

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

I. PREAMBLE

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

Prior to the Effective Date of this CIA (as defined below), Cephalon established a voluntary compliance program (known as "Global Compliance" or "Global Compliance Program") applicable to all Cephalon employees including employees in Worldwide Pharmaceutical Operations. Cephalon's Global Compliance Program includes an Executive Vice President, Chief Compliance Officer who reports directly to the Audit Committee of the Board of Directors and to the CEO, and a Compliance Committee. The Global Compliance Program also includes a Code of Conduct applicable to all employees that is regularly reviewed and disseminated, written policies and procedures that, as represented by Cephalon, promote high ethical standards, educational and training initiatives that, as represented by Cephalon, help to ensure compliance with applicable laws and regulations, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations and appropriate disciplinary procedures, screening measures for Ineligible Persons, and regular internal auditing procedures.

Cephalon shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Cephalon may modify its

Compliance Program as appropriate, but, at a minimum, Cephalon 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 Cephalon under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the first day of the first calendar month following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Cephalon's final Annual Report; or (2) any additional materials submitted by Cephalon 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 who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, and United States-based employees of Cephalon; and

b. all contractors, subcontractors, agents, and other persons who perform Promotional and Product Services Related Functions (as defined below in Section II.C.4) on behalf of Cephalon.

Notwithstanding the above, this term 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 per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes all Covered Persons whose job responsibilities relate to Promotional and Product Services Related Functions.
3. "Government Reimbursed Products" refers to all Cephalon products that are reimbursed by Federal health care programs. This term includes products that are promoted by Cephalon for which it may not hold the New Drug Application.
4. The term "Promotional and Product Services Related Functions" includes: (a) the promotion, marketing, and sale of Government Reimbursed Products; and (b) the development or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products.
5. The term "Third Party Educational Activity" shall mean any continuing medical education (CME), independent medical education (IME), disease awareness, or other scientific, educational, or professional program, meeting, or event sponsored by Cephalon, including but not limited to, sponsorship of symposia at medical conferences.
6. The term "Third Party Personnel" shall mean personnel of the entities with whom Cephalon has or may in the future enter into agreements to co-promote a Government Reimbursed Product in the United States or engage in joint promotional activities in the United States relating to such a product. Cephalon has represented that: (1) the Third Party Personnel are employed by other independent entities; (2) Cephalon does not control Third Party Personnel; and (3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Cephalon agrees to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.3, and V.B.4 related to Third Party Personnel who meet the definition of Covered Persons. Provided that Cephalon complies with the requirements of Sections III.B.2, V.A.3, and V.B.4, Cephalon shall not be required to fulfill the other CIA

obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

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

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

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

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

2. *Compliance Committee.* Prior to the Effective Date, Cephalon established a Compliance Committee, and Cephalon shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior managers of relevant departments, such as legal, medical affairs, sales, marketing, human resources, and internal audit). The Chief Compliance Officer shall chair the Compliance Committee and the Committee shall support the Chief Compliance Officer in fulfilling his/her

responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall receive reports on compliance-related monitoring, audits, and investigations).

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

3. *Board of Directors.* The Board of Directors (Board) or a Committee of the Board, if applicable, 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, or a Committee of the Board, shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee Cephalon's Global Compliance Program, including but not limited to the performance of the Chief Compliance Officer and Global Compliance department.

b. for each Reporting Period of the CIA, adopting a resolution (pursuant to the process outlined in the bylaws for adopting resolutions) summarizing its review and oversight of Cephalon's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. Each individual member of the Board or, if applicable, each member of the Committee of the Board having responsibility for compliance, shall sign a statement indicating that he or she agrees with the resolution.

At minimum, the resolution shall include the following language:

"The Board of Directors [or a Committee of the Board] has made a reasonable inquiry into the operations of Cephalon's Global Compliance Program, including the performance of the Chief Compliance Officer and the Global Compliance department. Based on its inquiry, the Board [or Committee] has concluded that, to the best of its knowledge, Cephalon has implemented an effective Global Compliance Program to meet the Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Board (or the Board Committee) is unable to provide such a conclusion in the resolution, the Board (or Committee) 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 Cephalon.

Cephalon 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:* Cephalon represents that compliance is a component of each employee's performance objectives. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Cephalon employees ("Certifying Employees") are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify in writing or electronically that the applicable area of authority is compliant with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Certifying Employees include, at a minimum, the following: Chairman and Chief Executive Officer, Executive Vice President of Worldwide Medical and Regulatory Operations, Executive Vice President of Worldwide Pharmaceutical Operations, all business unit sales vice presidents, all business unit marketing vice presidents, all business unit sales directors, all business unit marketing directors, the Vice President of Worldwide Medical Affairs, and all medical directors of communications and medical science liaisons (MSLs).

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

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

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Cephalon developed, implemented, and distributed a written Code of Conduct to all Covered Persons. Cephalon currently requires all newly employed persons to certify in writing or electronically that they have received, read, understood, and shall abide by Cephalon's Code of Conduct. Cephalon shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees.

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

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

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

To the extent not already accomplished, within 120 days after the Effective Date, the Code of Conduct shall be distributed to each Covered Person and each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Cephalon's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

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

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

3. *Policies and Procedures.* Prior to the Effective Date, Cephalon implemented written Policies and Procedures regarding the operation of the Compliance Program and Cephalon's compliance with Federal health care program and FDA requirements (Policies and Procedures). To the extent not already accomplished, within 120 days after the Effective Date, Cephalon shall ensure that the Policies and Procedures address or shall continue to address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);
- c. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable FDA requirements;
- d. the mechanisms through, and manner in which, Cephalon receives and responds to requests for information about non-FDA approved (or "off-label") uses of Cephalon's products; the form and content of information disseminated by Cephalon in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Cephalon develop a database to track requests for information about Cephalon's products that are made to Cephalon's Medical Services (MS) department. This database shall be referred to as the "Inquiries Database." The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Cephalon's products: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of the requesting health care professional (HCP) or health care institution (HCI); 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Cephalon (including a record of the materials provided to the HCP or HCI in response to the request); and 6) the name of the Cephalon representative who called on or interacted with the HCP or HCI. Any response from Medical Services to an HCP or HCI shall identify whether the information provided addresses an indication that is part of the approved

product label. The status and findings of any follow-up review conducted by Cephalon in situations in which it appears that the Inquiry may have related to improper off-label promotion shall be maintained by Global Compliance and the information shall be included in the Inquiry Reports further discussed in Section III.A.2 of Appendix B;

- e. development of call plans for field sales representatives who promote Government Reimbursed Products. For each product, the Policies and Procedures shall require that Cephalon review the call plans for the product and the bases upon which specified physician specialties and institutional provider types are included in, or excluded from, the call plans. The Policies and Procedures shall also require that Cephalon modify the call plans as necessary to ensure that Cephalon is promoting its 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 the FDA approves a new or additional indication for a Government Reimbursed Product;
- f. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, speaker programs, speaker training programs, advisory boards, or any other financial relationship with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;
- g. programs to educate field representatives, including preceptorships. 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;

- h. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that Cephalon's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- i. funding of, or participation in, any Third Party Educational Activity. These Policies and Procedures shall be designed to ensure that Cephalon's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements.

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

- j. review of promotional materials by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel),

and the review of other materials and information intended to be disseminated outside Cephalon in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Cephalon's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information, when finally approved, comply with all applicable Federal health care program and FDA requirements;

- k. sponsorship or funding of research or related activities. These Policies and Procedures shall be designed to ensure that Cephalon's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- l. compensation (including salaries and bonuses) for Relevant Covered Persons. These Policies and Procedures shall be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Cephalon's products;
- m. disciplinary policies and procedures for violations of Cephalon's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

C. Training and Education.

Cephalon represents that it provides training to its employees on a regular basis concerning a variety of topics. The training required by this CIA need not be separate and distinct from the regular training provided by Cephalon, but instead may be integrated fully into such regular training so long as the training covers the areas specified below.

1. *General Training.* Within 120 days after the Effective Date, Cephalon shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Cephalon's:

- a. CIA requirements; and
- b. Cephalon's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

To the extent that Cephalon provided General Training to Covered Persons during the 180 days immediately prior to the Effective Date that satisfied the requirements set forth in Section III.C.1.b above, the OIG shall credit that training for purposes of satisfying Cephalon's General Training obligations of Section III.C.1 for the first Reporting Period. Cephalon may satisfy its remaining General Training obligations for the Covered Persons who received the training described in the preceding sentence by notifying them within 90 days after the Effective Date in writing or in electronic format of the fact that Cephalon entered a CIA and providing an explanation of Cephalon's requirements and obligations under the CIA.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Specific Training in addition to the General Training required above.

This Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Promotional and Product Services Related Functions;**
- b. all applicable FDA requirements relating to Promotional and Product Services Related Functions;**
- c. all Cephalon policies, procedures, and other requirements applicable to Promotional and Product Services Related Functions;**
- d. the personal obligation of each individual involved in Promotional and Product Services Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;**
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and**
- f. examples of proper and improper practices related to Promotional and Product Services Related Functions.**

To the extent that Cephalon provided Specific Training to Relevant Covered Persons during the 180 days immediately prior to the Effective Date that satisfied the requirements set forth in Section III.C.2 above, the OIG shall credit that training for purposes of satisfying Cephalon's Specific Training obligations of this Section III.C.2 for the first Reporting Period.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A Cephalon employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to Promotional and Product Services Related Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

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

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

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area of the training, including applicable Federal health care program and FDA requirements. The training and education required under this Section III.C may be provided by supervisory employees, knowledgeable staff, Cephalon trainers, and/or outside consultant trainers selected by Cephalon or may be satisfied by relevant, accredited continuing education programs provided they cover topics outlined above in Section III.C.2.

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

6. *Computer-based Training.* Cephalon may provide the training required under this CIA through appropriate computer-based training approaches. If Cephalon chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training. In addition, if Cephalon chooses to provide computer-based General or Specific Training, all applicable requirements to provide a number of "hours" of training in this Section III.C may be met with respect to computer-based training by providing the required number of "normative" hours as that term is used in the computer-based training industry.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Cephalon 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 Cephalon in assessing and evaluating its Promotional and Product Services Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by Cephalon shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with Cephalon, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

The IRO(s) shall conduct reviews that assess Cephalon’s systems, processes, policies, procedures, and practices relating to Promotional and Product Services Related Functions (Promotional and Product Services Reviews).

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the Promotional and Product Services Review shall consist of two components - a Systems Review and a Transactions Review. The Systems Review shall assess Cephalon’s systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions. If there are no material changes in Cephalon’s systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the Promotional and Product Services Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If Cephalon materially changes its systems, processes,

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

The Promotional and Product Services Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components, including a review relating to Inquiries included in Cephalon's Inquiries Database, a review of Cephalon's Call Plan Assessments, and a review of a records relating to a sample of the Payments that are reported by Cephalon pursuant to Section III.M below. In addition, beginning with the second Reporting Period, each Transactions Review shall also include a review of up to three additional areas or practices of Cephalon identified by the OIG in its discretion (hereafter "Additional Items").

For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with Cephalon and may consider internal audit work conducted or planned by Cephalon, Cephalon's product portfolio, the nature and scope of Cephalon's promotional practices and arrangements with HCPs, and other information known to it. As set forth more fully in Section III.D of Appendix B, Cephalon may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow Cephalon's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify Cephalon of the nature and scope of the IRO review for each of the Additional Items no later than 90 days prior to the end of the second through fifth Reporting Periods. Prior to

undertaking the review of the Additional Items, the IRO and/or Cephalon shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

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

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

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

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

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

E. Disclosure Program.

Cephalon represents that it has a disclosure program designed to facilitate communications relating to compliance with Federal health care program and FDA requirements and Cephalon's policies (the "Disclosure Program"). During the term of the CIA, Cephalon shall maintain a Disclosure Program that includes a mechanism (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 Cephalon's policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Cephalon shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

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

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not),

the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

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

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

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

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

b. "Exclusion Lists" include:

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

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

c. "Screened Persons" include: prospective and current owners of Cephalon (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading); and prospective and current officers, directors, employees, and contractors and agents of Cephalon. For purposes of employees residing outside the United States, "Screened Persons" shall be limited to Covered Persons.

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

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

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

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

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

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

4. *Pending Charges and Proposed Exclusions.* If Cephalon has actual notice that a Screened Person is charged with a criminal offense that falls within the

ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Screened Person's employment or contract term, Cephalon shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

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

H. Reporting.

1. *Reportable Events.*

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

i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or applicable to any FDA requirements relating to the promotion of Cephalon products for which penalties or exclusion may be authorized;
or

ii. the filing of a bankruptcy petition by Cephalon.

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

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

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

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

iii. any further steps Cephalon plans to take to address the Reportable Event and prevent it from recurring.

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

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

I. Notification of Communications with FDA.

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

J. Review of Records Reflecting the Content of Detailing Sessions.

Cephalon shall implement a Message Recall Monitoring Program designed to identify, for each Reporting Period, potential-off-label promotional activities by Cephalon's field sales force through the analysis of studies generated by an independent entity (Survey Entity) reflecting physician recall of the marketing messages delivered by Cephalon's sales force (Message Recall Studies) for up to three Covered Products (as defined below). Cephalon shall obtain Message Recall Studies for each Reporting Period. In order to satisfy its obligations under this Section III.J, Cephalon may propose that it obtain an alternative type of survey record (e.g. verbatims or similar records) rather than Message Recall Studies. The OIG will consider Cephalon's proposal, and after considering Cephalon's proposal shall, in its discretion, identify the type of survey records to be obtained.

For each Reporting Period and for each Covered Product, Cephalon shall contract with the Survey Entity to conduct Message Recall Studies. The OIG shall select and notify the Survey Entity of a one week period within every other quarter of the Reporting Period for which the Message Recall Studies shall be conducted beginning in the second full quarter after the Effective Date. For each Covered Product, Cephalon shall obtain Message Recall Studies covering the identified week in all regions across the United States.

Prior to the start of the second Reporting Period and every Reporting Period thereafter, based on the information provided and other information known to it, and after consultation with Cephalon, the OIG shall select up to three Government Reimbursed Products to be the basis for the review outlined in this Section III.J and shall notify Cephalon of its selection. These identified products shall be known as the "Covered Products." The parties have already identified the Covered Products for the first Reporting Period.

Cephalon shall review the records obtained from the Survey Entity and shall identify any instances in which the records appear to indicate that Covered Persons may have discussed and/or disseminated information about off-label uses of the Covered Products. Cephalon shall make findings based on its review (Off-Label Findings) and shall take any responsive action it deems necessary. If necessary for purposes of its review, Cephalon shall endeavor to gather additional factual information about the circumstances relating to any Off-Label Findings. As part of each Annual Report,

Cephalon shall provide the OIG with copies of the underlying records of the detailing interactions, a copy of Cephalon's Off-Label Findings, and a description of the action(s), if any, Cephalon took in response to the Off-Label Findings.

K. Field Force Monitoring and Review Efforts.

To the extent not already accomplished, within 120 days after the Effective Date, Cephalon shall establish a Field Force Monitoring Program (FFMP) to evaluate and monitor field sales force representatives' interactions with HCPs. The FFMP shall be a formalized process designed to directly observe the appropriateness of field sales force representative's interactions with HCPs and to identify potential off-label promotional activities.

Under this program, Cephalon compliance personnel, or appropriately trained designees who are not from marketing or the field sales organizations and who are not within three levels of the field sales force representative's reporting structure, shall conduct direct field observations (Observations) of field sales force representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with Cephalon's Policies and Procedures. These Observations shall be full day ride-alongs with field sales representatives, and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. The Observations shall be scheduled throughout the year, randomly selected by Cephalon compliance personnel, include each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each Observation, Cephalon compliance personnel or the designee shall prepare a report which includes:

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

Cephalon compliance personnel shall conduct at least 30 full-day Observations during each Reporting Period. The number of inspections conducted for each therapeutic

area and product shall be proportional in number to the size of each therapeutic area and product, and shall be conducted across the United States.

In the event that a compliance issue, including potential off-label promotion, is identified during any Observation, Cephalon shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken. The Compliance Officer shall disclose Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during an Observation and any corrective action shall be recorded in the files of Global Compliance.

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

L. Notice to Health Care Providers and Entities.

Within 90 days after the Effective Date, Cephalon shall send, by postage prepaid first class mail, Certificate of Mailing requested, an exact copy of the notice attached hereto as Attachment A, showing the date of the mailing, to any health care provider or entity that Cephalon currently details. This mailing shall notify each health care provider and entity of the terms of the global settlement with the United States, including an explanation of the conduct to which Cephalon pled guilty and the conduct resolved by the civil settlement. The mailing shall also notify each health care provider or entity that they may report any questionable conduct by Cephalon representatives to a compliance telephone number or e-mail address established by Cephalon or to the FDA.

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

Implementation Report and each Annual Report, Cephalon shall provide to the OIG a summary of the calls and messages received.

M. Reporting of Physician Payments.

1. Phase I Reporting

By January 31, 2010, Cephalon shall post in a prominent position on its website an easily accessible and readily searchable listing of all physicians who received any Phase I Payments (as defined below in Section III.M.3) directly or indirectly from Cephalon during Calendar Year 2009 and the aggregate value of such payments in the calendar year.

After the initial posting, 30 days after the end of each subsequent calendar quarter until March 2011, Cephalon shall also post on its website a listing of updated information about all Phase I Payments provided during the applicable calendar year during the preceding quarter(s). The quarterly listing shall be easily accessible and readily searchable.

Each listing shall include a complete list of all individual physicians to whom Cephalon directly or indirectly made Phase I Payments in the preceding calendar year. Each listing shall be arranged alphabetically according to the physicians' last name. The Payment amounts in the lists shall be reported in \$10,000 increments (*e.g.*, \$0 - \$10,000; \$10,001- \$20,000; *etc.*) For each physician, the applicable listing shall include the following information: i) full name; ii) city and state of the physician's practice; and iii) the aggregate value of the payment(s) in the preceding quarter(s) or year (as applicable). The reporting described in this Section III.M.1 shall be referred to hereafter as "Phase I Reporting."

2. Phase II Reporting

No later than March 31, 2011 and during the remaining term of the CIA, Cephalon shall post in a prominent position on its website an easily accessible and readily searchable listing of physicians and Related Entities (as defined in Section III.M.3) who received any Payments directly or indirectly from Cephalon and the aggregate value of such Payments in the preceding Calendar Year. After the initial posting, 30 days after the end of each subsequent calendar quarter Cephalon shall also post on its website a listing

of updated information about all Payments provided during the applicable calendar year during the preceding quarter(s). The quarterly listing shall be easily accessible and readily searchable.

Each listing shall include a complete list of all individual physicians and Related Entities to whom Cephalon directly or indirectly made Payments in the preceding calendar year. Each listing shall be arranged alphabetically according to the physicians' last name and the name of the Related Entity. The Payment amounts in the lists shall be reported in \$10,000 increments (*e.g.*, \$0 - \$10,000; \$10,001- \$20,000; *etc.*) For each physician and Related Entity, the applicable listing shall include the following information: i) full name; ii) city and state of the physician's practice; iii) name, city, and state in which the Related Entity is located; and iv) aggregate value of the Payment(s) in the preceding quarter(s) or year (as applicable). The reporting described in this Section III.M.2 shall be referred to hereafter as "Phase II Reporting."

3. Miscellaneous Provisions

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

If the proposed Physician Payments Sunshine Act of 2008 or similar legislation is enacted, the OIG shall determine whether the purposes of this Section III.M are reasonably satisfied by Cephalon's compliance with such legislation. In such case, and in its sole discretion, the OIG may agree to modify or terminate provisions of Section III.M as appropriate.

For purposes of this Section III.M, the term "Payments" is defined to include all payments or transfers of value (whether in cash or in kind) made to physicians and/or to Related Entities. The term Payments includes, for example, payments or compensation for services rendered, grants, fees, honoraria, and payments relating to research or education. The term Payments also includes food, entertainment, gifts, trips or travel,

product(s)/item(s) provided for less than fair market value; or other economic benefit. The term Payments does not include: i) samples of drug products that meet the definition set forth in 21 C.F.R. § 203.3(i), or ii) discounts, rebates, or other pricing terms.

For purposes of this Section III.M, the term "Phase I Payments" is defined as those Payments made in connection with physicians serving as speakers, participating in speaker training, or serving as consultants (including for advisory boards, or preceptorships.)

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

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Cephalon changes locations or closes a business unit or location related to Promotional and Product Services Related Functions, Cephalon shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

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

C. Sale of Unit or Location. In the event that, after the Effective Date, Cephalon proposes to sell any or all of its business units or locations related to the Promotional and Product Services-Related Functions that are subject to this CIA, Cephalon shall notify OIG of the proposed sale no later than the date the sale is publicly disclosed. This notification shall include a description of the business unit or location to be sold, a brief

description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

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

1. the name, address, phone number, and position description of the Chief Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to Cephalon's letter;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of Cephalon's Code of Conduct required by Section III.B.1;
6. to the extent not already provided to the OIG, a copy of all Policies and Procedures required by Section III.B.3;
7. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
8. the following information regarding each type of training required by Section III.C:

- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

9. a description of the Disclosure Program required by Section III.E;
10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Cephalon and the IRO;
11. a certification from the IRO regarding its professional independence and objectivity with respect to Cephalon;
12. a description of the process by which Cephalon fulfills the requirements of Section III.F regarding Ineligible Persons;
13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F;
14. a list of all of Cephalon's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Cephalon currently submits claims (if applicable);
15. a description of Cephalon's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;

16. a certification by the Chief Compliance Officer that the notice required by Section III.L was mailed to each health care provider and entity, the number of health care providers and entities that received a copy of the notice, a sample copy of the notice required by Section III.L, and a summary of the calls and messages received in response to the notice; and

17. the certifications required by Section V.C.

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

Each Annual Report shall include, at a minimum:

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

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B.3 and the reasons for such changes (e.g., change in applicable requirements);

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

4. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each entity employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to Cephalon's letter;

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

- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

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

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

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

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

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

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

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

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

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

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

16. all information required by Section III.J;

17. all information required by Section III.K;

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

19. a description of all changes to the most recently provided list of Cephalon's locations (including addresses) as required by Section V.A.14; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Cephalon currently submits claims (if applicable);

20. a certification from the Chief Compliance Officer that information regarding payments has been posted on Cephalon's website as required Section III.M; 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. The following certifications shall be included in the Implementation Report and Annual Reports:

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

2. Chief Compliance Officer: In each Implementation Report and Annual Report, Cephalon shall include the following individual certification by the Chief Compliance Officer:

a. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful;

b. to the best of his or her knowledge, except as otherwise described in the applicable report, Cephalon is in compliance with Federal health care program and FDA requirements and the obligations of the CIA;

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

d. Cephalon's: 1) Policies and Procedures as referenced in Section III.B.3 above; 2) templates for standardized contracts and other similar documents; and 3) 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, Cephalon's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Cephalon have been reviewed by competent regulatory, medical and/or legal personnel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed and elevated 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 regulatory, medical and/or legal personnel. The certification shall include a description of the document(s) reviewed and approximately when the

review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

e. Cephalon's call plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.e) and, for each product the call plans were found to be consistent with Cephalon's policy objectives as referenced above in Section III.B.3.e.

D. Designation of Information. Cephalon 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. Cephalon 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

CEPHALON: Executive Vice President, Chief Compliance Officer
Cephalon, Inc.
40 Moores Road
Frazer, PA 19355
Phone: (610) 727-6280
Facsimile: (610) 727-6001

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Cephalon's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Cephalon's locations for the purpose of verifying and evaluating: (a) Cephalon's compliance with the terms of this CIA; and (b) Cephalon'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 Cephalon to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Cephalon's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Cephalon shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Cephalon's employees may elect to be interviewed with or without a representative of Cephalon present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

Cephalon 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, Cephalon 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 Cephalon fails to establish, implement, or accomplish any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board resolution;
- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons;
- g. a Disclosure Program as required by Section III.E;

h. Ineligible Persons screening and removal requirements;

i. notification of Government investigations or legal proceedings;

j. notification of communications with FDA regarding off-label matters;

k. Message Recall Studies (or alternative information permitted by Section III.J);

l. a program for FFMP;

m. notification to any health care providers or entities as required by Section III.L; or

n. posting of any Payments as required by Section III.M.

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

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

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Cephalon fails to submit the annual IRO Review Report(s) in accordance with the requirements of Sections III.D and V.B.6 and Appendix B.

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

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

7. A Stipulated Penalty of \$1,000 for each day Cephalon fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Cephalon, stating the specific grounds for its determination that Cephalon has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Cephalon shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Cephalon 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. Cephalon 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 Cephalon fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Cephalon receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Cephalon 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 Cephalon of: (a) Cephalon'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, Cephalon 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 Cephalon elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Cephalon 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 the OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Cephalon has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:
 - a. a failure by Cephalon to report a Reportable Event and take corrective action, as required in Section III.H;
 - b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
 - c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
 - d. a failure to engage and use an IRO in accordance with Section III.D; or
 - e. a failure of the Board to issue a resolution in accordance with Section III.A.3.

