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.