

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
NOVO NORDISK INCORPORATED**

**I. PREAMBLE**

Novo Nordisk Incorporated hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Novo Nordisk Incorporated shall be referred to as “NNI.”

Contemporaneously with this CIA, NNI is entering into a Settlement Agreement with the United States. NNI will also enter into settlement agreements with various States, and NNI’s agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA (as defined below), NNI established a voluntary compliance program applicable to all NNI employees (Compliance Program). NNI’s Compliance Program includes a Chief Compliance Officer and a Compliance Committee. The Compliance Program also includes a U.S. Code of Business Conduct (Code of Conduct), written policies and procedures, educational and training initiatives, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations and disciplinary procedures, screening measures for Ineligible Persons, and internal auditing procedures.

NNI shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. NNI may modify its Compliance Program as appropriate, but, at a minimum, NNI shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

## II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by NNI under this CIA shall be 5 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). The first Reporting Period shall be from the Effective Date through May 31, 2012. The second and subsequent Reporting Periods shall from June 1 through May 31 of each of the subsequent four years of the term of the CIA. May 31, 2016 shall be the last day of the fifth Reporting Period of the CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

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

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

1. "Covered Persons" includes:

- a. all owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading);
- b. all officers, directors, and employees of NNI who have responsibilities relating to Promotional Functions or Product Related Functions, except as carved out below in this Section II.C.1; and
- c. all contractors, subcontractors, agents, and other persons who perform Promotional Functions or Product Related Functions on behalf of NNI.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year,

except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.

2. “Relevant Covered Persons” includes all Covered Persons whose job responsibilities relate to Promotional Functions or Product Related Functions.
3. “Government Reimbursed Products” refers to all NNI human pharmaceutical products promoted or sold by NNI in the United States or pursuant to contracts with the United States that are reimbursed by Federal health care programs.
4. The term “Promotional Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products.
5. The term “Product Related Functions” includes: (a) the preparation or external dissemination of non-promotional materials about Government Reimbursed Products, including those functions relating to any applicable review committees and to NNI’s Medical Affairs Department (Medical Affairs); (b) contracting with healthcare professionals (“HCPs”) in the United States to conduct post-marketing clinical trials and post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products in government-listed compendia (such as Drugdex or other compendia of information about Government Reimbursed Products.)
6. The term “Third Party Educational Activity” shall mean any continuing medical education (CME), disease awareness, or other scientific, educational, or professional program, meeting, or event governed by Federal health care program and/or FDA requirements supported by NNI, including but not limited to, sponsorship of symposia at medical conferences.

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

Prior to the Effective Date, NNI established a Compliance Program. NNI shall establish and maintain a Compliance Program throughout the term of the CIA that includes the following elements:

#### **A. Compliance Responsibilities of Certain NNI Employees and the Board of Directors.**

1. *Chief Compliance Officer.* Prior to the Effective Date, NNI appointed an individual to serve as its Chief Compliance Officer, and NNI shall maintain a Chief Compliance Officer for the term of the CIA. The Chief Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. The Chief Compliance Officer shall be a member of senior management of NNI, shall report directly to the Chief Executive Officer of NNI, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of NNI or a Committee of the Board of Directors of NNI, and shall be authorized to report on such matters to the Board of Directors or a Committee of the Board of Directors of NNI at any time. The Chief Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Chief Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by NNI as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Chief Compliance Officer shall be limited and must not interfere with the Chief Compliance Officer's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee.* Prior to the Effective Date, NNI appointed a Compliance Committee. The Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., President of NNI, NNI Chief Financial Officer, and other NNI senior executives of relevant departments, such as legal, medical and

regulatory affairs, sales, and marketing, human resources, and commercial operations). The Chief Compliance Officer shall chair the Compliance Committee and the Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the NNI's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

NNI 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 30 days after such a change.

3. *Board of Directors Compliance Obligations.* The NNI Board of Directors (Board) or a Committee of the NNI Board of Directors (Committee of the Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board or a Committee of the Board shall, at a minimum, be responsible for the following:

a. The Board or a Committee of the Board shall meet at least quarterly to review and oversee NNI's Compliance Program, including but not limited to the performance of the Chief Compliance Officer and other compliance personnel.

b. For each Reporting Period of the CIA, the Board or a Committee of the Board shall adopt a resolution, signed by each individual member of the Board or a Committee of the Board, summarizing its review and oversight of NNI's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors [or a Committee of the Board of Directors] has made a reasonable inquiry into the operations of NNI's Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the performance and activities of the Chief Compliance Officer and other compliance personnel for the time period [**insert time period**]. Based on these steps, the Board [or a Committee of the Board of Directors] has concluded that, to the best of its knowledge, NNI has

implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

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

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

4. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain NNI officers or employees (“Certifying Employees”) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify, in writing or electronically, that the applicable NNI business unit is compliant with applicable Federal health care program and FDA requirements, and with the obligations of this CIA. These NNI Certifying Employees shall include the following: NNI President; Corporate Vice President, Biopharmaceuticals; Senior Director, Market Access; Senior Brand Director, NovoSeven; Associate Brand Director, NovoSeven; Director, Operations Hormone Therapy Marketing; Associate Brand Director, Hormone Therapy; Director, Brand Director, Norditropin; Associate Brand Director, Norditropin; Vice President, Biopharmaceutical Sales; Business Regional Director, Mid Atlantic; Business Regional Director, Central; Business Regional Director, West; Business Regional Director, Rocky Mountain; Business Regional Director, Northeast; Business Regional Director, Southeast; Corporate Vice President, National Diabetes Sales; Corporate Vice President, Diabetes Marketing; Corporate Vice President, Clinical Development, Medical and Regulatory Affairs; Vice President, Diabetes Sales East; Vice President, Diabetes Sales Southeast; Vice President, Diabetes Sales West; Vice President, Managed Market Sales; Vice President, Degludec/Degludec Plus; Vice President, Diabetes Portfolio Management; Vice President, Levemir; Vice President, NovoLog; Vice President, Victoza; and Vice President, Managed Markets.

For each Reporting Period, each Certifying Employee shall sign a certification, in writing or electronically, that states:

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“I am the \_\_\_\_\_ [insert title] of \_\_\_\_\_ [insert name of the department or functional area]. I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the \_\_\_\_\_ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and NNI policies, and I have taken steps to promote such compliance. In the event that I have identified potential issues of noncompliance with these requirements, I have referred all such issues consistent with NNI processes for reporting potential misconduct for further review and follow-up. Apart from those referred issues, I am not currently aware of any violations of applicable Federal health care program requirements, FDA requirements, requirements of the Corporate Integrity Agreement, or the requirements of NNI policies. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, NNI developed, implemented, and distributed a written Code of Conduct to all Covered Persons. NNI shall 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. NNI’s commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health program requirements and FDA requirements;

- b. NNI's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with NNI's own Policies and Procedures;
- c. the requirement that all of NNI's Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by NNI, suspected violations of any Federal health care program or FDA requirements or of NNI's own Policies and Procedures; and
- d. the right of all individuals to use the Disclosure Program described in Section III.E, and NNI's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished within the last 90 days, within 90 days after the Effective Date, each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by NNI's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

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

2. *Policies and Procedures.* Prior to the Effective Date, NNI implemented written Policies and Procedures regarding the operation of its compliance program which include certain compliance program requirements outlined in this CIA, and NNI's compliance with Federal health care program and FDA requirements. To the extent not already accomplished, within 120 days after the Effective Date, NNI shall ensure that the Policies and Procedures address or shall continue to address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);
- c. appropriate ways to conduct Product Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b(b)), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);
- d. appropriate ways to conduct Promotional Functions in compliance with all applicable FDA requirements;
- e. appropriate ways to conduct Product Related Functions in compliance with all applicable FDA requirements;
- f. the materials and information that may be distributed by NNI sales representatives about Government Reimbursed Products and the manner in which NNI sales representatives respond to requests for information about non-FDA approved (or “off-label”) uses of Government Reimbursed Products. These Policies and Procedures shall require that sales representatives refer all requests for information about non-FDA approved (“off-label”) uses of Government Reimbursed Products to Medical Affairs;
- g. the materials and information that may be distributed by Medical Affairs, and the mechanisms through, and manner in which, Medical Affairs receives and responds to requests for information from an HCP or a managed markets customer about off-label uses of NNI’s Government Reimbursed Products; the form and content of information disseminated by NNI in response to such

requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Medical Affairs develop a database(s) (“Inquiries Database”) to track all requests for information about NNI’s products to Medical Affairs. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about NNI’s products: 1) date of Inquiry; 2) form of Inquiry (*e.g.*, fax, phone, etc.); 3) name of the requesting HCP, managed markets customer, or health care institution (HCI) in accordance with applicable privacy laws; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from NNI (including a record of the materials provided to the HCP or HCI in response to the request); and 6) the name of the NNI representative who called on or interacted with the HCP, customer, or HCI, if known;

- h. the manner and circumstances under which medical personnel from Medical Affairs interact with or participate in meetings or events with HCPs or HCIs (either alone or with sales representatives or account executives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to unsolicited requests about off-label indications of Government Reimbursed Products;
- i. the development, implementation, and review of call plans for sales representatives who promote Government Reimbursed Products. For each Government Reimbursed Product, the Policies and Procedures shall require that NNI review the call plans for the product and the bases upon, and circumstances under which HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the call plans. The Policies and Procedures shall also require that NNI modify the call plans as necessary to ensure that NNI is promoting Government Reimbursed Products in a

manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;

- j. the development, implementation, and review of plans for the distribution of samples of Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from NNI. The Policies and Procedures shall also require that NNI modify the Sample Distribution Plans as necessary to ensure that NNI is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;
- k. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;
- l. programs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities, if any. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA

requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;

- m. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that NNI's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- n. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.6 above. These Policies and Procedures shall be designed to ensure that NNI's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements;

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

- o. review of promotional materials and information intended to be disseminated outside NNI by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns

are properly addressed during NNI's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program and FDA requirements. The Policies and Procedures shall require that: 1) applicable review committees review all promotional materials prior to the distribution or use of such materials; and 2) deviations from the standard review committee practices and protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;

- p. sponsorship, funding of, and disclosures relating to Product Related Functions. These Policies and Procedures shall be designed to ensure that NNI's funding, sponsorship, and disclosure complies with all applicable Federal health care program and FDA requirements;
- q. compensation (including through salaries, bonuses, and contests) for Relevant Covered Persons who are sales representatives. These Policies and Procedures shall: 1) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of NNI's Government Reimbursed Products; and 2) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate off-label promotion of Government Reimbursed Products;
- r. the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the Product ("Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (*e.g.*, any changes based on NNI's discovery of erroneous or scientifically unsound information or data associated with the

information in the Compendia.) The Policies and Procedures shall include a requirement that NNI conduct an annual review of all arrangements, processing fees, or other payments or financial support (if any) provided by the company to any Compendia. NNI compliance personnel shall be involved in this review;

- s. disciplinary policies and procedures for violations of NNI's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

Within 120 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons whose job functions relate to these policies and procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), NNI shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be made available to all Covered Persons whose job functions relate to these policies and procedures.

#### C. Training and Education.

NNI represents that it provides training to its employees on a regular basis concerning a variety of topics. The training covered by this CIA need not be separate and distinct from the regular training provided by NNI, but instead may be integrated fully into such regular training so long as the training meets the following requirements:

1. *General Training.* Within 90 days after the Effective Date, NNI shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain NNI's:

- a. CIA requirements; and
- b. NNI's Compliance Program, including the Code of Conduct.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date,

whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least a one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 90 days after the Effective Date, each Relevant Covered Person each Relevant Covered Person engaged in Promotional Functions and/or Product Related Functions shall receive at least three hours of Specific Training applicable to their specific job functions in addition to the General Training required above. This Specific Training shall include a discussion of:

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

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least 3 hours of Specific Training in each subsequent Reporting Period.

3. *Board Member Training.* Within 90 days after the Effective Date, NNI shall provide at least one hour of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

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

5. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area of the training, including applicable Federal health care program and FDA requirements.

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

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

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, NNI shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist NNI in assessing and evaluating its Promotional Functions and its Product Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

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

The IRO(s) shall conduct two types of reviews that assess NNI’s systems, processes, policies, procedures, and practices relating to Promotional Functions and to Product Related Functions (collectively, “IRO Reviews”).

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

Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendix B.

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

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

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

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

Prior to initiating a Validation Review, OIG shall notify NNI 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, NNI may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. NNI agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any

IRO Review issues with NNI prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

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

E. Disclosure Program.

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

- (1) permits a determination of the appropriateness of the alleged improper practice; and
- (2) provides an opportunity for taking corrective action, NNI shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

F. Ineligible Persons.

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

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
  
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
  - ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

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

- a. as part of the hiring or contracting process, NNI shall require all prospective and current Covered Persons to disclose whether they are Ineligible Persons and shall screen such Covered Persons against the Exclusion Lists prior to engaging their services.
- b. NNI shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. NNI shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

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

4. *Pending Charges and Proposed Exclusions.* If NNI has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract, NNI shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, NNI shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to NNI conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that NNI has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. NNI shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reportable Events.

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

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

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

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

days after making the determination that the Reportable Event exists. NNI shall not be required to report as a Reportable Event any matter previously disclosed under Section III.G.

3. *Reportable Events under Sections III.H.1.a-c.* For Reportable Events under Sections III.I.1.a-c, the report to OIG shall include:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program or FDA authorities implicated;
- b. a description of NNI's actions taken to correct the Reportable Event; and
- c. any further steps NNI plans to take to address the Reportable Event and prevent it from recurring.

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

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

J. Field Force Monitoring and Review Efforts.

To the extent not already accomplished, within 120 days after the Effective Date, NNI shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales representatives' interactions with HCPs and HCIs. The FFMP shall

be a formalized process designed to directly and indirectly observe the appropriateness of sales representatives' interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: 1) a Speaker Monitoring Program; 2) direct field observations (Observations) of sales representatives; and 3) the monitoring and review of other records relating to sales representatives' interactions with HCPs and HCIs (Records Reviews).

Prior to the Effective Date, NNI had systems to address detailing, sampling, and medical inquiries. The detailing systems shall continue to include controls designed to ensure compliance with Federal health care program and FDA requirements and shall permit the tracking of detailing-related activities, including the submission of Inquiries (as defined above in Section III.B.2.g) and the distribution of samples of Government Reimbursed Products to HCPs. The detailing systems shall continue to include centralized mechanisms through which sales representatives may submit Inquiries to Medical Affairs. With regard to the distribution of samples, the detailing systems and its controls shall prevent the delivery of samples of particular Government Reimbursed Products to HCPs that NNI has identified as belonging to a specialty group that is unlikely to prescribe the particular Government Reimbursed Product for a use consistent with the FDA-approved label for the product.

1. *Speaker Program Activities.* With regard to speaker programs, NNI shall maintain processes to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements that the speaker may only use NNI approved materials and may not directly or indirectly promote the product for off-label uses.) NNI shall maintain centralized processes and related electronic systems through which all speaker programs are tracked. This system shall establish controls regarding eligibility and qualifications of speakers and venues for the programs, NNI shall ensure that speakers are paid and tracked according to a centrally managed process, and using a pre-set rate structure determined based on a fair-market value analysis conducted by NNI.

NNI shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, NNI shall track and review the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs conducted during each Reporting Period. NNI shall require certified evaluations by sales representatives or other NNI personnel regarding whether a

speaker program complied with NNI requirements, and in the event of non-compliance, NNI shall ensure appropriate follow up activity to address the violation.

To the extent not already accomplished, NNI shall institute a Speaker Monitoring Program under which NNI compliance personnel, other appropriately trained NNI personnel who are independent from the functional area being monitored or outside personnel acting on behalf of NNI shall attend 50 speaker programs during each Reporting Period and conduct live audits of the programs (Speaker Program Audits). The programs subject to Speaker Program Audits shall be selected both on a risk-based targeting approach and on a sampling approach. For each program reviewed, personnel conducting the Speaker Program Audits shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and NNI representative activities during the program to assess whether the programs were conducted in a manner consistent with NNI's Policies and Procedures. NNI shall maintain the controls around speaker programs as described above, and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

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

- 1) the identity of the sales representative;
- 2) the identity of the NNI compliance personnel or other appropriately trained NNI personnel;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;

- 5) an overall assessment of compliance with NNI policy; and
- 6) the identification of any potential off-label promotional activity or other improper conduct by the sales representative.

NNI compliance personnel or other appropriately trained NNI personnel who are independent from the monitored functional area shall conduct at least 20 Observations during each Reporting Period.

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

These Records Reviews shall include the monitoring and review of: 1) records and systems relating to sales representatives' interactions with HCPs and HCIs (including sample distribution records, sales representative corporate charge card expense records, and aggregate spend records concerning sales representatives' interactions with HCPs); 2) requests for or inquiries relating to medical information; 3) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of sales representatives' interactions with HCPs and HCIs; 4) sales representative call notes or other NNI records reflecting the details of sales representative visits with HCPs or HCIs; 5) sales representatives' e-mails and other electronic records; and 6) recorded results of the Observations of sales representatives and applicable notes or information from the sales representatives' managers.

4. *Reporting and Follow-up.* Personnel conducting the Speaker Program Audits, Observations, and Records Reviews shall have access to all relevant records and information necessary to assess potential or actual compliance violations. Results from the FFMP audits, including the identification of potential violations of policies and/or

legal requirements, shall be compiled and reported to the Compliance Department for review and follow-up as appropriate. In the event that a potential violation of NNI's Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, is identified during any aspect of the FFMP, NNI shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified in Speaker Program Activities, Observation and/or Records Review and any corrective action shall be recorded in the files of the Compliance Department.

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

K. Monitoring of Non-Promotional Activities.

To the extent not already accomplished, within 120 days after the Effective Date NNI shall develop and implement a monitoring program for the following types of activities: 1) consultant arrangement activities; and 2) medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program.

1. *Consultant Arrangement Activities.* To the extent that NNI engages U.S. based HCPs or HCIs for services that relate to Promotional Functions or to Product Related Functions as defined in Sections II.C.4 and II.C.5 of this Agreement other than for speaker programs (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs or HCIs shall be referred to herein as Consultants. NNI shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid based on a fair-market value analysis conducted by NNI.

Within 120 days of the Effective Date, NNI shall establish a process through which individuals (e.g., sales representatives or managers) who propose that NNI fund a particular consulting arrangement event are required to seek and obtain approval for the

event. At a minimum, the process shall include evaluation of the following for each proposed consultant arrangement: i) the business purpose/necessity of the engagement including the broader context of other approved events (i.e., a needs assessment); ii) the general qualifications and experience of the consultant to provide the service; iii) the number of consultants necessary for the event; iv) venue/location (as applicable); v) payment and anticipated expenses; and v) compliance with other applicable legal standards. Representatives from NNI's Advisory Board Oversight Committee, HCP Process Management Group, Legal or Medical Departments shall participate in the review and approval process described in this paragraph. A proposed consultant arrangement must be approved in accordance with NNI policy before a consultant event may occur. Violations of the policy (including failure to implement an event in compliance with the direction provided by the engagement reviewer(s)) are referred for further investigation in accordance with NNI policy and may result in disciplinary action, up to and including termination.

The consultant arrangements subject to the preceding paragraph shall be explicitly defined in NNI policies. The arrangements subject to review include, but are not limited to, most types of consulting meetings, advisory boards, speaker training and novel types of promotional programs, and consultant programs for sales representative training.

To the extent not already accomplished, within 120 days after the Effective Date, NNI shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, NNI received the work product generated by the Consultant.

Within 120 days after the Effective Date, NNI shall establish a Consultant Monitoring Program through which it shall conduct audits for each Reporting Period (Consultant Program Audits) of at least 30 Consultant arrangements with HCPs. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a sampling approach. NNI compliance personnel conducting the Consultant Program Audits shall review needs assessment documents, consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with NNI's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Department for review and follow-up as appropriate.

2. *Medical Education Grant Activities.* Within 120 days of the Effective Date, NNI shall establish a process for the prospective review of medical education grants. All medical education grant requests received by NNI shall be evaluated prior to approval or rejection. NNI policy shall expressly prohibit the involvement of Sales and Marketing personnel in the medical education grant decision-making process.

Grant requests shall be processed in accordance with standardized criteria developed by NNI. Throughout the term of the CIA, NNI shall adhere to a medical education grant review and approval process that comport with the requirements of this CIA and shall notify the OIG in writing at least 60 days prior to the implementation of any new system subsequent to the Effective Date.

To the extent not already accomplished, within 120 days after the Effective Date, NNI shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 30 medical education grants. The Grants Monitoring Program shall select grants for review both on a risk-based targeting approach and on a sampling approach. NNI compliance personnel conducting the Grants Monitoring Program shall review proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the grant office's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with NNI's Policies and Procedures. Results from the Grant Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Department for review and follow-up as appropriate.

3. *Follow Up Reviews and Reporting.* In the event that a potential violation of NNI's Policies and Procedures or of legal or compliance requirements, including but not limited to potential off-label promotion, are identified during any aspect of the Non-Promotional Monitoring Program, NNI shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during any Non-Promotional Monitoring Program referenced above, and any corrective action, shall be recorded in the files of the Compliance Department.

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

#### **IV. CHANGES TO BUSINESS UNITS OR LOCATIONS**

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, NNI changes locations or closes a business unit or location related to Promotional Functions or Product Related Functions, NNI shall notify OIG of this fact as soon as possible, but not later than within 30 days, after the date of the change or closure of the location.

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

C. Sale of Unit or Location. In the event that, after the Effective Date, NNI proposes to sell any or all of its business units or locations that are subject to this CIA, NNI shall notify OIG of the proposed sale at no later than five days after the sale is publicly disclosed by NNI. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the

purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, NNI shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Chief Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Chief Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. the names of the members of the Board of Directors or the Committee of the Board referenced in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of NNI's Code of Conduct required by Section III.B.1;
6. 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);
7. a summary of all Policies and Procedures required by Section III.B.2 (a copy of such Policies and Procedures shall be made available to OIG upon request);
8. the following information regarding each type of training required by Section III.C:

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

9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between NNI and the IRO;

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

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

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

13. a list of all of NNI'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 number and/or supplier number(s) (if applicable); and the name and address of any each Federal health care program contractor to which NNI currently submits claims (if applicable);

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

15. the certifications required by Section V.C.

B. Annual Reports. NNI shall submit to OIG annually a report with respect to the status of, and findings regarding, NNI'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 Chief Compliance Officer and any change in the membership of the Compliance Committee, the Board of Directors or the Committee of the Board of Directors, or the group of Certifying Employees described in Sections III.A.2-4;

2. a copy of the resolution by the Board or the Committee of the Board required by Section III.A.3;

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

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

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

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

b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

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

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

7. NNI's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;
8. a summary and description of any and all current and prior engagements and agreements between NNI and the IRO, (if different from what was submitted as part of the Implementation Report);
9. a certification from the IRO regarding its professional independence and objectivity with respect to NNI;
10. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs or Government Reimbursed Products;
11. any changes to the process by which NNI fulfills the requirements of Section III.F regarding Ineligible Persons;
12. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
13. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
14. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.I. This summary shall include a description of the matter and the status of the matter;
15. a summary of the FFMP and the results of the FFMP required by Section III.J, including copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that NNI took as a result of such determinations;
16. a summary of the Non-Promotional Monitoring Program and the results of the program described in Section III.K, including detailed description of any identified

instances in which it was determined that the activities violated NNI's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) NNI took as a result of such determinations;

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

18. a description of any additional, updated, supplemental or changed information submitted to any Compendia in accordance with Section III.B.2.r; and a description of all arrangements, processing fees, and other payments or financial support (if any) with or made to any Compendia evaluated during the annual review described in Section III.B.2.r; and

19. 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.

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

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

1. to the best of his or her knowledge, except as otherwise described in the report, NNI is in compliance with in compliance with the Federal health care program and FDA requirements and 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. NNI's: 1) Policies and Procedures as referenced in Section III.B.2 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found by these individuals to be in compliance with all applicable Federal health care program and FDA requirements. In addition, NNI's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside NNI have been reviewed by competent regulatory, medical, or, as appropriate, legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by NNI and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved have been found by these individuals to be in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

4. NNI's call plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.2.f) and, for each product the call plans were found to be consistent with NNI's policy objectives as referenced above in Section III.B.2.i.

D. Designation of Information. NNI 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. NNI shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

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

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

OIG: Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

NNI: Francis Bigley  
Chief Compliance Officer  
Novo Nordisk Incorporated  
100 College Road West  
Princeton, NJ 08540  
Phone: 609.987.5800  
Fax: 609.919.7741

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

## **VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of NNI's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of NNI's locations for the purpose of verifying and evaluating: (a) NNI's compliance with the terms of this CIA; and (b) NNI's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by NNI 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 NNI'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. NNI shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. NNI's employees may elect to be interviewed with or without a representative of NNI present.

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

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

#### **IX. DISCLOSURES**

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

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

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, NNI 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 NNI fails to establish and

implement any of the following obligations as described in Section III:

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

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 NNI fails to submit the Implementation Report or any Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

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 NNI fails to submit any IRO

Review Report in accordance with the requirements of Section III.D and Appendix B.

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

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

6. A Stipulated Penalty of \$1,000 for each day NNI fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to NNI stating the specific grounds for its determination that NNI has failed to comply fully and adequately with the CIA obligation(s) at issue and steps NNI shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after NNI 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. NNI 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 NNI 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 NNI 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 NNI 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 NNI of: (a) NNI's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, NNI 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 NNI elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until NNI cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

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

### D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:
  - a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
  - b. a failure by NNI to report a Reportable Event and take corrective action as required in Section III.H;

- c. a failure to engage and use an IRO in accordance with Section III.D and Appendix B;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- e. a failure of the Board or the Committee of the Board to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by NNI constitutes an independent basis for NNI's exclusion from participation in the Federal health care programs. Upon a determination by OIG that NNI has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify NNI of: (a) NNI'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.* NNI 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. NNI 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) NNI has begun to take action to cure the material breach; (ii) NNI is pursuing such action with due diligence; and (iii) NNI has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, NNI fails to satisfy the requirements of Section X.D.3, OIG may exclude NNI from participation in the Federal health care programs. OIG shall notify NNI in writing of its determination to exclude NNI (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 NNI'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, NNI 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 NNI 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, NNI 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 NNI was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. NNI 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 NNI to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless NNI 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 NNI 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) NNI had begun to take action to cure the material breach within that period; (ii) NNI has pursued and is pursuing such action with due diligence; and (iii) NNI provided to OIG within that period a reasonable timetable for curing the material breach and NNI 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 NNI, only after a DAB decision in favor of OIG. NNI's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude NNI 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 NNI 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. NNI 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 NNI, NNI 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**

NNI and OIG agree as follows:

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

ON BEHALF OF NOVO NORDISK INCORPORATED

/Francis Bigley/

Francis Bigley  
Chief Compliance Officer  
Novo Nordisk Incorporated

May 26, 2011  
DATE

James C. Shehan, Corporate Vice President  
Legal/Government & Quality Affairs  
Novo Nordisk Incorporated

DATE

Paul E. Kalb  
Sidley Austin  
Counsel for Novo Nordisk Incorporated

DATE

Jay T. Jorgensen  
Sidley Austin  
Counsel for Novo Nordisk Incorporated

DATE

Novo Nordisk Incorporated  
Corporate Integrity Agreement

ON BEHALF OF NOVO NORDISK INCORPORATED

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Francis Bigley  
Chief Compliance Officer  
Novo Nordisk Incorporated

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DATE

/James C. Shehan/

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(James C. Shehan, Corporate Vice President  
Legal/Government & Quality Affairs  
Novo Nordisk Incorporated

May 26, 2011  
DATE

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Paul E. Kalb  
Sidley Austin  
Counsel for Novo Nordisk Incorporated

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DATE

/Jay T. Jorgensen/

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Jay T. Jorgensen  
Sidley Austin  
Counsel for Novo Nordisk Incorporated

5/26/11  
DATE

Novo Nordisk Incorporated  
Corporate Integrity Agreement

ON BEHALF OF NOVO NORDISK INCORPORATED

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Francis Bigley  
Chief Compliance Officer  
Novo Nordisk Incorporated

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DATE

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James C. Shehan, Corporate Vice President  
Legal/Government & Quality Affairs  
Novo Nordisk Incorporated

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DATE

/Paul E. Kalb/

Paul E. Kalb  
Sidley Austin  
Counsel for Novo Nordisk Incorporated

5/26/11  
DATE

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Jay T. Jorgensen  
Sidley Austin  
Counsel for Novo Nordisk Incorporated

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DATE

Novo Nordisk Incorporated  
Corporate Integrity Agreement

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

/Gregory E. Demske/

\_\_\_\_\_  
GREGORY E. DEMSKE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

5/31/11  
DATE

/Keshia B. Thompson/

KESHIA B. THOMPSON ✓  
Senior Counsel  
Office of Counsel to the Inspector General  
U. S. Department of Health and Human Services

5/31/2011  
DATE

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

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

#### A. IRO Engagement

1. NNI 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 its reviews in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by NNI in response to a request by OIG, whichever is later, OIG will notify NNI if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, NNI may continue to engage the IRO.

2. If NNI 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, NNI shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by NNI at the request of OIG, whichever is later, OIG will notify NNI if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, NNI may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional Functions and to Product Related Functions. The assigned individuals also shall be knowledgeable about the general requirements of the Federal health care program(s) under which Government Reimbursed Products are reimbursed;

2. assign individuals to design and select samples for the Transactions Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

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

D. IRO Independence and Objectivity

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

E. IRO Removal/Termination

1. *Provider and IRO.* If NNI terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, NNI must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. NNI must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier.

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 NNI to engage a new IRO in accordance with Paragraph A of this Appendix. NNI must engage a new IRO within 60 days of termination of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier.

Prior to requiring NNI to engage a new IRO, OIG shall notify NNI 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, NNI may present additional information regarding the IRO's qualifications, independence, or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with NNI prior to requiring NNI to terminate the IRO. However, the final determination as to whether or not to require NNI to engage a new IRO shall be made at the sole discretion of OIG.

**Appendix B to CIA  
Promotional and Product Related Review**

I. Promotional and Product Related Review, General Description

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

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

II. IRO Systems Review

A. Description of Reviewed Policies and Procedures

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

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

- 1) NNI's systems, policies, processes, and procedures applicable to the manner in which NNI sales representatives handle and submit requests or inquiries for information about the uses of NNI Government Reimbursed Products (including non-FDA-approved (i.e., off-label) uses) and the

dissemination of materials relating to off-label uses of NNI Government Reimbursed Products.

This review shall include:

- a) the manner in which NNI sales representatives handle and submit or generate requests for information about off-label uses of Government Reimbursed Products to Medical Affairs;
  - b) the manner in which Medical Affairs personnel handle and respond to requests for information about off-label uses of Government Reimbursed Products (including tracking the requests and using the materials provided in response to the request);
  - c) the form and content of information and materials related to Government Reimbursed Products that are disseminated to physicians, pharmacists, or other health care professionals (collectively "HCPs") or health care institutions (HCIs) by NNI;
  - d) NNI's systems, processes, and procedures (including the Inquiries Database) used to track requests for information about off-label uses of NNI Government Reimbursed Products and responses to those requests;
  - e) the manner in which NNI collects and supports information reported in any systems used to track and respond to requests for product information, including the Inquiries Database;
  - f) the processes and procedures by which Medical Affairs and NNI's Compliance Department or their designees monitor and identify situations in which it appears that improper off-label promotion may have occurred; and
  - g) NNI's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;
- 2) NNI's systems, processes, policies and procedures applicable to the manner and circumstances under which personnel from Medical Affairs (e.g., medical science liaisons or other medical or scientific personnel) interact with or participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) and the role of the Medical Affairs personnel at such meetings or events, including the manner in which the Medical Affairs personnel handle responses to unsolicited requests about off-label indications of Government Reimbursed Products. This review shall include any internal monitoring plan designed to monitor the activities of Medical Affairs personnel;
- 3) NNI's systems, policies, processes, and procedures relating to NNI's

internal review and approval of information and materials related to Government Reimbursed Products that are disseminated to HCPs or HCIs by NNI;

- 4) NNI's systems, processes, polices, and procedures relating to incentive compensation (including through salaries, bonuses, or contests) for Relevant Covered Persons who are sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of NNI's Government Reimbursed Products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that NNI establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;
- 5) NNI's systems, processes, policies, and procedures relating to the development, implementation, and review of Call Plans (as defined in Section III.B.2.i of the CIA.) This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the Call Plans based on, among other factors, expected utilization of Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;
- 6) NNI's systems, processes, policies, and procedures relating to the development, implementation, and review of Sample Distribution Plans (as defined in Section III.B.2.j of the CIA). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from NNI (including, separately, from NNI sales representatives and other NNI personnel, components, or vendors);
- 7) NNI's systems (including any centralized electronic system), processes, policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;
- 8) NNI's systems, processes, policies, and procedures relating to non-speaker related consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, presentations, consultant task force meetings, advisory boards, preceptorships, mentorships (if any), and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements; and
- 9) NNI's systems, processes, policies and procedures relating to the

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

#### B. IRO Systems Review Report

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

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;
- 2) a detailed description of NNI’s systems, policies, processes, and procedures relating to the items identified in Sections II.A. 1-9 above, including a general description of NNI’s control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
- 3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A. 1-9 above are made known or disseminated within NNI;
- 4) a detailed description of any system(s) used to track and respond to requests for information about NNI’s Government Reimbursed Products (including the Inquiries Database);
- 5) a detailed description of NNI’s incentive compensation system for Relevant Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that NNI may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;
- 6) findings and supporting rationale regarding any weaknesses in NNI’s systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
- 7) recommendations to improve any of the systems, policies, processes, or

procedures relating to the Reviewed Policies and Procedures, if any.

### III. IRO Transaction Review

As described more fully below in Sections III.A-D, the Transactions Review shall include: (1) a review of a sample of Inquiries reflected in the Inquiries Database; (2) a review of NNI's Call Plans and NNI's Call Plan review process; and (3) a review of Sampling Events as defined below in Section III.C and NNI's Sample Distribution Plan review process. The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

#### A. Review of Inquiries and Inquiries Database

##### 1) Description of Inquiries Database

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

##### 2) Internal Review of Inquiries Database

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

##### 3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of 50 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. Forty of the Inquiries reviewed by the IRO shall be Inquiries for which NNI conducted an Off-Label Review, and the other 10 shall be Inquiries for which NNI did not conduct an Off-Label Review. If NNI conducted an Off-Label Review on fewer than 40 Inquiries, additional Inquiries may be selected for which an Off-Label Review was not conducted to reach a total of 50 Inquiries. For each Inquiry reviewed, the IRO shall determine:

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

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

NNI maintains Call Plan Master Data Files. These files contain lists of HCPs and HCIs from which NNI prepares call plans for individual sales representatives. These Call Plan Master Data Files shall hereinafter be called "Call Plans."

The IRO shall conduct a review and assessment of NNI's review of its Call Plans as set forth in Section III.B.2.i of the CIA. NNI shall provide the IRO with: i) a list of Government Reimbursed Products promoted by NNI during the Reporting Period; ii) information about the FDA-approved uses for each NNI Government Reimbursed Product; and iii) the Call Plans for each Government Reimbursed Product. NNI shall also provide the IRO with information about the reviews of Call Plans that NNI conducted during the Reporting Period and any modifications to the Call Plans made as a result of NNI's reviews.

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

The IRO shall note any instances in which it appears that the sampled HCPs and HCIs on a particular Call Plan are inconsistent with NNI's criteria relating to the Call Plan and/or NNI's Policies and Procedures. The IRO shall also note any instances in which it appears that NNI failed to follow its criteria or Policies and Procedures.

#### C. IRO Review of the Distribution of Samples of NNI Government Reimbursed Products

The IRO shall conduct a review and assessment of the distribution of samples of NNI Government Reimbursed Products to HCPs and HCIs. NNI shall provide the IRO with: i) a list of Government Reimbursed Products for which NNI distributed samples during the Reporting Period; ii) information about the FDA-approved uses for each NNI Government Reimbursed Product; and iii) information about NNI's policies and procedures relating to the distribution of samples of each type of product, including NNI's Sample Distribution Plans showing which particular medical specialties or types of clinical practices are eligible to receive samples of particular NNI Government Reimbursed Products. NNI shall also provide the IRO with information about the reviews of Sample Distribution Plans that NNI conducted during the Reporting Period as set forth in Section III.B.2.j of the CIA and any modifications to the plans made as a result of NNI's reviews.

For each Government Reimbursed Product for which NNI distributed samples during the Reporting Period, the IRO shall randomly select a sample of 50 separate instances in which NNI provided samples of the Government Reimbursed Product to HCPs or HCIs. Each such instance shall be known as a "Sampling Event."

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

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

For each Sampling Event, the IRO shall compare the medical specialty and type of clinical practice of the HCPs and HCIs that received the sample with uses of the Government Reimbursed Product approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the Government

Reimbursed Product approved by the FDA. For each such situation, the IRO shall note the process followed by NNI in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. The IRO shall also note any instances in which it appears that NNI failed to follow its Sample Distribution Plan for the Government Reimbursed Product(s) provided during the Sampling Event.

D. Promotional and Product Related Transactions Review Report

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

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

2) Results to be Included in Report

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

(Relating to the Review of Inquiries)

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

- d) the findings and supporting rationale regarding any weaknesses in NNI's systems, processes, policies, procedures, and practices relating to the Inquiries, and the Inquiries Database, if any;
- e) recommendations for improvement in NNI's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

(Relating to the Call Plan Reviews)

- f) a list of the Government Reimbursed Products promoted by NNI during the Reporting Period and a summary of the FDA-approved uses for such products;
- g) for each NNI Government Reimbursed Product: i) a description of the criteria used by NNI in developing or reviewing the Call Plans and for including or excluding specified types of HCPs or HCIs from the Call Plans; ii) a description of the review conducted by NNI of the Call Plans and an indication of whether NNI reviewed the Call Plans as required by Section III.B.2.i of the CIA; iii) a description of all instances for each Call Plan in which it appears that the HCPs and HCIs included on the Call Plan are inconsistent with NNI's criteria relating to the Call Plan and/or NNI's Policies and Procedures; and iv) a description of all instances in which it appears that NNI failed to follow its criteria or Policies and Procedures relating to Call Plans or the review of the Call Plans;
- h) the findings and supporting rationale regarding any weaknesses in NNI's systems, processes, policies, procedures, and practices relating to NNI's Call Plans or the review of the Call Plans, if any;
- i) recommendations, if any, for changes in NNI's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to Call Plans or the review of the Call Plans;

(Relating to the Sampling Event Reviews)

- j) for each NNI Government Reimbursed Products for which samples were distributed during the Reporting Period: i) a description of the Sample Distribution Plan (including whether sales representatives may provide samples of the Government Reimbursed Product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice a sales representative may provide samples); ii) a description of the review conducted by NNI of the Sample Distribution Plans and an indication of whether NNI reviewed the Sample Distribution Plans as required by Section III.B.2.j of the CIA; iii) a detailed description of

any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the Government Reimbursed Product approved by the FDA. This description shall include a description of the process followed by NNI in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iv) a detailed description of any instances in which it appears that NNI failed to follow its Sample Distribution Plan for the Government Reimbursed Product(s) provided during the Sampling Event;

- k) the findings and supporting rationale regarding any weaknesses in NNI 's systems, processes, policies, procedures, and practices relating to the distribution of samples of NNI Government Reimbursed Products, if any;
- l) recommendations, if any, for changes in NNI's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples;