

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

I. PREAMBLE

Serono Holding, Inc., 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 the statutes, regulations and written directives of the Food and Drug Administration (FDA) (FDA requirements). This CIA shall apply to Serono Holding, Inc., and all of its U.S. biopharmaceutical operating subsidiaries and affiliates, including, but not limited to, Serono, Inc. (collectively referred to hereafter as "Serono.") For purposes of clarification, this CIA shall be applicable only to those U.S. operations of Serono that are subject to U.S. Federal health care program and FDA laws, regulations, and requirements (collectively referred hereafter as "Serono U.S. biopharmaceutical operations.") Contemporaneously with this CIA, Serono is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement. Serono also will enter into settlement agreements with various States, and Serono's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA, Serono established a voluntary compliance program, which, as represented by Serono includes, among other things, the appointment of a Corporate Compliance Officer and Compliance Committee, the development and dissemination of a Code of Business Conduct, the establishment of written policies and procedures, the provision of training and education, a Disclosure Program, screening measures for Ineligible Persons, review and disciplinary proceedings, and regular internal auditing. As represented by Serono, these policies and programmatic elements are aimed at meeting Serono's goal of promoting high ethical standards in the conduct of Serono's business practices.

Serono shall continue the operation of its compliance program in accordance with the terms set forth below for the term of this CIA. Serono may modify its voluntary compliance program as appropriate, but, at a minimum, Serono shall ensure that during the term of this CIA, it shall comply with the integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

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

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Serono's final Annual Report; or (2) any additional materials submitted by Serono pursuant to OIG's request, whichever is later. The OIG will notify Serono, in writing, when the term of this CIA has expired.

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

1. "Covered Persons" includes:

- a. all officers, directors, and employees of Serono directly involved in or having responsibilities directly relating to Serono's U.S. biopharmaceutical operations; and
- b. all contractors, subcontractors, agents, and other persons who perform sales, marketing, promotional, pricing, government contract, and research and development activities (except preclinical researchers and clinical investigators) on behalf of Serono's U.S. biopharmaceutical operations.

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. Other Entities or Individuals Included or Excluded.

- a. Serono has entered or may enter joint venture agreements and/or agreements to co-market its products with other entities. The personnel of the entities with whom Serono has or may, in the future, have such agreements shall be collectively referred to as "Third Party Personnel." Serono has represented that: 1) the Third Party Personnel are employed by other pharmaceutical manufacturers; 2) Serono does not control the Third Party Personnel; and 3) it would be commercially impracticable to compel their compliance with the requirements set forth in this CIA.

However, Serono agrees to use its best efforts to promote compliance by the Third Party Personnel with Federal health care program and FDA requirements. In order to fulfill this obligation, Serono agrees to the following:

1. Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Serono shall send a letter to all entities with which it has entered joint venture and/or co-market agreements to market Serono products. The letter shall outline Serono's obligations under the CIA and its commitment to full compliance with all Federal health care program requirements. The letter shall include a description of Serono's compliance program. Serono shall attach a copy of its Code of Conduct to the letter and shall ask that the other entity either: (a) make a copy of Serono's Code of Conduct and the description of Serono's compliance program available to all relevant personnel within its organization; or (b) represent to Serono that it has and enforces a substantially comparable Code of Conduct and compliance program for relevant persons within its organization.
2. Serono shall submit: i) a copy of each such letter (including all attachments); ii) a list of all Serono existing joint venture and/or co-marketing agreements; and iii) a description of the entities' response

to Serono's letter to the OIG with the Implementation Report and each Annual Report.

- b. The terms "Covered Persons" and "Relevant Covered Persons," specifically include all personnel, apart from Third Party Personnel, who comprise Serono's contract sales force, if any.
- c. The terms "Covered Persons" does not include any contractors or agents retained to provide consulting or business advice to Serono who are not engaged directly in: a) Promotional and Product Services Related Functions (as defined below in Section II.C.3.a); b) reporting of pricing information for any Serono products reimbursed by Federal health care programs; c) obligations related to any government contracts; or d) research and development activities, on behalf of Serono.

3. "Promotional and Product Services Relevant Covered Persons" include:

- a. all employees of Serono whose job responsibilities relate to the sales, marketing, or promotion of Serono products or the provision of information about or services relating to Serono's products (Promotional and Product Services Related Functions). This includes, but is not limited to, individuals who work in marketing or the sales force (including in the Reproductive Health, Metabolic Endocrinology, and Neurology Therapy Areas), Managed Care, Finance (and, if in a different department, all other employees having reimbursement and/or third party payor responsibilities), Medical Information, Regulatory Affairs, members of the Grants and Review Committee(s), members of Legal, Human Resources, and Strategic Development whose job responsibilities relate to Promotional and Product Services Related Functions; and
- b. all contractors, subcontractors, agents, and other persons

who otherwise meet the definition of “Covered Person” and perform Promotional and Product Services Related Functions on behalf of Serono.

4. An “Educational Activity” shall mean any Continuing Medical Education (CME) program or event and any other third party scientific or educational conference or professional meeting, including but not limited to, programs or events held, sponsored, or supported by Serono Symposia International, Inc.

5. “Educational Sponsorship Arrangement” shall mean every arrangement or transaction that: involves, directly or indirectly, Serono’s provision of economic support (e.g., through a grant or other funding mechanism) or other program support (e.g., through the provision of materials, speakers, logistical support) to a provider of an Educational Activity. This includes support that Serono provides to an individual or entity that itself directly performs or sponsors the Educational Activity and support that Serono provides to an individual or entity that makes arrangements for another individual or entity to perform or sponsor the Educational Activity.

III. CORPORATE INTEGRITY OBLIGATIONS

To the extent not already accomplished, Serono shall establish and maintain a Compliance Program throughout the term of this CIA that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Serono presently has a Compliance Officer with responsibility for administering Serono’s Compliance Program. Serono shall continue to employ an individual to serve as its Compliance Officer during the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and the FDA requirements referenced in the CIA. The Compliance Officer shall be a member of senior management of Serono, shall make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Serono Holding, Inc., and Serono, Inc., and shall be authorized to report on such matters to the Boards of Directors at any time. The

Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Serono as well as for any reporting obligations created under this CIA.

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

2. *Compliance Committee.* Prior to the Effective Date, Serono established a Compliance Committee, and Serono shall maintain the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as General Counsel, Chief Financial Officer, Chief Medical Officer, the Vice Presidents of Human Resources, Regulatory Affairs, Managed Markets, and one or more therapeutic area business managers). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Serono 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.

B. Written Standards.

1. *Code of Conduct.* To the extent not already accomplished, within 90 days after the Effective Date, Serono shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Within 120 days after the Effective Date, each Covered Person who has not already done so shall certify, in writing, that he or she has received, read, understood, and shall abide by Serono's Code of Conduct. Serono 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 shall, at a minimum, set forth:

- a. Serono's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, and advertise its products in accordance with Federal health care program and FDA requirements;
- b. Serono's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with Serono's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);
- c. the requirement that all of Serono's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by Serono suspected violations of any Federal health care program or FDA requirements or of Serono's own Policies and Procedures;
- d. the possible consequences to both Serono and Covered Persons of failure to comply with Federal health care program or FDA requirements and with Serono's own Policies and Procedures and the failure to report such noncompliance;
- e. the right of all individuals to use the Disclosure Program described in Section III.G, and Serono's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures; and
- f. the expectation that employees will comply with law and company policy, and provision for disciplinary procedures up to and including termination for violation.

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.

Serono 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, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, Serono shall implement written Policies and Procedures regarding the operation of Serono's compliance program and its compliance with Federal health care program and FDA requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. selling, marketing, and promoting Serono products in compliance with all applicable Federal health care program requirements, including, but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b(b);
- c. selling, marketing, promoting, advertising, and disseminating information about off-label uses of Serono's products in compliance with all applicable FDA requirements (collectively "FDA Advertising and Promotional Requirements"), including procedures governing the response to requests for information about off-label uses;
- d. policies and procedures relating to compensation (including salaries and bonuses) for Covered Persons that are designed to ensure that financial incentives do not inappropriately motivate sales and marketing personnel to engage in the improper promotion, sales, and marketing of Serono's products;
- e. disciplinary policies and procedures for violations of Serono's Policies and Procedures, including those policies relating to Federal health care program and FDA requirements;
- f. the manner in which Medical Information receives and responds to requests for information about off-label uses of Serono's products; the form and content of information disseminated by Medical

Information in response to such requests; and the internal review process for the information disseminated;

g. speaker meetings, advisory board meetings, focus group meetings, and all other consultant arrangements (including, but not limited to, those for speakers, *etc.*) or related events. These policies shall be designed to ensure that the consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program requirements and FDA Advertising and Promotional Requirements. The policies shall include requirements about the content and circumstances of such arrangements and events;

h. funding of any Educational Activity, as defined in Section II.C.4 above (*e.g.*, third party educational grants and sponsorship for CME or other third-party educational programs or events). These policies shall be designed to ensure that Serono's funding and/or sponsorship of such programs satisfies all applicable Federal health care program requirements and the FDA statutory and regulatory requirements related to the sponsorship of any Educational Activity (FDA Sponsorship Requirements). The policies and procedures shall require the disclosure of Serono's financial support of the Educational Activity and any financial relationships with faculty, speakers, or organizers at such Educational Activity; shall require that the Educational Activity have an educational focus; shall require that the Educational Activity be independent; and shall require that the Educational Activity be non-promotional in tone/nature;

i. charitable grants or sponsorships in a manner that is designed to ensure that Serono's funding and/or sponsorship of such grants complies with all applicable Federal health care program requirements and FDA requirements;

j. sponsorship or funding of research activities (including clinical trials, market research, or authorship of articles or other publications) by Serono in a manner that is designed to ensure that Serono's funding or sponsorship of such activities complies with all applicable Federal health care program requirements and FDA requirements

relating to 21 C.F.R. Part 54 (concerning Financial Disclosure by Clinical Investigators); and

k. the requirements set forth in Section III.D (Compliance with Requirements Applicable to Educational Activities), including but not limited to the collection, tracking, and maintenance of records relating to Educational Sponsorship Arrangements (as set forth in Section III.D.1.a), the internal review and approval process, and the tracking of Serono's sponsorship of Educational Activities.

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

At least annually (and more frequently, if appropriate), Serono 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 distributed to all Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education.

Serono provides training on a regular, calendar-year basis concerning a variety of topics to its employees. The training requirements required by this CIA need not be separate and distinct from the regular training provided by Serono, but instead may be integrated fully into such regular training so long as the training satisfies the requirements set forth in this CIA. The Compliance Officer shall be responsible for determining how many of the hours of regular training shall be credited toward the General and Specific training requirements set forth in this Section III.C.

The training and education required under Section III.C of this CIA may be provided by supervisory employees or outside consultant trainers selected by Serono and/or through electronic or any other effective means.

1. *General Training.* In accordance with Serono's established training schedule, within 150 days after the Effective Date, Serono shall provide at least two hours

of General Training to each Covered Person¹. This training, at a minimum, shall explain Serono's:

- a. CIA requirements;
- b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues); and
- c. in general, the proper methods of promoting, marketing, selling, and conducting product research in accordance with Federal health care program requirements and FDA Advertising and Promotional Requirements.

To the extent that General Training provided to Covered Persons during the 180 days immediately prior to the execution of this CIA satisfies the requirements of Sections III.C.1.b-c, above, the OIG shall credit the training toward the training requirements set forth in this Section III.C.1 for the first Reporting Period. Serono may satisfy its remaining General Training obligation for those Covered Persons who received training as described above by notifying the Covered Persons of the fact that Serono entered a CIA and notifying them of Serono'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 annually.

2. *Specific Training.* In accordance with Serono's established training schedule, within 150 days after the Effective Date, Promotional and Product Services Relevant Covered Persons shall receive at least two hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

¹ Covered Persons employed by Serono Research Institute, Inc., and/or who are exclusively engaged in drug development functions need only receive General Training covering the topics set forth in Sections III.C.1.a-b, above.

- a. all Federal health care program requirements relevant to the proper methods for selling, marketing, promoting, and providing information about Serono's products, including, but not limited to, the requirements of the Federal anti-kickback statute; the Civil Monetary Penalties Law; the civil False Claims Act; and the Medicaid Drug Rebate statute;
- b. all FDA Advertising and Promotional Requirements, including but not limited to, the requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations;
- c. the personal obligation of each Covered Person involved in the sales, marketing, promotion, advertising, or dissemination of information about off-label uses of Serono's products to comply with all applicable legal requirements;
- d. the legal sanctions for violations of the Federal health care program requirements or FDA Advertising and Promotional Requirements; and
- e. examples of proper and improper sales, marketing, and promotion practices.

Relevant Promotional and Product Services 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 Serono 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 annually.

3. *Certification.* Each individual who is required to attend training shall certify, that he or she has received the required training. An electronic process that tracks completion of such training shall meet the foregoing requirement. 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(s) of their training, including the applicable Federal health care program and FDA requirements.

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

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

D. Compliance with Requirements Applicable to Educational Activities.

1. *Educational Sponsorship Arrangements Procedures.* Serono represents that it has in place a policy and certain procedures relating to professional and patient Educational Sponsorship Arrangements (Arrangements Procedures). The Arrangements Procedures apply to grants for independent third-party medical educational programs (both accredited CME, and certain non-accredited independent third-party medical education) and for patient education programs (e.g., through disease societies). As represented by Serono, the Arrangements Procedures are reasonably designed to ensure that each existing and any new or renewed Educational Sponsorship Arrangement does not violate the Federal anti-kickback statute and/or FDA Sponsorship Requirements. Consistent with Section III.B.2.h, Serono's policies and procedures shall continue to: 1) require the disclosure of Serono's financial support of the Educational Activity and any financial relationships with faculty, speakers, or organizers at such Educational Activity; 2) require the Educational Activity to have an educational focus; 3) require the Educational Activity to be independent; and 4) require that the Educational Activity be non-promotional in tone/nature.

Serono's Arrangements Procedures shall require that all agreements for Educational Sponsorship Arrangements be in writing and signed by Serono and the

sponsor. The Arrangements Procedures shall also provide for the following:

- a. the collection, tracking, and maintenance of all records relating to all existing, new, or renewed Educational Sponsorship Arrangements. For example, these records shall include, but not be limited to, records relating to initial requests for educational grants, Serono's internal consideration and evaluation of potential grants, communications between Serono and the parties to the Educational Sponsorship Arrangement, and grant applications, agreements and certification materials. The records need not include non-substantive records relating to Educational Sponsorship Arrangements (*e.g.*, administrative routing documents, routine administrative e-mails, *etc.*) The records shall also include those records relating to any support provided by Serono in connection with Educational Sponsorship Arrangements; the identity of the sponsors; the type of support provided; the budget funding source within Serono (*e.g.*, department or division) from which the Educational Sponsorship Arrangement is funded; the amount of any financial support provided; and the general topic of the education to be provided;
- b. the establishment of processes and criteria used to determine whether and under what circumstances an Educational Sponsorship Arrangement will be provided to a particular sponsor (including the role, if any, played by field sales representatives), and the amounts paid by Serono under the Educational Sponsorship Arrangement. This shall include an identification of the circumstances under which there may be exceptions to the processes or criteria;
- c. prohibition of approval of any Educational Sponsorship Arrangement to reward past prescription, purchase, referral, arrangement for, or ordering of Serono products; and prohibition of approval of any Educational Sponsorship Arrangement to induce future prescription, purchase, referral, arrangement for, or ordering of Serono products;
- d. prohibition of Educational Sponsorship Arrangements made to individuals, except for bona fide scholarships for medical students, residents, fellows, or other healthcare professionals in training to

attend major educational, scientific, or policy-making conferences or meetings, when the sponsors are selected by the institution at which they are being trained;

e. prohibition of oral or written commitment to provide an Educational Sponsorship Arrangement prior to a submission of a written application containing detailed information about the Educational Activity to be supported and approval of the Arrangement;

f. compliance with Serono's policies regarding control over the content of the Educational Activity. Specifically, the sponsor of the Educational Activity is responsible for the control of content of the Activity. Serono shall not direct the content of the Educational Activity or influence the sponsor with regard to the content. Serono and its agents shall not "script," emphasize, or direct the content of the Activity;

g. compliance with Serono's policies regarding control over the selection of speakers, presenters, and/or moderators (collectively "speakers") at the Educational Activity. Specifically, the sponsor of the Educational Activity is responsible for the selection of any speakers at the Activity. Serono and its agents shall respond only to sponsor-initiated requests for suggestions of speakers and/or sources of potential speakers. If possible, Serono shall suggest more than one name, provide speaker qualifications, and disclose financial and other relationships between Serono and the potential speakers. Serono shall provide this information to the sponsor in writing;

h. a written review and approval process for all Educational Sponsorship Arrangements (including, but not limited to, a legal review by counsel with expertise in the anti-kickback statute and FDA Sponsorship Requirements of those individual Educational Sponsorship Arrangements exceeding \$5,000 or more in value and in instances where the aggregate amount provided to any single sponsor during the Reporting Period exceeds \$10,000 or more) and appropriate documentation of all internal controls. The purpose of this review and approval process shall be to ensure that all new and

existing or renewed Educational Sponsorship Arrangements do not violate the Federal anti-kickback statute and/or FDA Sponsorship Requirements;

i. requiring the Compliance Officer to review the records required to be collected, tracked and maintained (in accordance with Section III.D.1.a) and the internal review and approval process for Educational Sponsorship Arrangements and other Arrangements Procedures on at least a semi-annual basis and to provide a report on the results of such review to the Compliance Committee; and

j. implementing effective responses when suspected violations of the Federal anti-kickback statute and FDA Sponsorship Requirements are discovered, including disclosing Reportable Events pursuant to Section III.J (Reporting) when appropriate.

2. *New or Renewed Arrangements.* Prior to entering into new Educational Sponsorship Arrangements or renewing existing Educational Sponsorship Arrangements, in addition to complying with the Arrangements Procedures set forth above, Serono shall comply with the following requirements (Arrangements Requirements):

a. As currently required, continue to ensure that the terms of each Educational Sponsorship Arrangement are set forth in writing and signed by Serono and the other parties to the Educational Sponsorship Arrangement;

b. Include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with Serono's Compliance Program. Additionally, Serono shall provide to each party to the Educational Sponsorship Arrangement a summary of its Code of Conduct and the applicable Serono Policies and Procedures;

c. Include in the written agreement a certification by the parties to the Educational Sponsorship Arrangement that the parties shall not violate the Federal anti-kickback statute or the FDA Sponsorship Requirements with respect to the performance of the Educational Sponsorship Arrangement; and

d. Include in the written agreement a requirement that the sponsor of the Educational Activity maintain all records relating to the activity and that the records shall be subject to audit by Serono or its agent.

3. *Records Retention and Access.* Serono shall retain and make available to OIG, upon request, all records relating to Educational Sponsorship Arrangements and all supporting documentation of the Educational Sponsorship Arrangements as required by this Section III.D and, to the extent available, all communications relating to the terms of the Educational Sponsorship Arrangements, the actual uses of the funding under the Arrangements, and the actual performance of the parties under the Arrangements.

E. Electronic Records.

Wherever the CIA requires Serono to deliver training, distribute policies or other materials, or to maintain documentation or certifications, Serono may meet this requirement through electronic methods and systems. In addition, where distribution of policies and materials is required, Serono may satisfy this requirement by posting the relevant materials on Serono's Intranet or other internal website, notifying relevant personnel of the materials, maintaining documentation of the manner of notification, and making qualified and knowledgeable employees available to answer questions or provide additional information.

F. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Serono shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the following reviews:

- i) a review to assist Serono in assessing its compliance with the obligations pursuant to Section III.D of this CIA (Educational Sponsorship Review); and
- ii) a review to assist Serono in assessing and evaluating its systems, processes, policies, and practices related to

Promotional and Product Services Related Functions
(Promotional and Product Services Engagement).

The Educational Sponsorship Review and the two components of the Promotional and Product Services Engagement (as set forth below) shall be referred to collectively as “the Reviews.”

Each IRO retained by Serono shall have expertise in the requirements of Federal health care program and FDA requirements applicable to sales, marketing, promotion, and education activities, as may be appropriate to the specific Engagement for which it is retained. Each IRO shall assess, along with Serono, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Description and Frequency of Reviews.* The Educational Sponsorship Review shall assess Serono’s practices relating to the sponsorship and/or funding of Educational Activities, as described more fully in this Section.

The Promotional and Product Services Engagement shall consist of two components – a systems review (the Promotional and Product Services Systems Review) and a transactions review (Promotional and Product Services Transactions Review), as described more fully in Appendix B to this CIA, which is incorporated by reference.

The Promotional and Product Services Transactions Review and the Educational Sponsorship Review shall each be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each of these annual Reviews. However, after the IRO(s) performs the first three of these Reviews, Serono, at its option, may request the OIG to permit that the Reviews be conducted internally and subject only to verification by the IRO for the remainder of the term of the CIA. The OIG retains sole

discretion over whether to permit those Reviews to be conducted internally by Serono and subject to validation by the IRO. In making its decision, the OIG will consider, among other factors, the results of the Reviews during the first three Reporting Periods of the CIA, and Serono's demonstrated audit capabilities to perform the Reviews internally. If the OIG denies Serono's request to shift the audit responsibilities, Serono agrees to engage the IRO to complete the remaining Reviews in accordance with the CIA.

If there are no material changes in Serono's systems, processes, policies, and practices relating to Promotional and Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. As set forth in Appendix B, if Serono materially changes its systems, processes, policies, and practices relating to Promotional and Product Services Related Functions, then the IRO shall perform a Promotional and Product Services Systems Review for the Reporting Period in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods.

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

d. Responsibilities and Liabilities. Nothing in this Section III.F affects Serono's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including the Federal anti-kickback statute or applicable to any FDA Sponsorship Requirements.

2. Arrangements Review. The IRO shall perform a review to assess whether Serono is complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.D.1 and III.D.2 by reviewing the documentation collected, tracked, and maintained with regard to a sample of Educational Sponsorship Arrangements. The IRO shall randomly select for review a sample of 15 of the Educational Sponsorship Arrangements with Serono Symposia International, Inc., that were entered into or renewed during the Reporting Period and a sample of 15 of the

Educational Sponsorship Arrangements with Serono Symposia International, Inc., that were entered into or renewed during the Reporting Period and a sample of 15 of the Educational Sponsorship Arrangements with other providers of Educational Activities that were entered into or renewed during the Reporting Period. The IRO shall assess whether Serono has implemented the Arrangements Procedures and Requirements. For each selected Educational Sponsorship Arrangement, the IRO shall assess whether Serono has complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Educational Sponsorship Arrangement.

The IRO's assessment shall include, but is not limited to: (a) verifying that the Educational Sponsorship Arrangement is documented and that records of the arrangement are collected, tracked, and maintained as required by Section III.D.1.a; (b) verifying that the Educational Sponsorship Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented; (c) verifying that the funding or other sponsorship related to the Arrangement is properly documented and that records are maintained; (d) verifying that Serono's involvement in the Educational Activity was properly limited in accordance with Sections III.D.1.f-g; (e) verifying that the Compliance Officer is reviewing records relating to Educational Sponsorship Arrangements, the internal review and approval process, and other Arrangements Procedures on a semi-annual basis and reporting the results of such review to the Compliance Committee; (f) verifying that effective responses are being implemented when violations of the Federal anti-kickback statute and/or FDA Sponsorship Requirements are discovered; (g) verifying that Serono has met the requirements of Section III.D.2; (h) determining whether (and if so, in what manner) Serono tracks or monitors the prescribing habits or product use of individuals or entities receiving the Educational Sponsorship Arrangements; (i) verifying that the Educational Activity for which Serono provided the Educational Sponsorship Arrangement actually occurred; and (j) verifying whether the use(s) to which the funds was put by the sponsor of the Educational Activity was consistent with the stated purpose of the funds as reflected in the application or request for sponsorship.

3. *Arrangements Review Report.* The IRO shall prepare a report based upon the Educational Sponsorship Arrangements Review performed (Arrangements Review Report). The Arrangements Review Report shall include the IRO's findings with respect to (a) whether Serono has generally implemented the Arrangements Procedures described in Section III.D.1; and (b) specific findings as to whether Serono has complied with the Arrangements Procedures and Arrangements Requirements with respect to each

of the selected Educational Sponsorship Arrangements reviewed by the IRO. The Arrangements Review Report shall also include any observations, findings and recommendations on possible improvements to Serono's policies, procedures, and systems in place to ensure that all Educational Sponsorship Arrangements do not violate the Federal anti-kickback statute and/or FDA Sponsorship Requirements.

4. *Promotional and Product Services Engagement Review Reports.* The IRO shall prepare a Report based upon each Promotional and Product Services Transaction Review and Promotional and Product Services Systems Review performed. Information to be included in each Report is described in Appendix B.

5. *Validation Review.* In the event OIG has reason to believe that: (a) any of Serono's IRO Reviews 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 Review in question complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Serono shall pay for the reasonable cost of any such Validation Review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted, as part of Serono's final Annual Report must be initiated no later than one year after Serono's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Serono 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, Serono 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 Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. Serono agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Review issues with Serono 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.

6. *Independence/Objectivity Certification.* The IRO shall include in its report(s) to Serono a certification or sworn affidavit that it has evaluated its professional independence and/or 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/or objective.

G. Disclosure Program.

Serono presently has a disclosure program designed to facilitate communications relating to compliance with Federal health care program and FDA requirements and with Serono's policies (Disclosure Program). During the term of this CIA, Serono shall continue to maintain a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Serono's policies, conduct, practices, or procedures with respect to Federal health care program requirements or FDA requirements believed by the individual to be a potential violation of criminal, civil, or administrative law. Serono 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 nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably:

- (1) permits a determination of the appropriateness of the alleged improper practice; and
- (2) provides an opportunity for taking corrective action, Serono 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.

H. 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://oig.hhs.gov>); and
- ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>).

c. "Screened Persons" include prospective and current owners (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading); officers; directors; employees; and those contractors and agents of Serono who are Covered Persons.

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

- a. Serono 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 persons to disclose whether they are an Ineligible Person.
- b. Serono shall screen all Screened Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

c. Serono 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) Serono to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

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

4. *Pending Charges and Proposed Exclusions.* If Serono 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 his or her employment or contract term, Serono shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

I. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at Serono's U.S. headquarters, Serono shall notify OIG, in writing, of any ongoing U.S.-based investigation or legal proceeding known to Serono conducted or brought by a governmental entity or its agents involving an allegation that Serono has committed a crime or has engaged in fraudulent activities in the United States (including the United States, the District of Columbia, and the territories and possessions of the United States). 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. Serono 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.

J. Notification of Reportable Events.

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves 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 prescription drugs or the sponsorship of any Educational Activity, for which penalties or exclusion may be authorized. A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Serono determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Serono 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 FDA authorities implicated;
- ii. a description of Serono’s actions taken to correct the Reportable Event; and
- iii. any further steps Serono plans to take to address the Reportable Event and prevent it from recurring.

Serono’s submission to OIG of any Reportable Event pursuant to the CIA does not preclude Serono from making the same disclosure through the OIG’s Self-Disclosure Protocol. Notwithstanding that fact, making a disclosure through the Self-Disclosure Protocol does not affect Serono’s obligation to comply with the requirements of this Section III.J.

K. Notification of Communications Regarding Off-Label Uses Issues.

Within 30 days after the date of any written report, correspondence, or communication from Serono to the FDA that materially discusses Serono’s or a Covered Person’s unlawful or improper promotion of Serono’s products (including any improper dissemination of information about off-label indications), Serono shall provide a copy of

the report, correspondence, or communication to the OIG. Serono 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.

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

Each Reporting Period, Serono shall obtain non-Serono records (*e.g.*, Verbatims or similar records) generated by an independent entity (Survey Entity) reflecting the purported content and subject matter of detailing interactions between sales representatives and health care practitioners (HCPs) for two Covered Products, as defined below. For each Covered Product, Serono shall contract with the Survey Entity to conduct inquiries into the content and subject matter of the detailing interactions. 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 surveys shall be conducted, beginning in the second full quarter after the Effective Date. For each Covered Product, Serono shall obtain records reflecting the purported content and subject matter of detailing sessions during the identified week in all regions across the United States.

Serono shall review the records obtained 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. Serono 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, Serono shall endeavor to gather additional factual information about the circumstances relating to any Off-Label Findings. As part of each Annual Report, Serono shall provide the OIG with copies of the underlying records of the detailing interactions, a copy of Serono's Off-Label Findings, and a description of the action(s), if any, Serono took in response to the Off-Label Findings.

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 Serono, the OIG shall select up to two Serono products to be the basis for a review of records reflecting the content of detailing sessions, and shall notify Serono of the products selected as the basis of the review. These identified products shall be known as the "Covered Products." The parties have already identified the Covered Products for the first Reporting Period.

M. Monitoring and Review of Requests for Off-Label Information.

Serono has in place a policy addressing the discussion and dissemination of information about non-FDA approved uses of products (off-label information). This policy provides, among other things, that Covered Persons may not directly or indirectly solicit, encourage, or promote unapproved uses of a product to HCPs. Serono also has established a Medical Information unit to handle unsolicited requests for information about possible off-label uses of Serono products.

Serono shall document and record all inquiries that Medical Information receives from HCPs regarding Serostim. Medical Information shall not supply information in response to a request for off-label information unless the request is made in writing.

1. Serostim Inquiry Database.

Medical Information personnel shall record in a database the following information about any and all inquiries relating to Serostim (Serostim Inquiry Database):

- a. date of inquiry;
- b. form of inquiry (e.g., mail/facsimile/phone);
- c. name of requesting HCP;
- d. nature/topic of request;
- e. nature/topic/form of response (including a record of the materials provided to the HCP in response to the request); and
- f. where available, the name of the Serono sales representative(s) assigned to call on the requesting HCP.

2. Serostim Inquiry Report.

On a quarterly basis, Medical Information shall submit a report to the Compliance Officer (Serostim Inquiry Report). The Serostim Inquiry Report shall: (a) contain the information described in Section III.M.1 for each inquiry; and (b) identify for each inquiry the sales territory from which the inquiry originated and, if available, the identity of the sales representative assigned to call on the requestor.

3. Compliance Officer Review and Analysis.

- a. On at least a semi-annual basis, the Compliance Officer shall review the Serostim Inquiry Reports provided by Medical Information, to assess whether an undue or unusual number of requests for off-label information has been generated in any particular sales territory or whether the information in the Serostim Inquiry Reports otherwise suggests that improper off-label promotion may have occurred. The Compliance Officer shall provide a report on the results of such review on at least a semi-annual basis to the Compliance Committee;
- b. On at least a semi-annual basis, the Compliance Officer shall review Medical Information's policies and procedures relating to the handling of inquiries concerning off-label use of Serostim, and to provide a report on the results of such review to the Compliance Committee; and
- c. If suspected violations of FDA Advertising and Promotion Requirements relating to off-label promotion are discovered, the Compliance Officer shall implement effective responses, including disclosing Reportable Events pursuant to Section III.J (Notification of Reportable Events) when appropriate.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Serono establishes or acquires a new business unit or location engaged in Promotional and Product Services Related Functions, Serono shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of the establishment or acquisition. This notification shall include the address of the new business unit or location, phone number, fax number, any Federal health care program provider number or supplier number, and the corresponding contractor's name and address that has issued each provider number. Each new business unit or location engaged in the functions specified above, and all Covered Persons at each such location, shall be subject to all the requirements of this CIA.

Serono shall use its best efforts to implement the requirements of this CIA in new business units engaged in Promotional and Product Services Related Functions as soon as practicable. Notwithstanding any other provision to the contrary, the requirements of this CIA shall not become effective for any new business until 120 days after the purchase or establishment or acquisition of such new business unit.

V. IMPLEMENTATION AND ANNUAL REPORTS

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

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, 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;

3. a copy of Serono's Code of Conduct required by Section III.B.1;

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

5. 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);

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

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

b. the number of 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.

7. a description of the records required to be collected, tracked, and maintained in accordance with Section III.D.1.a;
8. a description of the internal review and approval process required by Section III.D.1.g;
9. a description of the documentation, recordkeeping, and review procedures and other Arrangements Procedures required by Section III.D.1;
10. a description of the Disclosure Program required by Section III.G;
11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between Serono and the IRO; and (d) the proposed start and completion dates of each Review;
12. a certification from the IRO regarding its professional independence and/or objectivity with respect to Serono;
13. a description of the process by which Serono fulfills the requirements of Section III.H regarding Ineligible Persons;
14. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.H; the actions taken in response to the screening and removal obligations set forth in Section III.H;
15. as required by Section IV, a list of all of Serono'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 and/or supplier number(s)(if applicable); and the name and address of each Federal health care program contractor to which Serono currently submits claims (if applicable);
16. a description of Serono's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
17. the certifications required by Section V.C.

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

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (*e.g.*, change in contractor policy) and copies of any compliance-related Policies and Procedures;

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

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

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

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

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

5. a description of any changes to the records collected, tracked, and maintained pursuant to Section III.D.1.a;

6. a description of any changes to the internal review and approval process required by Section III.D.1.g;

7. a description of any changes to the documentation, recordkeeping, and review procedures and other Arrangements Procedures required by Section III.D.1;

8. a list of the parties with whom Serono entered or renewed Educational Sponsorship Arrangements during the Reporting Period; a description of the aggregate number of Educational Sponsorship Arrangements that Serono entered with each particular individual or entity during the Reporting Period; and a description of the aggregate amount of funding provided by Serono to each individual or entity provider of Educational Activities during the Reporting Period;

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

10. Serono's response and corrective action plan(s) related to any issues raised by the Reports prepared pursuant to Section III.F;

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

12. a certification from the IRO regarding its professional independence and/or objectivity with respect to Serono;

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

14. a summary of the disclosures in the disclosure log required by Section III.G that relate to Federal health care programs or to FDA requirements;

15. any changes to the process by which Serono fulfills the requirements of Section III.H regarding Ineligible Persons;

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

17. a summary describing any ongoing investigation or legal proceeding

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

18. a summary describing any ongoing communication with the FDA required to have been reported pursuant to Section III.K. The summary shall include a description of the matter, and the status of such matter;

19. as required by Section III.L, a copy of Serono's Off-Label Findings, the underlying records reflecting the content of detailing sessions between HCPs and Covered Persons, and a description of responsive action(s), if any, taken by Serono in connection with its Off-Label Findings;

20. a summary describing any Serostim Inquiry Report(s) indicating that an undue or unusual number of requests for off-label information has been generated in any particular sales territory or that otherwise suggest that improper off-label promotion may have occurred, the Compliance Officer's review and inquiry into any such occurrence(s), and the results and resolution of the matter;

21. a list and description of all actively promoted Serono products and, if available from third parties or other sources, information about the estimated relative usage (*e.g.*, the percentage) of those products for off-label purposes.

22. a description of all changes to the most recently provided list of Serono's locations (including addresses) as required by Section V.A.15; 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 Serono currently submits claims (if any);

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

24. the certifications required by Section V.C.

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

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, Serono is in compliance with all of the requirements of this CIA;

2. 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;

3. if applicable, Serono 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;

4. Serono's: (a) Policies and Procedures as referenced in Section III.B.2 above; (b) training materials used for purposes of Section III.C, above; (c) standard form or template contracts; (d) materials for training personnel on product education and promotion; and (e) promotional materials containing claims about Serono's products, have been reviewed by Serono's legal counsel and have been found to be in compliance with all applicable Federal health care program requirements and FDA Advertising and Promotional Requirements;

5. to the best of his or her knowledge, Serono has implemented procedures reasonably designed to ensure that all Educational Sponsorship Arrangements do not violate the Federal anti-kickback statute or FDA Sponsorship Requirements, including the Arrangements Procedures required in Section III.D of the CIA; and

6. to the best of his or her knowledge, Serono has fulfilled the requirements for New and Renewed Arrangements under Section III.D.2 of the CIA.

D. Designation of Information. Serono 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. Serono 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 made in writing and 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

Serono: Robert A. Freeman
U.S. Compliance Officer and Compliance Counsel
Serono, Inc.
1 Technology Place
Rockland, MA 02370
Telephone: 781.681.2490
Facsimile: 781.681.2933

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.

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 Serono's books, records, and other documents and supporting materials and/or conduct on-site

reviews of any of Serono's locations for the purpose of verifying and evaluating: (a) Serono's compliance with the terms of this CIA; and (b) Serono's compliance with the requirements of the Federal health care programs in which it participates and with applicable FDA requirements. The documentation described above shall be made available by Serono 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 Serono'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. Serono shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Serono's employees may elect to be interviewed with or without a representative of Serono present.

VIII. DOCUMENT AND RECORD RETENTION

Serono 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).

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

X. BREACH AND DEFAULT PROVISIONS

A breach of this CIA does not constitute a breach of the Settlement Agreement between Serono and the United States or the settlement agreements with individual states referred to in the Preamble. Any breach of the terms of those agreements does not constitute a breach of this CIA, except to the extent that such a breach independently also constitutes a breach of the CIA. Section X of this CIA specifies all of the remedies available to the OIG if Serono fails to satisfy its obligations under this CIA. The remedies available to the OIG under this Section X do not preempt or limit any actions that individual States may take against Serono under appropriate authorities.

Serono 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, Serono 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 Serono fails to establish and implement any of the following obligations as described each corresponding subsection of Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons;
- f. the Arrangements Procedures and/or Arrangements Requirements described in Sections III.D.1 and III.D.2;
- g. a Disclosure Program;

- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings;
- j. notification of communications regarding off-label related matters;
- k. a review of records reflecting the content of detailing sessions; and
- l. monitoring and review of requests for off-label information.

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 Serono fails to engage an IRO, as required in Section III.F 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 Serono 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 Serono fails to submit the Report associated with any of the Reviews in accordance with the requirements of Section III.F and Appendices A-B.

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Serono 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 Serono fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Serono, stating the specific grounds for its determination that Serono has failed to comply fully

and adequately with the CIA obligation(s) at issue and steps Serono shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Serono 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. Serono 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 Serono 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 Serono 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 Serono 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 Serono of: (a) Serono'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"). Such Demand Letter shall state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after receipt of the Demand Letter, Serono 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 Serono elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Serono 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 certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

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 Serono 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 Serono to report a Reportable Event and take corrective action as required in Section III.J.2;
- 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; or
- d. a failure to engage and use an IRO in accordance with Section III.F and Appendices A-B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Serono constitutes an independent basis for Serono's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Serono has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Serono of: (a) Serono's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Serono shall have 30 days from the date of receipt

of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. Serono is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Serono has begun to take action to cure the material breach; (ii) Serono is pursuing such action with due diligence; and (iii) Serono has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Serono fails to satisfy the requirements of Section X.D.3, OIG may exclude Serono from participation in the Federal health care programs. OIG shall notify Serono in writing of its determination to exclude Serono (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Serono's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Serono may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution.

1. *Review Rights.* Upon OIG's delivery to Serono of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Serono shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after

receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

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

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

- a. whether Serono was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Serono had begun to take action to cure the material breach within that period; (ii) Serono has pursued and is pursuing such action with due diligence; and (iii) Serono provided to OIG within that period a reasonable timetable for curing the material breach and Serono has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Serono, only after a DAB decision in favor of OIG. Serono's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Serono upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines

that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Serono may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Serono shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Serono, Serono shall be reinstated effective on the date of the original exclusion.

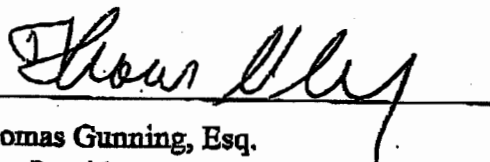
4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for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

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Serono and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Serono;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
- D. The undersigned Serono signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF SERONO HOLDING, INC.



Thomas Gunning, Esq.
Vice President and General Counsel
Serono Holding, Inc.

10/14/05

DATE


John T. Bentivoglio, Esq.
King & Spalding LLP
Counsel for Serono

DATE

ON BEHALF OF SERONO HOLDING, INC.

Thomas Gunning, Esq.
Vice President and General Counsel
Serono Holding, Inc.

DATE



John T. Bentivoglio, Esq.
King & Spalding LLP
Counsel for Serono

10/14/05
DATE

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

L. Morris

Lewis Morris
Chief Counsel to the Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

10/13/05

DATE

APPENDIX A
INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

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

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

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Educational Sponsorship Review and the Promotional and Product Services Engagement who have expertise in the Federal health care program and FDA requirements applicable to sales, marketing and promotion of pharmaceutical products, and to the sponsorship of Continuing Medical Education activities and other third-party scientific and educational conferences or meetings. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Serono products are reimbursed;
2. assign individuals to design and select the Educational Sponsorship Review and the Promotional and Product Services Engagement samples who are knowledgeable about appropriate statistical sampling techniques; and
3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Educational Sponsorship Review and Promotional and Product Services Engagement in accordance with the specific requirements of the CIA, including the Appendices to the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in the Educational Sponsorship Review and the Promotional and Product Services Engagement;
3. respond to all OIG inquires in a prompt, objective, and factual manner; and
4. prepare timely, clear, well-written reports that include all the information required by the CIA and Appendices A and B.

D. IRO Independence/Objectivity.

The IRO must perform the Educational Sponsorship Review and the Promotional and Product Services Engagement in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Serono.

E. IRO Removal/Termination.

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

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

Prior to requiring Serono to engage a new IRO, OIG shall notify Serono of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Serono may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Serono shall provide any additional information as may be requested by OIG under this

Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Serono prior to requiring Serono to terminate the IRO. However, the final determination as to whether or not to require Serono to engage a new IRO shall be made at the sole discretion of OIG.

**Appendix B to CIA for Serono Holding, Inc.
Promotional and Product Services Engagement**

I. IRO Engagement, General Description

As specified more fully below, Serono shall retain an Independent Review Organization(s) (IRO) to perform engagements to assist Serono in assessing and evaluating its systems, processes, policies, and procedures related to sales, marketing, promotion, and product services activities (Promotional and Product Services Engagement). The Promotional and Product Services Engagement shall consist of two components - a systems review (the Promotional and Product Services Systems Review) and a transactions review (the Promotional and Product Services Transactions Review), as described more fully below. Serono may engage, at its discretion, a single entity to perform both components of the Promotional and Product Services Engagement, provided that the entity has the necessary expertise and capabilities to perform both.

The Promotional and Product Services Systems Review shall be a review of Serono's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to sales, marketing, promotion, and product services activities. If there are no material changes in Serono's applicable systems, processes, policies, and procedures during the term of the CIA, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. If Serono materially changes its systems, processes, policies, and procedures relating to sales, marketing, promotion, and product services activities, the IRO shall perform an additional Promotional and Product Services Systems Review covering the Reporting Period in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and practices previously reported did not materially change; and 3) a review of the systems, processes, policies, and practices that materially changed.

The Promotional and Product Services Transactions Review shall include two elements: 1) reviews of samples of Control Documents, as defined below in Sections III.A.2; and 2) interviews with sales representatives, supervisory personnel, and others as necessary to investigate any Material Errors. The IRO shall perform the Promotional and Product Services Transactions Review on an annual basis and shall cover each Reporting Period.

Consistent with Section III.F.1.b of the CIA, after the third Reporting Period, the OIG may, at its discretion and upon written request of Serono, permit Serono to perform the Promotional and Product Services Transactions Reviews described in this Appendix B, subject to verification by the IRO. In such an instance, the OIG will provide additional guidance about the exact scope of the IRO's verification review after consultation with Serono. However, at a minimum, the IRO shall review at least 20% of the Sample Units reviewed by Serono in its internal Promotional and Product Services Transactions Review (Verification Review). In addition, as part of Serono's Annual Report, the IRO shall submit a report verifying that the requirements outlined in Section III.F and in Appendices A-B to the CIA have been satisfied and shall report the results, Sample Unit by Sample Unit, of the Verification Review performed. The IRO's report shall identify any discrepancies between the IRO's findings and those of Serono's internal review, and shall identify possible reasons for the discrepancies.

II. Promotional and Product Services Systems Review

A. General Business Policies and Practices for Review

For at least the first and fourth Reporting Periods, the IRO shall review Serono's systems, processes, policies, and procedures associated with the following activities, systems, and policies (Reviewed Policies and Practices):

1) Serono's systems, policies, processes, and procedures applicable to the manner in which Serono representatives handle requests or inquiries relating to off-label uses of Serono products and the manner in which Serono disseminates materials relating to off-label uses and other medical information about its products. This review includes:

- (i) the manner in which sales personnel and Medical Information receive and respond to requests for information about off-label uses;
- (ii) the form and content of information disseminated by Medical Information;
- (iii) Serono's internal review process for the information disseminated by Medical Information;
- (iv) Serono's systems, processes, and procedures to track information requests and responses to those requests;
- (v) the manner in which Medical Information collects and documents information in the Serostim Inquiry Database;
- (vi) the manner in which Medical Information provides Serostim

Inquiry Reports to the Compliance Officer; and
(vii) the internal review of Serostim Inquiry Reports and related processes, procedures, and resolution of any issues identified;

2) Serono's policies and procedures applicable to the manner and circumstances under which medical affairs personnel (including medical science liaisons) participate in meetings or events with physicians, pharmacists, or other health care professionals (HCPs) (either alone or with members of the sales force) and the role of the medical affairs personnel at such meetings or events;

3) Serono's systems, policies, processes, and procedures relating to the retention of HCPs as consultants (*e.g.*, including as members of advisory boards, focus groups, or clinical research project teams) or speakers. This shall include a review of:

- (i) the criteria used to determine whether, how many, and under what circumstances (including the venue for the performance of any services) Serono will enter contracts for such arrangements;
- (ii) the processes and criteria used to identify and select HCPs with whom Serono enters consultant, speaker, or other contractual arrangements, including the role played by sales representatives in the process. This includes a review of Serono's internal review and approval process for such contracts, and the circumstances under which there may be exceptions to the process;
- (iii) Serono's tracking or monitoring of services provided or the work performed by the consultants or speakers (including the receipt of the consultants' work product, if any);
- (iv) the uses made of work product received from consultants or speakers, if any;
- (v) Serono's processes for establishing the amounts paid to HCPs and the reasons or justifications for any differentials in the amounts paid to different HCPs;
- (vi) the criteria used to determine under what circumstances entertainment, recreation, travel, lodging, meals and/or other items or reimbursements are provided to consultants or speakers, and Serono's processes for establishing the amounts reimbursed or the type of entertainment or recreation provided;
- (vii) whether and in what manner Serono tracks or monitors the

prescribing habits or product use of individuals or entities with whom it enters consulting, speakers, or other contractual arrangements, if any; and

(viii) the budget funding source within Serono (*e.g.*, department or division) for the consulting or contractual arrangement;

4) Serono's systems, policies, processes, and procedures relating to charitable contributions or sponsorships by Serono. This review shall include a review of the following items:

(i) the processes and procedures used to approve charitable contributions or sponsorships;

(ii) the criteria used to determine whether and under what circumstances the charitable contributions or sponsorships will be provided;

(iii) the processes and criteria used to select and approve recipients of the charitable contributions or sponsorships from Serono, including the role played by sales representatives in the processes (if any), and the circumstances under which there may be exceptions to the processes;

(iv) Serono's policies and procedures related to circumstances, if any, under which the recipient or the recipient's agent is required to disclose Serono's charitable contribution or sponsorship and any financial relationship Serono may have with the recipients;

(v) Serono's policies or procedures for determining and memorializing the amounts paid to recipients of the charitable contribution or sponsorship and the purpose or justifications for the amounts paid;

(vi) Serono's policies and procedures relating to the independence of any programs funded through the charitable contribution or sponsorship;

(vii) Serono's policies and procedures relating to the content and promotional nature of any programs sponsored through the charitable contributions or sponsorships;

(viii) whether and in what manner Serono tracks or monitors the prescribing habits or product use of individuals or entities receiving the charitable contribution or funding, if any; and

(ix) the budget funding source within Serono (*e.g.*, department or division) from which the charitable contributions or sponsorships are

provided;

5) Serono's systems, policies, processes, and procedures relating to funding or sponsoring of research agreements, grants, and/or research collaborations (including clinical trials and independent research) (collectively "Research Activities") entered into or funded by Serono. This review shall include a review of the following items:

- (i) the processes and procedures used by Serono to approve Research Activities;
- (ii) the criteria used to determine whether, and under what circumstances, Serono will fund or otherwise participate in the Research Activities;
- (iii) the processes and criteria used to select and approve the funding or other participation by Serono in Research Activities, including the role played by sales representatives in the processes (if any), and the circumstances under which there may be exceptions to the processes;
- (iv) Serono's policies and procedures for requiring the recipient of the funding for the Research Activity to disclose Serono's participation in or funding of Research Activities and any financial relationship Serono may have with the recipient;
- (v) Serono's policies or procedures for determining and memorializing the amounts paid to participants in the Research Activities and the purpose or justifications for the amounts paid;
- (vi) Serono's policies and procedures relating to the independence of the programs funded through Research Activities;
- (vii) Serono's policies and procedures relating to the content and promotional nature of any programs sponsored through or associated with the Research Activities;
- (viii) whether and in what manner Serono tracks or monitors the prescribing habits or product use of individuals or entities receiving funding or otherwise participating in the Research Activities, if any; and
- (ix) the budget funding source within Serono (*e.g.*, department or division) for the Research Activity;

6) Serono's systems, policies, processes, and procedures relating to the provision of any gifts, meals, receptions, travel, entertainment or other items of value (collectively "Expenses") to HCPs. This shall include a review of:

- (i) the criteria used to determine whether, how many, and under what circumstances (including the venue for the performance of any services) Serono will reimburse for Expenses of HCPs;
- (ii) the processes and criteria used to identify and select HCPs to whom Serono provides reimbursement of Expenses. This includes a review of Serono's internal review and approval process for such Expenses, the circumstances under which there may be exceptions to the processes, and the role played by sales representatives in the process;
- (iii) Serono's tracking or monitoring of services provided, or the work performed by the HCPs in exchange for the Expenses, if any;
- (iv) the uses made of work product received from HCPs receiving Expenses from Serono, if any;
- (v) Serono's processes for establishing the amounts paid to HCPs and the reasons or justifications for any differentials in the amounts paid to different HCPs;
- (vi) whether and in what manner Serono tracks or monitors the prescribing habits or product use of HCPs who receive Expenses from Serono, if any; and
- (vii) the budget funding source within Serono (e.g., department or division) for the Expenses;

7) Serono's systems, policies, processes, and procedures relating to: (i) expenditures for third-party advice about reimbursement or claims submission for Serono products; (ii) the provision of or payment for customer or patient assistance programs; and (iii) the provision of debt forgiveness, debt reduction, or other like assistance to customers, purchasers, or prescribers;

8) Serono's systems, policies, processes, and procedures for tracking expenditures (individual and aggregate) associated with the Reviewed Policies and Practices;

9) Serono's policies, processes, and procedures relating to the disciplinary actions that Serono may impose in the event a Covered Person violates a Serono policy or procedure; and

10) Serono's systems, policies, processes and procedures for compensating (including with salaries and bonuses) non-Overtime Eligible employees,

with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate sales and marketing personnel to engage in the improper promotion, sales, and marketing of Serono's products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance.

B. Promotional and Product Services Systems Review Report

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

- a) a description of the documentation (including policies) reviewed and any personnel interviewed;
- b) a detailed description of Serono's systems, policies, processes, and practices with regard to the items identified in Sections II.A.1-7 above, including a general description of Serono's control and accountability systems (*e.g.*, documentation and approval requirements, tracking mechanisms) and written policies regarding the Reviewed Policies and Practices;
- c) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-7 above are made known or disseminated within Serono;
- d) a detailed description of any system used to track and respond to requests for information about Serono's products that come to Medical Information;
- e) a description of Serono's systems, policies, processes, and procedures for tracking expenditures associated with the Reviewed Policies and Practices or other promotional activities;
- f) a general description of the disciplinary measures Serono has established for failure to comply with its systems, processes, policies and procedures relating to the Reviewed Policies and Practices;
- g) a detailed description of Serono's compensation system

(including salaries and bonuses) for non-Overtime Eligible employees, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Serono may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

- h) findings and supporting rationale regarding any weaknesses in Serono's promotional and product services related systems, processes, policies, and practices reviewed, if any; and
- i) recommendations to improve any of the reviewed promotional and product information related systems, policies, processes, or practices, if any.

Prior to the IRO's submission of the report to the OIG, Serono shall be provided with a copy of the report and an opportunity to respond to each comment made by the IRO. Provided it does not delay the timely filing of the Annual Reports, any responses by Serono may be included in the IRO report submitted to the OIG. Otherwise, any responses by Serono to the IRO's findings may be submitted separately to the OIG following the Annual Report submission.

III. Promotional and Product Services Transactions Review

Except as otherwise provided in Section III.F.1.b of the CIA and in Section I of this Appendix, the IRO shall conduct a Promotional and Product Services Transactions Review for each of the Reporting Periods. The Transactions Review shall include two general elements: (1) reviews of Sample Units of Control Documents associated with certain Reviewed Activities; and (2) interviews with sales representatives, contract sales representatives, managers, and other supervisory personnel relating to any identified Material Errors.

A. Promotional and Product Services Transactions Review

1) Reviewed Activities

For each Reporting Period, the IRO shall review Serono's systems, policies, procedures, and practices pertaining to the following types of activities:

- a) retention of HCPs, and other purchasers and/or prescribers of Serono's Products, for speaking arrangements;
- b) retention of HCPs, and other purchasers and/or prescribers of Serono's Products, for consulting arrangements;
- c) awarding or payment of research grants and the funding or other participation in research activities;
- d) awarding or payment of charitable contributions or sponsorships; and
- e) provision of gifts, meals, entertainment, recreation or other items to HCPs.

This list of activities shall hereafter be referred to as the "Reviewed Activities."

2) Description of Reviewed Activities Control Documents

For purposes of the Promotional and Product Services Transactions Review, the term "Control Documents" shall mean those documents associated with, or reflecting expenditures, for the Reviewed Activities outlined in Section III.A.1 above. The IRO shall review and evaluate Control Documents associated with these expenditures. By way of example, Control Documents that the IRO may review could include, but are not limited to, the following types of documents:

- a) Agreements with HCPs engaged to be speakers for Serono;
- b) Agreements with HCPs to provide consulting services;
- c) Contracts or agreements relating to sponsorship of Educational Activities;
- d) Contracts or agreements relating to research funding;
- e) Documents reflecting charitable contributions or sponsorships; and
- f) Expense Reports of field sales and marketing personnel.

3) Review of Reviewed Activities Control Documents

The Control Documents associated with each type of Reviewed Activity listed in Section III.A.1 shall be considered a separate universe of Control Documents. Each set of Control Documents relating to a particular instance of a Reviewed Activity shall be referred to as a Sample Unit. For example, all Control Documents associated with a speaking arrangement entered into by Serono and a particular HCP shall be considered a Sample Unit.

For each Reviewed Activity, the IRO shall randomly select and review the following number of Sample Units from each universe:

- a) in connection with the Reviewed Activities identified in Section III.A.1.a, 50 Sample Units;
- b) in connection with the Reviewed Activities identified in Section III.A.1.b, 50 Sample Units;
- c) in connection with the Reviewed Activities identified in Section III.A.1.c, 10 Sample Units;
- d) in connection with the Reviewed Activities identified in Section III.A.1.d, 20 Sample Units;
- e) in connection with the Reviewed Activities identified in Section III.A.1.e, 50 Sample Units.

For each Sample Unit the IRO shall determine:

- i) whether all required Control Documents associated with the Reviewed Activity exist in appropriate files in accordance with Serono's policies;
- ii) whether all required Control Documents associated with the Reviewed Activity were completed and archived in accordance with the requirements set forth in Serono's policies; and
- iii) whether the Control Documents associated with the Reviewed Activity reflect that all required written approvals were obtained in accordance with Serono's policies.

4) Identification of Material Errors and Additional Engagement

Any Sample Unit that does not satisfy the criteria set forth above in Section III.A.3 shall be considered an exception and shall be so denoted by the IRO. The IRO will consider a Control Document to have a Material Error if either of the following is identified:

- a) all the appropriate and required Control Documents relating to a Reviewed Activity do not exist and (i) no corrective action has been taken prior to the IRO review; or (ii) the IRO cannot confirm that Serono has otherwise followed its policies and procedures; or
- b) information or data is omitted from key fields in the Control Documents that prevents the IRO from understanding the nature of the expenditure and/or assessing compliance with Serono's Policies and Procedures.

If the IRO finds any Material Errors, it shall conduct an Additional Engagement to review the expenditures or activities reflected in the erroneous Sample Unit. The IRO shall perform this Additional Engagement in a manner designed to determine the root cause of the Material Errors. For instance, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel (e.g., sales representatives, contract sales representatives, managers, and other supervisory personnel) to identify the root cause(s) of the errors.

B. Promotional and Product Services Transactions Review Report

Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a Report based on its Promotional and Product Services Transactions Review. Each Report shall include the following:

1. Elements to Be Included:

- a) Promotional and Product Services Transactions Review Objectives: A clear statement of the objectives intended to be achieved by the Review;
- b) Engagement Protocol: A detailed narrative description of the procedures performed and a description of the universes of Sample Units from which samples were selected; and
- c) Sources of Data: A full description of documentation (and/or other information) relied upon by the IRO when performing the Promotional and Product Services Transactions Review.

2. Results to Be Included:

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

- a) a description of each type of Sample Unit reviewed, including the number of each type of Sample Units reviewed (*i.e.*, the number of Sample Units associated with each type of Reviewed Activity) and an identification of the types of Control Documents reviewed for each type of Sample Unit;
- b) for each Sample Unit, the IRO shall state its findings and supporting

rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all requirements set forth in the applicable Serono's policy; (iii) each Control Document reflects that Serono's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (iv) any disciplinary action was taken in those instances in which a Serono policy was not followed;

c) for each Sample Unit reviewed, the IRO shall identify and describe all exceptions discovered. The IRO shall describe those situations where corrective action was taken prior to the IRO review, including a description of the circumstances requiring corrective action and the nature of the corrective action. The IRO shall also describe the situations in which it attempted to confirm whether Serono otherwise followed its policies and procedures, and the steps undertaken by the IRO to make that determination;

e) if any Material Errors were discovered for any Sample Unit, the IRO shall describe the Material Error in detail and the additional review procedures it performed, including any interviews conducted. The IRO shall state its findings as to the root cause of each Material Error(s);

f) the findings and supporting rationale regarding any weaknesses in Serono's systems, processes, policies, and practices relating to the Reviewed Activities, if any; and

g) recommendations for improvement in Serono's systems, processes, policies, and practices relating to the Reviewed Activities, if any.