recoupment program (Executive Financial Recoupment Program) that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay for a Covered Executive if the individual or his/her subordinates engaged in significant misconduct as described in greater detail in Appendix C. The specific terms and conditions of the Executive Financial Recoupment Program are described in Appendix C.

I. Notification of Government Investigation or Legal Proceeding.

Within 30 days after discovery, Aegerion shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Aegerion conducted or brought by a governmental entity or its agents involving an allegation that Aegerion, Novelion Therapeutics Inc., or Novelion Services USA, Inc. 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. Aegerion 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 proceeding, if any.

J. 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 FDA requirements relating to the promotion of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.K below;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by Aegerion.

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

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

3. *Reportable Events under Sections III.J.1.a and III.J.1.b.* For Reportable Events under Sections III.J.1.a and III.J.1.b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event;
- c. the Federal health care program and/or FDA authorities affected by the Reportable Event; and
- d. a description of Aegerion's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.1.c, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Persons employment or contractual relationship;

- c. a description of the Exclusion List screening that Aegerion completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Reportable Event was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA authorities implicated.

K. Notification of Communications with FDA.

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

L. Field Force Monitoring and Review Efforts.

Within 120 days after the Effective Date, Aegerion shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's (or contracted sales personnel's) interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential improper promotional activities or other improper conduct. As described in

more detail below, the FFMP shall include: (1) direct field observations (Observations) of sales personnel; (2) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews); and (3) if applicable, a Speaker Monitoring Program

1. *Observations.* As a component of the FFMP, Aegerion compliance or other appropriately trained Aegerion personnel who are independent from the functional area being monitored or appropriately trained contractors engaged by Aegerion (collectively "Monitoring Personnel") shall conduct observations of field sales representatives and remote telephonic sales representatives (including any contract field or remote telephonic sales personnel) to assess whether the messages delivered and materials distributed to HCPs and HCIs, as applicable, are consistent with applicable legal requirements and with Aegerion's Policies and Procedures. Each Observation of a field sales representative shall be a ride-along that consists of directly observing all meetings between such sales representative and HCPs and HCIs during the workday. Each Observation of a remote telephonic sales representative shall be a "listen-along" that consists of listening to live or recorded telephone calls or other communications between such sales representatives and HCPs and HCIs during a workday, or other communications between such sales representatives and HCPs and HCIs, or a combination of both.

The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, include a review of each therapeutic area (as applicable) and actively promoted Government Reimbursed Product, and be conducted across the United States.

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Monitoring Personnel who conducted the Observation;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Aegerion's Policies and Procedures; and

- 6) the identification of any potential improper promotional activity or other improper conduct by the field or remote telephonic sales representative.

Monitoring Personnel shall conduct at least 15 Observations during each Reporting Period.

2. *Records Reviews.* As a component of the FFMP, Aegerion shall also review various types of records to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations. For each Reporting Period, Aegerion shall develop and implement a plan for conducting Records Reviews associated with at least two Government Reimbursed Products. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate district and/or region (as applicable) who promoted the Government Reimbursed Products under review.

These Records Reviews shall include the monitoring and review of the following: (1) records and systems associated with field sales representatives' interactions with HCPs and HCIs (including records relating to consultant activities, samples, travel and entertainment, expense reports, any payments to HCPs or HCIs, speaker program activities and/or and sales communications from managers); (2) to the extent purchased by Aegerion, message recall studies or other similar records (such as Verbatims) purporting to reflect the details of representatives interactions with HCPs and HCIs; (3) records relating to requests for medical information about or Inquiries relating to, the Government Reimbursed Products under review; (4) field sales representative call notes; (5) field sales representatives' e-mails and other electronic records; and (6) recorded results of the Observations of field sales force representatives, coaching guides, and district manager notes.

3. *Speaker Program Activities.* If during the term of the CIA, Aegerion institutes the practice of speaker programs, it shall comply with the requirements set forth in this Section III.L.3.

Aegerion shall implement a process 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

regarding the use of Aegerion approved materials and requirements that speakers may not directly or indirectly promote the product for non-approved uses.) Aegerion shall establish a centralized, electronic system to initiate and track all speaker programs that includes controls designed to ensure that speaker programs are used for legitimate and lawful purposes in accordance with all applicable Federal health care program and FDA requirements. The controls shall also be designed to ensure that there is a legitimate need for the speaker programs.

Aegerion shall ensure that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by or for Aegerion. Aegerion shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, Aegerion shall use its centralized system to handle all logistics and spending associated with speaker programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs. Aegerion shall require certifications by sales representatives or other Aegerion personnel that a speaker program complied with Aegerion requirements, or in the event of non-compliance, Aegerion shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

Aegerion shall institute a Speaker Monitoring Program under which Monitoring Personnel shall attend a designated number of speaker programs during each Reporting Period and conduct live audits of the programs (Speaker Program Audits). The number of programs to be audited shall be determined by OIG after taking into account the number of speaker programs conducted by Aegerion. The programs subject to Speaker Program Audits shall be judgmentally selected by Monitoring Personnel. For each program reviewed, Monitoring Personnel shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and Aegerion sales representative activities during the program to assess whether the programs were conducted in a manner consistent with Aegerion's Policies and Procedures. Aegerion shall maintain the controls around speaker programs, as described above, and shall conduct its Speaker Program Audits, as described above, throughout the term of the CIA.

4. *Reporting and Follow-up.* Monitoring Personnel shall have access to all relevant records and information necessary to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations. Results from the FFMP shall be compiled and reported to the Compliance Officer for review and remediation as appropriate. Potential violations related to improper promotion of a Government Reimbursed Product or potential violations of Federal health care program or FDA requirements shall be reported to the Compliance Officer for appropriate follow-up activity. In the event that a compliance issue, including but not limited to any potential improper promotion or noncompliance with Aegerion's Policies and Procedures or legal or compliance requirements, is identified during any portion of the FFMP, Aegerion shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the investigative procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events pursuant to Section III.J above, as applicable. Any compliance issues identified during the FFMP and any corrective action shall be recorded in the files of the Compliance Officer.

As required by Section V.B.16, Aegerion 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, Aegerion also shall provide 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 Aegerion took as a result of such determinations. Aegerion shall make the Observation reports for all other Observations available to OIG upon request.

M. Monitoring of Non-Promotional Activities.

Within 120 days after the Effective Date, Aegerion shall develop and implement a monitoring program for its (1) consultant arrangement activities; (2) donations to Independent Charity PAPs; and (3) Grants. This program shall be referred to as the Non-Promotional Monitoring Program (NPMP).

1. *Consulting Arrangement Activities.* To the extent that Aegerion engages HCPs for services other than for speaker programs (e.g., as a member of an advisory board, to attend a consultant meeting, or to conduct Research), such HCPs shall

be referred to herein as Consultants. Aegerion shall require all Consultants to enter written agreements describing the scope of work to be performed, the consultant fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by or for Aegerion.

Within 90 days after the Effective Date, Aegerion shall establish a process to develop an annual budgeting plan that identifies the business needs for, and the estimated numbers of, the various Consultant engagements and activities to occur during the following year. The annual Consultant budgeting plan shall also identify the budgeted amounts to be spent on Consultant-related activities. Aegerion compliance personnel shall be involved in the review and approval of such 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 and lawful purposes in accordance with applicable Federal health care program and FDA requirements and Aegerion Policies and Procedures.

Within 90 days after the Effective Date, Aegerion shall establish a process to ensure that a needs assessment has been completed 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 and HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and the type of work product to be generated). Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Aegerion compliance personnel.

Within 120 days after the Effective Date, Aegerion shall confirm or 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, Aegerion received the work product generated by the Consultant.

Within 120 days after the Effective Date, Aegerion shall establish a Consultant Monitoring Program through which it shall conduct audits (Consultant Program Audits) of at least 15 engagements/arrangements with HCPs during each Reporting Period. The

Consultant Monitoring Program shall judgmentally select Consultant arrangements for review. However, the numbers of the various types of arrangements to be reviewed (e.g., advisory boards, non-promotional speaker programs, etc.) shall be proportional to the numbers of the types of arrangements.

Monitoring Personnel 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 Aegerion's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of Aegerion policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow up as appropriate.

2. *Activities Relating to Independent Third-Party Patient Assistance Programs.* Aegerion has represented that it does not currently make monetary donations to Independent Charity PAPs. To the extent that Aegerion changes its practice and resumes making monetary donations to Independent Charity PAPs during the term of the CIA, it shall comply with the provisions of this Section III.M.2.

Role and Responsibilities of Independent Charity Group. Aegerion shall vest sole responsibility and authority for budgeting and other activities relating to Independent Charity PAPs (including interactions with such PAPs) in a department or group within Aegerion (Independent Charity Group) that is separate and independent from the commercial business units of Aegerion (including from the sales and marketing departments). The Independent Charity Group shall operate independently from Aegerion's commercial organization. Aegerion's commercial organization shall have no involvement in, or influence over, the review, approval, or implementation of any budget or other decisions or activities relating to arrangements with or funding of Independent Charity PAPs.

The Independent Charity Group shall be the exclusive component of Aegerion that is authorized to or responsible for communicating with, or receiving information from, Independent Charity PAPs. The commercial organization shall not influence or be involved in any such communications. Within Aegerion, the Independent Charity Group

shall not share information related to donations to Independent Charity PAPs or donations to any specific disease state funds with the commercial organization. Members of the commercial organization (such as sales representatives) shall not be permitted to discuss specific Independent Charity PAPs or the disease state funds of such Independent Charity PAPs with HCPs or patients.

Budgeting Process. Aegerion's Independent Charity Group shall establish a budget process to be followed for Aegerion donations to Independent Charity PAPs. The Independent Charity Group shall develop the annual budget for donations to Independent Charity PAPs based on objective criteria in accordance with general guidelines approved by the Legal Department (with input from the Compliance Department.) The commercial organization shall have no involvement in the budget process for donations to Independent Charity PAPs. Aegerion shall approve the annual budget for donations to Independent Charity PAPs at a level above the commercial organization (e.g., at the executive level). After the annual budget is approved, the Independent Charity Group shall have sole responsibility (with no involvement from the commercial organization) for allocating the approved budget across donations to Independent Charity PAPs and to any disease state funds established by the Independent Charity PAPs.

The Independent Charity Group shall have sole responsibility for assessing requests for additional or supplemental funding from Independent Charity PAPs outside of the annual budget. Such requests shall be assessed against standardized, objective criteria established by the Independent Charity Group (with input from legal and compliance). Aegerion legal and compliance personnel shall also be involved in the review and approval of requests for additional/supplemental funding, as requested by the Independent Charity Group. The purpose of this review shall be to ensure that any supplemental funding to the Independent Charity PAP is provided in accordance with applicable Federal health care program requirements, OIG Guidance, and Aegerion Policies and Procedures.

Criteria/Contractual Terms Relating to Donations to Independent Charity PAPs. The Independent Charity Group (with input from the Legal Department and Compliance Departments) shall establish standardized, objective written criteria that govern donations to Independent Charity PAPs and any specific disease state funds of such Independent Charity PAPs. The criteria shall be designed to ensure that the Independent Charity PAP

does not function as a conduit for payments or other benefits from Aegerion to patients and does not impermissibly influence patients' drug choices.

Aegerion's Independent Charity Group shall gather information about Independent Charity PAPs and their disease funds in a manner that does not exert or attempt to exert any direct or indirect control over the entity operating the Independent Charity PAP or over its assistance program. Aegerion shall not influence or attempt to influence, directly or indirectly, the identification, delineation, establishment, or modification of, or the parameters relating to, any disease state fund operated by the Independent Charity PAP.

Aegerion shall not provide donations to any Independent Charity PAP or to any disease state fund of an Independent Charity PAP until after a written agreement is executed and in place between Aegerion and the entity operating the Independent Charity PAP (Charity Entity) relating to the donation. Such agreement shall be reviewed and approved by personnel from Aegerion's Legal and Compliance Departments prior to execution. The donations to the Independent Charity PAPs shall be provided only pursuant to, and in a manner consistent with, the written agreement.

The written agreement between Aegerion and the Charity Entity shall preclude Aegerion from exerting (directly or through any affiliate) any influence or control over the Charity Entity or its assistance program. More specifically, the written agreement shall include the following terms at a minimum:

- 1) Aegerion does not and shall not exert (directly or through any affiliate) any influence or control over the identification, delineation, establishment, or modification of any specific disease state funds operated by the Charity Entity. Among other things, Aegerion has not made and shall not make (directly or through any affiliate) suggestions or requests to the Charity Entity about the identification, delineation, establishment, or modification of disease state funds;
- 2) Aegerion does not and shall not exert (directly or through any affiliate) any direct or indirect influence or control over the Charity Entity's process or criteria for determining eligibility of patients who qualify for its assistance program(s);

- 3) Aegerion does not and shall not solicit or receive (directly or indirectly through third parties) any data or information from the Charity Entity that would enable it to correlate the amount or frequency of its donations with support for Aegerion's Government Reimbursed Products or any related services; and
- 4) Aegerion does not and shall not provide donations for a disease state fund that covers only a single product or that covers only Aegerion's Government Reimbursed Products.

Aegerion shall continue the Independent Charity PAP processes described above (or equivalent processes) throughout the term of the CIA, and shall notify the OIG in writing at least 60 days prior to the implementation of any modifications to the process described above.

PAP Review Program. Within 90 days after the Effective Date, Aegerion shall establish an Independent Charity PAP Review Program (PAP Review Program) through which it shall conduct annual audits of donations to Independent Charity PAPs. The number of programs to be audited shall be determined by OIG after taking into account the number of Aegerion's donations to Charity Entities and to the disease state funds of those entities. The PAP Review Program shall judgmentally select donations for review.

Monitoring Personnel shall review, to the extent available: 1) budget documents; 2) documents relating to any decision to provide donations to a particular Independent Charity PAP; 3) the written agreements in place between Aegerion and the Charity Entities; 4) correspondence and other documents reflecting communications and interactions between the Aegerion and the Independent Charity PAPs; and 5) any other available information relating to the arrangements and interactions between Aegerion and the Independent Charity PAPs. The purpose of the PAP Review Program shall be to assess whether the activities were conducted in a manner consistent with Aegerion's Policies and Procedures described above and with OIG Guidance. Results from the PAP Review Program, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

3. *Grant Activities.* Within 120 days after the Effective Date, Aegerion shall confirm that it has established or shall establish a grants management system which shall be the exclusive mechanism through which requestors may request or be awarded grants for Third Party Educational Activities, other similar grant activities, and non-patient assistance program charitable contributions supported by Aegerion (collectively "Grants"). Aegerion's sales and marketing personnel shall have no involvement in, or influence over, the review and approval of Grant requests. Grant requests shall be submitted through a centralized Grants management system and processed in accordance with standardized, objective criteria developed by Aegerion (such as based upon the qualifications of the requestor, or the quality of the program funded by the Grant.) In addition, the Grants shall be provided only pursuant to a written agreement with the funding recipient, and if payments to the funding recipient are consistent with the written agreement. Aegerion shall continue the 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.

Within 120 days after the Effective Date, Aegerion shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 5 Grants. The Grants Monitoring Program shall judgmentally select Grants for review. Monitoring Personnel shall review proposal documents (including Grant requests), approval documents, contracts, payments and materials relating to the Grant management system'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 were conducted in a manner consistent with Aegerion's Policies and Procedures. Results from the Grants Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

4. *Follow Up Reviews and Reporting.* In the event that a potential violation of Aegerion's Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, is identified during any aspect of the NPMP, Aegerion 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.J above, if applicable.

As required by Section V.B.17, Aegerion shall include a summary of the NPMP and the results of the NPMP as part of each Annual Report. As part of each Annual Report, Aegerion also shall provide OIG with descriptions of any instances identified through the NPMP in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated Aegerion's Policies and Procedures, and a description of the action(s) that Aegerion took as a result of such determinations. Aegerion shall make the documents relating to the NPMP available to OIG upon request.

N. Notice to Health Care Providers and Entities. Within 30 days after the Effective Date, Aegerion shall post in a prominent place on the main page of its company website that is likely to be accessed by HCPs (or other placement agreed to in advance by the OIG), a copy of a letter signed by Aegerion's Board Chair containing the language set forth below:

As you may be aware, Aegerion Pharmaceuticals, Inc. (Aegerion) recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with Aegerion's promotion and sales of its product Juxtapid. This letter provides you with additional information about the global settlement, explains Aegerion's commitments going forward, and provides you with access to information about those commitments.

In general terms, the Government alleges that Aegerion engaged in several types of unlawful and improper conduct. More specifically, the Government alleges that Aegerion unlawfully distributed Juxtapid for intended uses not approved by FDA and failed to comply with a Risk Evaluation and Mitigation Strategy required by the FDA for Juxtapid. The Government also alleges that certain Aegerion employees made false and misleading statements about Juxtapid, that the company violated certain patient privacy requirements, and that Aegerion made payments to an independent charity for patient co-payment assistance that violated the

#### Anti-kickback Statute.

To address these issues, Aegerion pleaded guilty to violating the Federal Food, Drug, and Cosmetic Act and agreed to pay approximately \$7 million in criminal fines and forfeiture. Aegerion also entered into a five-year Deferred Prosecution Agreement to resolve claims that it violated the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Separately, Aegerion agreed to enter into a civil Consent Decree of Permanent Injunction to be monitored by the U.S. Food and Drug Administration (FDA).

In addition, the federal government and several individual states alleged that Aegerion's conduct violated the federal False Claims Act and equivalent state statutes. To resolve those allegations, Aegerion entered into a separate civil False Claims Act settlement whereby Aegerion agreed to reimburse federal and state health care programs approximately \$29 million.

Finally, the Securities and Exchange Commission alleged that Aegerion's conduct violated federal security statutes. To resolve those allegations, Aegerion entered into a separate civil securities settlement whereby Aegerion agreed to pay approximately \$4 million. Copies of and more information about these settlements may be found at the following website: <https://www.justice.gov/civil/current-and-recent-cases# Pharm2>

As part of the global settlement, Aegerion 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, Aegerion 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 Aegerion's representatives to Aegerion's Compliance organization or the FDA using the information set out below.

Please call Aegerion at 1-855-463-8974 or visit us at <http://novelion.com/about-novelion/aegerion-pharmaceuticals/aegerion-government-settlement> if you have questions about the settlement referenced above. Please call Aegerion at 1-855-233-8089 or visit us at <https://novelioncompliance.tnwreports.com> to report any instances in which you believe that an Aegerion representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by an Aegerion Representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about Aegerion products to 1-855-303-2347 or <http://www.novelion.com/physician-resources/global-medical-information>.

The notice shall remain posted for a period of at least 180 days. The 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 log of all calls and messages received in response to the notice shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, Aegerion shall provide to OIG a summary of the calls and messages received.

O. Reporting of Physician Payments.

1. *Reporting of Payment Information.* Within 90 days after the Effective Date, Aegerion shall post on its website a description of the types of Payments it makes to Covered Recipients and include a link to CMS's Open Payments Data website ([www.openpaymentsdata.cms.gov](http://www.openpaymentsdata.cms.gov)). Aegerion also shall include on its website instructions regarding how to utilize the CMS Open Payments Data search tool to search for information regarding Payments provided to Covered Recipients from Aegerion.

2. *Definitions.* For purposes of this Section III.M, the terms "Payments" and "Covered Recipient" are defined as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by CMS.

P. Other Transparency/Disclosure Initiatives. Within 120 days after the Effective Date, Aegerion shall begin posting on its company website the following information with respect to all Grants: (i) the name of the recipient; (ii) the program name and a brief description of the program; and (iii) the amount of the Grant. Aegerion shall post (and provide updates to) the above-described information about Grants on at least an annual basis throughout the term of this CIA. Aegerion shall notify OIG in writing at least 60 days prior to any change in the substance of its policies regarding the funding of Grants or posting of the above-referenced information relating to such funding.

#### IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Aegerion proposes to: (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) that are engaged in any Covered Functions or subject to the CIA, or (b) purchase or establish a new business, business unit or location related to or engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any new business, business unit, or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG.

If, in advance of a proposed sale or a proposed purchase, Aegerion wishes to obtain a determination by OIG that the proposed purchaser or proposed acquisition will not be subject to the requirements of the CIA, Aegerion must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the proposed purchaser.

#### V. IMPLEMENTATION AND ANNUAL REPORTS

##### A. Implementation Report.

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

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations referenced in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4 and a written copy of the process followed to complete the certification requirements set forth in Section III.A.4;
5. a list of all Policies and Procedures required by Section III.B;
6. the Training Plan required by Section III.C.1 and a description of the Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);
7. a description of the RAMP required by Section III.D;
8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Aegerion;
9. a description of the Disclosure Program required by Section III.F;
10. a description of the Ineligible Persons screening and removal process required by Section III.G;

11. a certification by the Compliance Officer that the notice required by Section III.N was posted in the manner required by Section III.N and a summary of the calls or messages received in response to the notice;

12. a certification from the Compliance Officer that the information regarding Payments and the link to CMS's Open Payments Data website has been posted on Aegerion's website as required by Section III.O;

13. a list of all of Aegerion's U.S.-based locations (including locations and mailing addresses); the corresponding name under which each location is doing business; and the location's Medicare and state Medicaid program provider number and/or supplier number(s) (if applicable);

14. a description of or a table depicting Aegerion's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

15. the certifications required by Section V.C.

B. Annual Reports.

Aegerion shall submit to OIG a report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board compliance obligations, and a current list of the Certifying Employees along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, and Certifying Employees;

2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);
3. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed and the process followed by the Board, as well as any additional steps taken in its oversight of the Compliance Program and in support of making the resolution;
4. a list of any new or revised Policies and Procedures developed during the Reporting Period;
5. a description of any changes to Aegerion's Training Plan developed pursuant to Section III.C and a summary of any Board training provided during the Reporting Period;
6. a description of any changes to the RAMP required by Section III.D, including the reasons for such changes;
7. a summary of the following components of the RAMP during the Reporting Period: mitigation or work plans developed, internal audits performed or commissioned, corrective action plans developed in response to such audits, and steps taken to track the implementation of the corrective action plans. Copies of any mitigation or work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;
8. a complete copy of all reports prepared pursuant to Section III.E and Appendix B, and Aegerion's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
9. a certification from the IRO regarding its professional independence and objectivity with respect to Aegerion;
10. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or Government Reimbursed Products, including at least the following information: a

description of the disclosure, the date the disclosure was received, the resolution of the disclosure, and the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

11. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G., including the reasons for such changes;

12. a summary of any changes to the Variable Compensation Program or the Executive Financial Recoupment Program required by Section III.H and Appendix C and the information required to be reported pursuant to Appendix C;

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

14. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period;

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

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

17. a summary of the NPMP and the results of the program described in Section III.M, including detailed description of any identified instances in which it was determined that the activities violated Aegerion's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) Aegerion took as a result of such determinations;

18. a summary of the calls and messages received in response to the

notice required by Section III.N and the disposition of those calls and messages;

19. a certification from the Compliance Officer that information regarding Payments has been posted on Aegerion's website as required by Section III.O which may be provided as part of the certification described in Section V.C.2;

20. a description of all changes to the most recently provided list of Aegerion's locations (including addresses) as required by Section V.A.13; and

21. the certifications required by Section V.C.

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

C. Certifications.

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

2. *Compliance Officer and President of Aegerion.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and the President of Aegerion that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Aegerion is in compliance with the requirements of this CIA;
- b. 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;
- c. Aegerion's: (i) Policies and Procedures as referenced in Section III.B above; (ii) templates for standardized contracts and other similar documents; and (iii) the training materials used for purposes of Section III.C all have been reviewed by

competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Aegerion's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Aegerion have been reviewed by competent regulatory, medical, or, as appropriate, legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by Aegerion and brought to the attention of the appropriate individuals when required, 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 legal counsel. 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

- d. Aegerion's call plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.h) and, for each product the call plans were found to be consistent with Aegerion's Policies and Procedures referenced above in Section III.B.h.

D. Designation of Information.

Aegerion 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. Aegerion shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for

exemption from disclosure under FOIA.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

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

### OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: (202) 619-2078  
Facsimile: (202) 205-0604

### Aegerion:

Craig Clesson  
Vice President, Ethics and Compliance Officer  
Aegerion Pharmaceuticals, Inc.  
One Main Street, Suite 800  
Cambridge, MA 02142  
Telephone: (857) 242-5134  
Email: [compliance.us@aegerion.com](mailto:compliance.us@aegerion.com)

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Aegerion may be required to provide OIG with an electronic copy of each notification or report required by this CIA 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 and/or request copies of Aegerion's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Aegerion's locations for the purpose of verifying and evaluating: (a) Aegerion's compliance with the terms of this CIA; and (b) Aegerion'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 Aegerion to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Aegerion's Covered Persons 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. Aegerion shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Aegerion's Covered Persons may elect to be interviewed with or without a representative of Aegerion present.

## **VIII. DOCUMENT AND RECORD RETENTION**

Aegerion shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and 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 Aegerion prior to any release by OIG of information submitted by Aegerion pursuant to its obligations under this CIA and identified upon submission by Aegerion as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Aegerion shall have the rights set forth at 45 C.F.R. § 5.65(d).

## **X. BREACH AND DEFAULT PROVISIONS**

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

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

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board's compliance obligations;
- d. the management certification obligations;
- e. written Policies and Procedures;
- f. training and education of Covered Persons, Relevant Covered Persons, and Board members;
- g. a RAMP;
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements;
- j. notification of Government investigations or legal proceedings;

- k. reporting of Reportable Events;
- l. notification of written communications with FDA as required by Section III.K;
- m. the FFMP required by Section III.L;
- n. the NPMP required by Section III.M;
- o. notification to HCPs and HCIs as required by Section III.N;
- p. posting of any Payment-related information as required by Section III.O; and
- q. implementation of the other requirements described in Section III.P.

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 Aegerion fails to engage and use an IRO as required by Section III.E and Appendices A and 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 Aegerion fails to submit a complete Implementation Report, Annual Report or any certification 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 Aegerion fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

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

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Aegerion as part of its Implementation Report, any 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 Aegerion fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Aegerion stating the specific grounds for its determination that Aegerion has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Aegerion shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Aegerion 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. Aegerion 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 Aegerion 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 days after Aegerion 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 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 Aegerion 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 Aegerion of: (a) Aegerion'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, Aegerion 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 Aegerion elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Aegerion 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.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Aegerion 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. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by Aegerion to report a Reportable Event and take corrective action as required in Section III.J;
- c. a failure to engage and use an IRO in accordance with Section III.E and Appendices A-B; or

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

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Aegerion constitutes an independent basis for Aegerion's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Aegerion has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Aegerion of: (a) Aegerion'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.* Aegerion shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

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

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Aegerion fails to satisfy the requirements of Section X.D.3, OIG may exclude Aegerion from participation in the Federal health care programs. OIG shall notify Aegerion in writing of its determination to exclude Aegerion. (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 Aegerion's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Aegerion 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 Aegerion 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, Aegerion 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. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

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 Aegerion was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Aegerion 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 Aegerion to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Aegerion 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 whether Aegerion was in material breach of this CIA and, if so, whether:

- a. Aegerion cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Aegerion's receipt of the Notice of Material Breach: (i) Aegerion had begun to take action to cure the material breach; (ii) Aegerion pursued such action with due diligence; and (iii) Aegerion provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Aegerion, only after a DAB decision in favor of OIG. Aegerion's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Aegerion 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 Aegerion 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. Aegerion 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 Aegerion, Aegerion 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**

Aegerion and OIG agree as follows:

- A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.
- B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.
- C. All requirements and remedies set forth in this CIA are in addition to and do not affect: (1) Aegerion's responsibility to follow all applicable Federal health care program and FDA requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program and FDA requirements.
- D. The undersigned Aegerion signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.
- E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF AGERION PHARMACEUTICALS, INC.**

/Barbara Chan/

\_\_\_\_\_  
**BARBARA CHAN**  
President and Chief Accounting Officer  
Aegerion Pharmaceuticals, Inc.

9/18/17  
DATE

/Craig A. Clesson/

\_\_\_\_\_  
**CRAIG CLESSON**  
Vice President, Ethics and Compliance Officer  
Aegerion Pharmaceuticals, Inc.

9/18/2017  
DATE

/Brett R. Friedman/

\_\_\_\_\_  
**JOSHUA S. LEVY**  
**BRETT R. FRIEDMAN**  
Ropes & Gray LLP  
Counsel for Aegerion Pharmaceuticals, Inc.

9/18/2017  
DATE

*Corporate Integrity Agreement  
Aegerion Pharmaceuticals, Inc.*

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

/Lisa M. Re/

\_\_\_\_\_  
LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

9/22/17  
DATE

/Mary E. Riordan/

\_\_\_\_\_  
MARY E. RIORDAN  
Senior Counsel  
Office of Counsel to the Inspector General

9/22/17  
DATE

*Corporate Integrity Agreement  
Aegerion Pharmaceuticals, Inc.*

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

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

#### A. IRO Engagement

1. Aegerion 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 the information identified in Section V.A.8 of the CIA or any additional information submitted by Aegerion in response to a request by OIG, whichever is later, OIG will notify Aegerion if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Aegerion may continue to engage the IRO.

2. If Aegerion engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Aegerion shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Aegerion at the request of OIG, whichever is later, OIG will notify Aegerion if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Aegerion may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and in all applicable Federal health care program and FDA requirements relating to Covered Functions and RAMP, including but not limited to expertise relating to marketing and promotional activities associated with pharmaceutical products. The assigned individuals also shall be experienced in risk identification and mitigation relating to pharmaceutical product marketing and promotion and knowledgeable about the general requirements of the Federal health care program(s) under which Government Reimbursed Products are reimbursed;

2. assign individuals to design and select the samples for the IRO Transactions 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. respond to all OIG inquiries in a prompt, objective, and factual manner; and
4. 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 each component of the IRO Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

E. IRO Removal/Termination

1. *Aegerion and IRO.* If Aegerion terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Aegerion must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Aegerion must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Aegerion in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Aegerion shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's

qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Aegerion regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Aegerion in writing that Aegerion shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Aegerion must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Aegerion to engage a new IRO shall be made at the sole discretion of OIG.

**Appendix B to CIA for  
Aegerion Pharmaceuticals, Inc.  
IRO Reviews**

**I. IRO Engagement, General Description**

As specified more fully below, Aegerion shall retain an Independent Review Organization(s) (IRO) to perform engagements to assist Aegerion in assessing and evaluating its systems, processes, policies, and procedures related to Aegerion's Covered Functions (as defined in the CIA) and Risk Assessment and Mitigation Process (RAMP) (collectively "IRO Review"). The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Aegerion may engage, at its discretion, a single entity to perform both components of the IRO Reviews, provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Aegerion's systems, processes, policies, and procedures relating to Covered Functions or RAMP, the IRO shall perform the Systems Review for the second and fourth Reporting Periods. If Aegerion materially changes its systems, processes, policies, and procedures relating to Covered Functions or its RAMP, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review as set forth above. The additional Systems Review(s) 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**

The Systems Review shall be a review of Aegerion's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Covered Functions and RAMP. Where practical, Aegerion 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 Aegerion pursuant to the preceding sentence.

More specifically, the IRO shall review Aegerion's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1) Aegerion's systems, policies, processes, and procedures applicable to the manner in which Aegerion sales personnel and personnel from the Medical Affairs department (or other department that undertakes a medical affairs function (hereafter "Medical Affairs")) handle requests or inquiries 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 shall include an assessment of the following:

- a) the manner in which Aegerion sales representatives and other sales personnel (including any member of a contract sales force) handle requests for information about off-label uses of products (*e.g.*, by referring all such requests to Medical Affairs), including the Inquiries Database that Aegerion uses to collect, process, and/or store such information;
  - b) the manner in which Medical Affairs personnel handle and respond to requests for information about off-label uses (including tracking the requests and using or distributing materials provided in response to the request);
  - c) the form and content of information and materials related to Government Reimbursed Products disseminated to HCPs, HCIs, or other individuals or entities outside Aegerion;
  - d) Aegerion'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 Aegerion 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 Affairs and Aegerion's Compliance Officer or compliance department monitor and identify situations in which it appears that improper promotion may have occurred; and
  - g) Aegerion's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;
- 2) Aegerion's systems, processes, policies and procedures applicable to the manner and circumstances under which Medical Science Liaisons (MSLs) interact with or participate in meetings or events with HCPs, HCIs, or payors (either alone or with sales

representatives) and the role of the MSLs at such meetings or events, including the manner in which they handle responses to requests about off-label indications of Government Reimbursed Products;

3) Aegerion's systems, policies, processes, and procedures relating to Aegerion's internal review and approval of information and materials relating to Government Reimbursed Products that are disseminated in the United States to individuals or entities outside Aegerion (including HCPs, HCIs, and payors);

4) Aegerion's systems, processes, policies, and procedures relating to incentive (variable) compensation for sales personnel (including, for the purposes of this review, employed and contracted sales representatives, sales managers, rare disease partners, and sales trainers) 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 Government Reimbursed 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 Aegerion establishes different systems, processes, policies, or procedures relating to compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;

5) Aegerion's systems, processes, policies, and procedures relating to the development and review of call plans (as described in Section III.B.h 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) If applicable, Aegerion's systems, processes, policies, and procedures relating to Sample Distribution Plans (as described in Section III.B.i of the CIA). 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 Aegerion (including, separately, from Aegerion sales representatives and other Aegerion personnel or components). It shall also include a review of whether samples of Government Reimbursed Products are distributed by Aegerion through sales representatives or are distributed from a central location and the rationale for the manner of distribution;

7) Aegerion'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) Aegerion's systems, processes, policies, and procedures relating to non-speaker related consultant arrangements entered into with HCPs or HCIs (including, but not limited to, presentations, consultant task force meetings, advisory boards, preceptorships, 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) Aegerion's systems, processes, policies and procedures relating to the funding of Grants (as defined in Section III.M.3 of the CIA) and all events and expenses relating to such activities;
- 10) Aegerion's systems, processes, policies and procedures relating to arrangements with (including donation funding of, sponsorship, or contributions to) independent third-party patient assistance programs;
- 11) if applicable, Aegerion'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");
- 12) Aegerion's systems, processes, policies, and procedures relating to Research (as defined in Section III.B.r of the CIA) including the decision to provide financial or other support for Research; the manner in which support is provided for the Research; and publication of the information about the Research, including publication of information about the trial outcomes and results and the uses made of publications relating to Research;
- 13) Aegerion's systems, processes, policies and procedures relating to authorship-related practices (as referenced in Section III.B.s of the CIA) including, but not limited to, the disclosure of any and all relationships between any author and Aegerion, 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;
- 14) Aegerion's systems, processes, policies and procedures relating to its RAMP, including but not limited to, a review of the: (i) the sources and types of information used in connection with the risk assessment (e.g., the individual personnel, departments or functional areas, and/or any data and systems involved); and (ii) the timing for development of the risk assessment and risk mitigation plans;
- 15) An assessment of whether, in developing the risk assessment or risk mitigation plans: (i) additional or different sources of information should be utilized; (ii) additional

or different types of data or information should be utilized; and (iii) additional or different timing cycles should be utilized;

16) A review of the experience and background of personnel responsible for the development of the risk assessment and risk mitigation plans; and an assessment of the completeness and appropriateness of the relevant training, policies, procedures, standard operating procedures, and guidance each such individual receives;

17) An assessment of whether risk monitoring and audit activities related to RAMP: (i) adequately identify and monitor all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential sales, marketing or promotional risk; and/or (iii) prevent reoccurrence of any problems associated with an identified risk;

18) An assessment of whether risk monitoring and audit activities related to the RAMP should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; and/or (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific Aegerion products reviewed; and

19) A review of the systems, policies, procedures, and processes by which Aegerion tracks and manages RAMP review and mitigation activities and an assessment of whether the systems, policies, procedures and processes ensure that risk mitigations plans are appropriately implemented and completed (including by identifying individuals responsible for the follow-up action items).

### **III. 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 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 Aegerion's systems, policies, processes, and procedures relating to the items identified in Sections II.1-19 above, including a general description of Aegerion'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.1-19 above are made known or disseminated within Aegerion;
- 4) a detailed description of any system(s) used to track and respond to requests for information about Aegerion's products (including the Inquiries Database);
- 5) a detailed description of Aegerion's variable compensation system for sales personnel as described above in Section II.4, 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 Aegerion may establish compensation differently for different Government Reimbursed Products, the IRO shall report separately on each such type of compensation arrangement;
- 6) whether the risk monitoring and risk mitigation activities associated with RAMP identify relevant risks and address identified risks;
- 7) whether sufficient controls exist to ensure that all monitoring and mitigation activities are tracked and monitored appropriately;
- 8) whether RAMP (including the options for risk mitigation activities) potentially mitigates identified risks;
- 9) whether sufficient controls exist to ensure that all agreed-upon risk monitoring activities and risk mitigation action items are implemented and completed as planned pursuant to RAMP;
- 10) findings and supporting rationale regarding any weaknesses in Aegerion's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures (including RAMP), if any; and
- 11) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures (including RAMP), if any.

#### **IV. IRO Transactions Review**

As described more fully below in Sections IV.A-C, the Transactions Review shall include: (1) a review of Aegerion's call plans and Aegerion's call plan review process; (2) a review of records relating to a sample of the Payments that are reported by Aegerion to CMS as referenced in Section III.O of the CIA; and (3) a review of up to three additional items identified by the OIG in accordance with Section III.E.2 of the CIA (hereafter "Additional Items".) The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

##### **A. IRO Review of Aegerion's Call Plans and Call Plan Review Process**

The IRO shall conduct a review and assessment of Aegerion's call plan process described in Section III.B.h of the CIA. Aegerion shall provide the IRO with: i) a list of Government Reimbursed Products promoted by Aegerion sales representatives (including contract sales representatives) during the Reporting Period; ii) information about the FDA-approved uses for each Government Reimbursed Product; and iii) the call plans for each Government Reimbursed Product. Aegerion shall also provide the IRO with information about the reviews of call plans that Aegerion conducted during the Reporting Period and any modifications to the call plans made as a result of Aegerion's reviews.

For each call plan, the IRO shall randomly 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 Aegerion in conducting its review and/or modification of the call plan in order to determine whether Aegerion 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 Aegerion's criteria relating to the call plan and/or Aegerion's Policies and Procedures. The IRO shall also note any instances in which it appears that Aegerion failed to follow its criteria or Policies and Procedures.

##### **B. IRO Review of Physician Payment Listings**

###### **1. Information to Be Reviewed**

As referenced in Section III.O of the CIA, Aegerion reports to CMS Payments to Covered Recipients that are listed on the Open Payments Data website. For purposes of this portion of the IRO Review, the term "Control Documents" shall include all material documents or electronic records associated with each Payment reflected in Open Payments database for the applicable calendar year. For example, the term "Control

Documents” includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments; contracts relating to the Payments; documents relating to the occurrence of Payments; documents reflecting any work product generated in connection with the Payments; documents submitted by sales representatives or headquarters personnel to request approval for the Payments; and business rationale or justification forms relating to the Payments.

## 2. Selection of Sample for Review

For each Reporting Period, the OIG shall have the discretion to identify up to 50 Covered Recipients who received Payments from Aegerion during the prior calendar year and 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 Covered Recipients to be included in the review.

For each selected Covered Recipient, the IRO shall review Control Documents associated with the Payments to the Covered Recipient for all categories reflected in the Open Payments Data website except for the Food/Beverage and Travel/Lodging categories of Payments.

## 3. IRO Review of Control Documents for Selected Covered Recipients

For each Covered Recipients 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 reported to CMS to evaluate the following:

- a) Whether Control Documents are available relating to each Payment for the sampled Covered Recipient;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Aegerion’s policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the information reported to CMS for the sampled Covered Recipient is consistent with the value of the Payment(s) reflected in the Control Documents; and
- d) Whether the Control Documents reflect that Aegerion’s policies were followed in connection with Payment(s) reflected in the report to CMS (e.g., all required written approvals for the activity were obtained in accordance with Aegerion’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 for the sampled Covered Recipient do not exist and:
  - i. no corrective action was initiated prior to the selection of the sampled Covered Recipient; or
  - ii. the IRO cannot confirm that Aegerion otherwise followed its policies and procedures relating to the Payment for the sampled Covered Recipient, including its policies and procedures relating to any Payment(s); or
- b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Aegerion'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 Aegerion has initiated corrective action prior to the selection of the sampled Covered Recipients, or if a Control Document does not exist but the IRO can determine that Aegerion otherwise followed its policies and procedures with regard to each Payment, 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.

#### C. IRO Review of Additional Items

As set forth in Section III.E.2 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".) If during the term of the CIA, Aegerion enters arrangements with (including donation funding of, sponsorship, or contributions to) any independent third-party patient assistance program, such arrangements will be subject to an IRO review under this Section IV.C.

No later than 150 days prior to the end of the applicable Reporting Period, the OIG shall notify Aegerion 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 Aegerion 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 Aegerion's systems, processes, policies, and procedures based on its review of each Additional Item.)

Aegerion 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.L of the CIA or the Non-Promotional Monitoring Program (NPMP) described in Section III.M of the CIA be substituted for one or more of the Additional Item reviews that would otherwise be conducted by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Aegerion's internal audit work 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 Aegerion's planned monitoring activities and internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Aegerion's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Aegerion's request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Aegerion shall engage the IRO to perform the Review as outlined in this Section IV.

If the OIG agrees to permit certain of Aegerion's internal audit work for a given Reporting Period to be substituted for a portion of an Additional Items review, such internal work shall 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 Aegerion in its internal audits.

#### D. Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Reviews. 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 Transactions Review.

## 2. Results to be Included in Report

The following results shall be included in each Transactions Review Report:

(Relating to the Call Plan Reviews)

- a) a list of the Government Reimbursed Products promoted by Aegerion during the Reporting Period and a summary of the FDA-approved uses for such products;
- b) for each Government Reimbursed Product promoted by Aegerion during the Reporting Period: i) a description of the criteria used by Aegerion 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 Aegerion of the call plans and an indication of whether Aegerion reviewed the call plans as required by Section III.B.h 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 Aegerion's criteria relating to the call plan and/or Aegerion's Policies and Procedures; and iv) a description of all instances in which it appears that Aegerion failed to follow its criteria or Policies and Procedures relating to call plans or the review of the call plans;
- c) the findings and supporting rationale regarding any weaknesses in Aegerion's systems, processes, policies, procedures, and practices relating to Aegerion's call plans or the review of the call plans;
- d) recommendations, if any, for changes in Aegerion'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 Reviews of Payments)

- e) a description of the entries in the Open Payments database for sampled Covered Recipient and a description of Control Documents reviewed in connection with each selected Covered Recipient;
- f) for each sampled Covered Recipient, findings and supporting rationale as to whether:
  - 1) all required Control Documents exist;
  - 2) each Control Document was completed in accordance with all of the requirements set forth in the applicable Aegerion policy;
  - 3) the aggregate value of the Payment(s) as reflected in the report to CMS for the sampled Covered Recipient is consistent with the value of the Payment(s) reflected in the Control Documents;
  - 4) each Control Document reflects that Aegerion's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and
  - 5) any corrective action or disciplinary action was undertaken in those instances in which Aegerion policies were not followed;
- g) for each sampled Covered Recipient 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 Covered Recipients, including a description of the circumstances requiring corrective action and the nature of the corrective action;
- h) 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;
- i) the findings and supporting rationale regarding any weaknesses in Aegerion's systems, processes, policies, procedures, and practices relating to the Payments to Covered Recipients; and

- j) recommendations, if any, for changes in Aegerion's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

(Relating to the Review of Additional Items)

- k) for each Additional Item reviewed, a description of the review conducted;
- l) for each Additional Item reviewed, the IRO's findings based on its review;
- m) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Aegerion's systems, processes, policies, procedures, and practices relating to the Additional Item; and
- n) for each Additional Item reviewed, recommendations, if any, for changes in Aegerion's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

## Appendix C to CIA for Aegerion Pharmaceuticals, Inc.

### Variable Compensation Program and Executive Financial Recoupment Program

#### I. Variable Compensation Program

To the extent not already accomplished, within 120 days after the Effective Date of the CIA, Aegerion shall develop policies and procedures relating to its incentive (known as "variable") compensation program (known as "the Variable Compensation Program") for sales personnel (including, for purposes of this Section I, employed and contracted sales representatives, sales managers, rare disease partners, and sales trainers).

These policies and procedures shall: (1) be designed to ensure that financial incentives do not improperly motivate sales personnel to engage in improper promotion, sales, and marketing of Aegerion's Government Reimbursed Products; (2) include mechanisms to exclude from variable compensation certain types of sales for which variable compensation is not appropriate (including sales resulting from improper promotion of Aegerion's Government Reimbursed Products); and (3) provide for the internal review and analysis of all variable compensation prior to payment. Aegerion shall maintain these policies and procedures throughout the term of the CIA.

As part of the Variable Compensation Program, Aegerion shall annually review and set appropriate variable compensation targets in collaboration with an expert third party compensation consultant. Before the annual targets are finalized, they shall be reviewed and approved by personnel from Aegerion's human resources, legal, and compliance departments to ensure that the targets are consistent with the market size and expected growth for FDA-approved uses of Aegerion's Government Reimbursed Products.

The Variable Compensation Program shall be designed to ensure that only clinically appropriate patients are started and maintained on Aegerion's products. With respect to Juxtapid, Aegerion will compile a monthly report of each new patient start, which shall be subject to a medical review to assess whether each new patient should be considered eligible for variable compensation credit. Based on the product label for Juxtapid as of the Effective Date of the CIA, all pediatric patients shall be considered ineligible for variable compensation credit. For adult patients, the medical review will evaluate whether the patient has a clinical or laboratory diagnosis inconsistent with the FDA-approved use for Juxtapid such that the patient should be excluded from variable compensation calculations. If a determination is made to exclude a patient based on the medical review, no variable compensation credit will be awarded for such patient.

Under the Variable Compensation Program, all potential variable compensation payments for sales personnel are reviewed and approved by Aegerion's commercial operations and business analytics departments and the President and Chief Accounting Officer prior to payment. In addition, proposed variable compensation amounts are reviewed by the compliance and human resources departments and the Vice President of U.S. Sales to ensure that any outliers are subject to additional review. If Aegerion determines that a sales personnel received improper variable compensation payments, future payments of variable compensation to such sales personnel may be offset or reduced as appropriate and permitted under applicable law.

In order to be eligible to participate in the Variable Compensation Program, sales personnel must satisfy certain baseline compliance requirements (including the completion of compliance training). In addition, compliance violations may lead to a loss of variable compensation and other disciplinary measures.

## II. Executive Financial Recoupment Program

Within 120 days after the Effective Date of the CIA, Aegerion shall establish and maintain throughout the term of the CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to three years of annual performance pay (including Bonuses and Equity Awards, each as defined below in Section II.A) for any Covered Executive (as defined below in Section II.A.1) who is the subject of an Affirmative Recoupment Determination (as defined below in Section II.C). This program shall be known as the "Executive Financial Recoupment Program." This recoupment program shall apply to Covered Executives who are either current Covered Persons under the CIA (including Aegerion employees or contractors) or former Covered Persons (including Aegerion employees or contractors) at the time of a Recoupment Determination.

### A. Description of Executive Financial Recoupment Program.

Within 120 days after the Effective Date of the CIA, Aegerion shall establish policies and procedures (and modify employment and other contracts as necessary) to provide that annual and other cash bonuses (including variable compensation, if applicable) on an after tax/net basis ("Bonus") for each Covered Executive is at risk of forfeiture in the event of misconduct that is discovered by Aegerion or by Novelson Therapeutics Inc. and/or Novelson Services USA, Inc. (collectively, "Novelson") before the Bonus is paid.

In the event of misconduct by any Covered Executive, Aegerion shall also reserve the right and full discretion to void and forfeit any unvested or unexercised stock options, stock appreciation rights, and rights to similar equity plans (collectively, "Equity

Awards"). If Aegerion or Novelson discovers any misconduct by a Covered Executive that would implicate the forfeitures or recoupments described in this Section II, Aegerion shall evaluate the situation and make a determination about whether any forfeiture or recoupment shall be implemented and the details of such action, as described below in Section II.C.

1. *Definition of Covered Executives.* Within 120 days after the Effective Date of the CIA, Aegerion shall modify and supplement its annual Bonus plans (and any employment and other contracts, as appropriate) by imposing the eligibility and repayment conditions described below on future Bonuses and Equity Awards and making the additional remedies described below applicable to (i) the following Covered Persons who are executives of Novelson Therapeutics Inc., by virtue of Novelson Therapeutics Inc.'s contractual service obligation to Aegerion Pharmaceuticals, Inc.: the Chief Executive Officer; the Chief Financial and Administration Officer; the General Counsel; the Global Chief Compliance Officer; the Chief Commercial Officer; the Head of Research & Development; and the Senior Vice President Human Resources (collectively, the "Novelson Covered Executives"); and (ii) Covered Persons who are executives of Aegerion at the level of Senior Vice President, President, or above (the "Aegerion Covered Executives"). Novelson Covered Executives and Aegerion Covered Executives are collectively referred to hereafter as "Covered Executives".

Aegerion shall implement policies and procedures and, as necessary, shall modify contracts with Covered Executives so that beginning in calendar year 2018 the Bonuses and Equity Awards may be recouped if an Affirmative Recoupment Determination is made. The forfeiture and recoupment rights described above shall apply prospectively to Covered Executives beginning with the calendar year 2018 Bonus plan and Equity Award years.

2. *Executive Bonus Eligibility and Repayment Conditions.* Aegerion shall implement an eligibility and repayment condition on Bonuses that will allow Aegerion, as a consequence of a Triggering Event, to pursue repayment from the Covered Executive of all or any portion of an amount equivalent to up to three years of Bonus monies paid to the Covered Executive. These Bonus eligibility and repayment conditions will survive the payment of the Covered Executive's Bonus and the separation of the Covered Executive's employment or completion of his/her contract term for a period of three years from the payment of the Bonus for the respective plan year.

If an Affirmative Recoupment Determination is made, Aegerion shall endeavor to collect repayment of any Bonus from the Covered Executive through reasonable and appropriate means according to the terms of its Bonus plan (or executive contract as applicable), and to the extent permitted by controlling law of the relevant jurisdiction. If

necessary to collect the repayment, Aegerion shall file suit against the Covered Executive unless good cause exists not to do so. For purposes of the Executive Financial Recoupment Program, good cause shall include, but not be limited to, a financial inability on the part of the Covered Executive to repay any recoupment amount or Aegerion's inability to bring such a suit under the controlling law of the relevant jurisdiction.

3. *Executive Equity Awards and Repayment Conditions.* Aegerion shall implement an eligibility and repayment condition on Aegerion's Equity Awards designed to survive the separation of a Covered Executive's employment or the completion of a contract term. More specifically, to the extent necessary, Aegerion shall implement an eligibility and repayment condition on the company's Equity Awards in order to clarify that, as a consequence of a Triggering Event, Aegerion may void and pursue forfeiture by a Covered Executive of all or any portion of the last three years' worth of any Equity Awards that were granted during the three years preceding the Affirmative Recoupment Determination.

To the extent permitted by controlling law, these eligibility and repayment conditions shall survive for a period of three years from the Covered Executive's employment termination date or contract completion date.

If an Affirmative Recoupment Determination is made, Aegerion shall void or pursue forfeiture of all or a portion of the Equity Awards granted during the three years prior to an Affirmative Recoupment Determination to the extent permitted by controlling law of the jurisdiction in which the Covered Executive works, including by means of filing suit against the Covered Executive, unless good cause exists not to do so.

4. *Tolling Remedy.* Aegerion shall make best efforts to obtain a written agreement from each Covered Executive under which, to the extent permitted by controlling law, for the three years during which the Bonus and Equity Award eligibility and repayment conditions exist, if (i) Aegerion reasonably anticipates that a Triggering Event has occurred and (ii) Aegerion has recoupment rights remaining under Sections II.A.2-3, Aegerion shall, upon notice to the Covered Executive, have the right to toll and extend such rights for an additional three years or until the Recoupment Committee (as defined below in Section II.C.2) determines that a Triggering Event has not occurred, whichever is earlier, to the extent permitted by controlling law of the relevant jurisdiction.

5. *Additional Remedies.* If, after expiration of the time period specified in Sections II.A.2-4 above, the Recoupment Committee determines that a Triggering Event has occurred, Aegerion shall make a determination as to whether to pursue

available remedies (*e.g.*, filing suit against the Covered Executive) existing under statute or common law to the extent available.

#### B. Definition of Triggering Events.

The forfeiture and repayment conditions described above shall be triggered upon a Recoupment Determination that is based on:

(i) significant misconduct (*e.g.*, a significant violation Aegerion policy or of regulation or law) by the Covered Executive relating to Covered Functions that, if discovered prior to payment, would have made the Covered Executive ineligible for a Bonus or Equity Award in that plan year or subsequent plan years; or

(ii) significant misconduct by subordinate employees relating to Covered Functions for which the Covered Executive has or had responsibility that a) does not constitute an isolated occurrence; and b) which the Covered Executive knew or should have known was occurring; and that c) if discovered prior to payment, would have made the Covered Executive and/or employees in question ineligible for a Bonus or Equity Awards in that plan year or subsequent plan years.

Either of the events described above in this Section II.B may be considered a "Triggering Event".

#### C. Administration of Recoupment Actions.

Aegerion shall engage in a standardized, formal process to determine, in its sole discretion, whether a Triggering Event has occurred, and, if so, the extent of Bonus monies or Equity Awards that will be subject to repayment or forfeiture by the Covered Executive, and the most appropriate method for securing recoupment of relevant monies previously paid to a Covered Executive. The recommendations resulting from this process shall be referred to as the "Recoupment Determination." The determination that Bonus and/or Equity Award amounts shall be forfeited by or recouped from a Covered Executive shall be referred to as an "Affirmative Recoupment Determination."

1. *Initiation.* Aegerion shall initiate the Recoupment Determination process upon: (1) a finding in a compliance investigation of potential significant misconduct that may rise to the level of a Triggering Event, or (2) written notification by a United States Federal government agency to Aegerion's Compliance Officer or Novilion's Global Chief Compliance Officer that results in a finding in a compliance investigation of potential significant misconduct that may rise to the level of a Triggering Event and either occurred in the United States or gives rise to liability relating to Federal

healthcare programs. This written notification shall either identify the Covered Executive(s) potentially at issue or provide information (e.g., a description of the alleged misconduct and the applicable time period) to allow Aegerion or Novilion to identify the Covered Executive.

2. *Recoupment Committee.* The Recoupment Determination shall be made by a committee of senior Novilion and/or Aegerion executives headed by the Novilion Global Chief Compliance Officer and further consisting of the Novilion General Counsel and the Novilion Senior Vice President Human Resources (together, the "Recoupment Committee"). A senior executive shall not participate in the Recoupment Committee while that individual is subject to a Recoupment Determination. If a Recoupment Determination involves a member of the Recoupment Committee, such individual is recused from the Recoupment Committee for purposes of the Recoupment Determination and the remaining members of the Recoupment Committee may replace such individual with a Delegate, as defined below in Section II.C.3

Novilion's Board may, in its discretion, provide that the Recoupment Committee shall consist exclusively of non-employee members of the Board if at least three such non-employee members are appointed to serve as the Recoupment Committee. Aegerion shall notify OIG in writing within 15 days of any change in the composition of the Recoupment Committee and provide an explanation for the change.

3. *Recoupment Determination Process.* Aegerion shall initiate the Recoupment Determination process within 30 days after Aegerion's completion of a compliance investigation that finds potential significant misconduct that may rise to the level of a Triggering Event, as described in Section II.B. Absent extraordinary reasons, the Recoupment Committee shall reach a Recoupment Determination within 90 days after initiation of the Recoupment Determination process.

As part of the Recoupment Determination process, the Recoupment Committee or appropriate Delegate (as defined below) shall: i) undertake an appropriate review of the report or records from the underlying compliance investigation of the facts and circumstances associated with the Triggering Event; ii) make any additional written findings regarding the facts and circumstances associated with the Triggering Event; and iii) set forth in writing its determinations (and the rationale for such determinations) about: 1) the factors that lead to the Recoupment Committee's determinations as to whether a Triggering Event occurred, including any mitigating factors; 2) the extent of Bonus monies or Equity Awards that will be subject to forfeiture and/or repayment by the Covered Executive, if any; 3) the means that will be followed to implement the forfeiture and/or secure the recoupment of Bonus monies or Equity Awards from the Covered

Executive; and 4) the timetables under which Aegerion will implement the forfeiture and/or attempt to recoup the Bonus monies or Equity Awards.

For purposes of this Section II.C, a "Delegate" shall refer to an individual from either Novelson or Aegerion to whom the Recoupment Committee has delegated one or more of its required tasks in furtherance of the Executive Financial Recoupment Program.

The Recoupment Committee will report its Recoupment Determinations to the proper corporate oversight board(s) in accordance with Aegerion's internal policies and procedures and this CIA.

D. Reporting.

1. *Reports to Board of Directors.* The Recoupment Committee shall provide annual reports to the Novelson Board (or an appropriate committee thereof) about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Section II.C.1 above; ii) a description of any Recoupment Determinations made during the preceding year (including any decision to require or not require forfeiture/recoupment from any Covered Executives, the amount and type of any forfeiture/recoupment, the means for collecting any recoupment and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Recoupment Determinations that were not fully completed in prior years.

2. *Reports to OIG.* The Recoupment Committee shall also provide annual reports to the OIG about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Section II.C.1 above; ii) a summary description of any Recoupment Determinations made during the preceding year (including any decision to require or not require forfeiture/recoupment from any Covered Executives, the amount and type of any forfeiture/recoupment, the method for collecting any recoupment, and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Recoupment Determinations that were not fully completed in prior years. Aegerion shall provide OIG with additional information regarding any Recoupment Determination upon OIG's request.

Aegerion commits to maintaining the Executive Financial Disclosure Program described above in Section II above for at least the duration of the CIA, absent agreement otherwise with the OIG.