

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

I. PREAMBLE

Cell Therapeutics, Inc. (CTI) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and the statutes, regulations and written directives of the Food and Drug Administration (FDA requirements). CTI is entering into this CIA pursuant to the terms of a Settlement Agreement entered with the United States effective April 13, 2007.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by CTI under this CIA shall be 5 years from the effective date of this CIA, unless otherwise specified. The effective date shall be the earlier of: (1) the date that CTI consummates the asset purchase agreement it entered into with Biogen Idec Inc. to acquire Zevalin; or (2) the date on which CTI begins to manufacture, market, sell, or distribute any product reimbursed by Federal health care programs (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) CTI's final Annual Report; or (2) any additional materials submitted by CTI 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 (other than shareholders who: (i) have an ownership interest of less than 5%; and (ii) acquired the ownership interest through public trading), officers, directors, and employees of CTI; and
- b. all contractors, subcontractors, agents, and other persons who perform Product Services Related Functions (as defined below in Section II.C.2) on behalf of CTI.

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 of CTI whose job responsibilities relate to the provision of information about or services relating to CTI’s products; distribution of CTI products; educational activities; pricing functions; government contracting or regulatory functions; research and development (except preclinical researchers and clinical investigators); or the sales, marketing, or promotion of CTI’s products (hereafter collectively referred to as “Product Services Related Functions.”)

3. An “Educational or Informational Activity” shall mean any continuing medical education (CME), disease awareness, or other scientific, educational, or professional program, meeting, or event, including, but not limited to, sponsorship of booths or activities at medical conferences or symposia.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee.

1. *Compliance Officer.* Within 90 days after the Effective Date, CTI shall appoint an individual to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and FDA requirements. The Compliance Officer shall be a member of senior management of CTI, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of CTI, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by CTI as well as for any reporting obligations created under this CIA.

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

2. *Compliance Committee.* Within 90 days after the Effective Date, CTI shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as clinical/medical affairs, regulatory, legal, human resources, sales, marketing, finance, commercial operations.) The Compliance Officer shall chair the Compliance Committee, and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Code of Conduct.* Within 90 days after the Effective Date, CTI shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. CTI 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. CTI's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to engage in Product Services Related Functions in accordance with such requirements;

b. CTI's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with CTI's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

c. the requirement that all of CTI's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by CTI, suspected violations of any Federal health care program or FDA requirements or of CTI's own Policies and Procedures;

d. the possible consequences to both CTI and Covered Persons of failure to comply with Federal health care program and FDA requirements and with CTI's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.E, and CTI's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by CTI'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.

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

2. *Policies and Procedures.* Within 90 days after the Effective Date, CTI shall implement written Policies and Procedures regarding the operation of CTI's Compliance Program and its compliance with Federal health care program and FDA requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. selling, marketing, promoting, and providing information about CTI products in compliance with all applicable Federal health care program requirements, including, but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b(b);
- c. selling, marketing, promoting, advertising, and providing information about CTI's products in compliance with all applicable FDA requirements, including procedures governing the response to requests for information about non-FDA approved (off-label) uses of the products;
- d. compensation arrangements (including salaries and bonuses) for Covered Persons. These Policies and Procedures shall be designed to ensure that financial incentives do not motivate Covered Persons to engage in Product Services Related Functions in an improper manner;

e. employee discipline for violations of CTI's Policies and Procedures, including those policies relating to Federal health care program and FDA requirements;

f. the mechanisms and manner in which CTI handles and responds to requests for information about the uses (including off-label uses) of CTI's products, including but not limited to, the following: the form and content of information disseminated by CTI personnel in response to such requests and the internal review and approval process for the information disseminated.

The Policies and Procedures shall include a requirement that CTI develop a database (the "Inquiries Database") that includes the following items of information for each inquiry (Inquiry) received for information about CTI's products: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone); 3) name of the requesting health care professional (HCP) or health care institution (HCI); 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label indication for the product; 6) nature/form of the response from CTI (including a record of the materials provided to the HCP or HCI in response to the request); 7) the name of the CTI representative who called on or interacted with the HCP or HCI; and 8) the status and findings of any follow-up review conducted by CTI in situations in which it appears that the Inquiry may have related to improper off-label promotion;

g. the mechanisms and manner in which CTI provides information about its products and the reimbursement of its products to Federal health care programs and/or government contractors (e.g., to CMS, Medicare carriers, Medicare intermediaries), HCPs, and HCIs, including, but not limited to, the following: the form and content of the information provided; and the review and approval process for the information provided;

h. consultant or fee-for-services arrangements entered between CTI and HCPs or HCIs (e.g., speaker programs, advisory board

programs, focus group programs, preceptorships) and all events or expenses associated with such arrangements (e.g., for meals, travel) 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 shall include requirements about the uses, content, and circumstances of such arrangements and events;

i. sponsorship or funding of, or participation in, any Educational or Informational Activity as defined in Section II.C.3 above (e.g., educational grants, sponsorship of CME or other educational programs or events). These Policies and Procedures shall be designed to ensure that CTI's sponsorship or funding of, or participation in, such programs satisfies all applicable Federal health care program and FDA requirements related to the sponsorship of any Educational or Informational Activity.

The Policies and Procedures shall require: 1) the disclosure of CTI's financial support of the Educational or Informational Activity and any financial relationships with faculty, speakers, or organizers at such Educational or Informational Activity; 2) that the Educational or Informational Activity have an educational focus; 3) that the Educational or Informational Activity be independent; 4) that the Educational or Informational Activity be non-promotional in tone/nature; and 5) that the information provided at the Educational or Informational Activity be fair, balanced, accurate and not misleading;

j. sponsorship or funding of grants or contributions. These Policies and Procedures shall be designed to ensure that CTI's sponsorship or funding complies with all applicable Federal health care program requirements and FDA requirements;

k. sponsorship or funding of, or participation in, research activities (including clinical trials, market research, or authorship of articles or other publications) by CTI in a manner that is designed to ensure that

CTI's funding or sponsorship of, or participation in, such activities complies with all applicable Federal health care program and FDA requirements. In addition, such Policies and Procedures shall ensure that sales and marketing activities are separate from research activities (e.g., clinical trial enrollment); and

1. call plan development for CTI's products. The Policies and Procedures shall require that CTI review the call plans for its products and the bases upon which physician specialties and institutional providers are included in, or excluded from, the call plans. The Policies and Procedures shall also require that CTI modify the call plans as necessary to ensure that CTI is promoting its products in a manner that complies with all applicable Federal health care program and FDA requirements. CTI shall review the call plans at least annually and shall also review the call plans each time the FDA approves a new or additional indication for a CTI product.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

C. Training and Education.

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

a. CIA requirements;

- b. CTI's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues); and
- c. in general, the proper methods of promoting, marketing, selling, conducting research (including clinical trials), and disseminating information about CTI's products in accordance with Federal health care program and FDA requirements.

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 one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 90 days after the Effective Date, each Relevant Covered Person shall receive at least four hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. all Federal health care program requirements relating to Product Services Related Functions, including, but not limited to, the requirements of the Federal anti-kickback statute; the Civil Monetary Penalties Law; the civil False Claims Act; and the Medicaid Drug Rebate statute;
- b. all applicable FDA requirements relating to Product Services Related Functions, including but not limited to the requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations, directives and guidance;
- c. the personal obligation of each Relevant Covered Person involved in Product Services Related Functions to comply with all applicable legal requirements;

d. the legal sanctions for violations of the Federal health care program requirements or FDA requirements relating to Product Services Related Functions; and

e. examples of proper and improper practices relating to Product Services 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. A CTI employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to Product Services Related Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

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

3. *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 Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

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

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

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

D. Review Procedures.

1. *General Description.*

a. Engagement of Independent Review Organization. Within 90 days after the Effective Date, CTI shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform a Promotional and Product Services Engagement. Each IRO engaged by CTI shall have expertise in Federal health care program and FDA requirements applicable to the Promotional and Product Services Engagement. Each IRO shall assess, along with CTI, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. Description and Frequency of Reviews. The Promotional and Product Services Engagement shall consist of two components – a systems review (the Promotional and Product Services Systems Review) and a transactions review (Promotional and Product Services Transactions Review), as described more fully in Appendix B to this CIA, which is incorporated by reference. These reviews shall be referred to collectively as the “Reviews”.

The Promotional and Product Services Transactions Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each of these annual Reviews.

If there are no material changes in CTI’s systems, processes, policies, and practices relating to Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods.

As set forth in Appendix B, if CTI materially changes its systems, processes, policies, and practices relating to Product Services Related Functions, then the IRO shall perform a Promotional and Product Services 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.

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

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

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

Prior to initiating a Validation Review, OIG shall notify CTI 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, CTI may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the Review in question or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. CTI 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 CTI 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/Objectivity Certification.* The IRO shall include in its report(s) to CTI a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the applicable Review and that it has concluded that it is, in fact, independent and/or objective.

E. Disclosure Program.

Within 90 days after the Effective Date, CTI shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with CTI'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. CTI 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 nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, CTI shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

F. Ineligible Persons.

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

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. “Exclusion Lists” include:

- i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
- ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

- c. “Screened Persons” include prospective and current owners (other than shareholders who: (i) have an ownership interest of less than 5%; and (ii) acquired the ownership interest through public trading), officers, directors, employees, contractors, and agents of CTI.

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

- a. CTI shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or

contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons.

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

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

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

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

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

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, CTI shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to CTI conducted or brought by a governmental entity or its agents involving an allegation that CTI 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. CTI 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. Notification of Reportable Event.

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, and/or applicable to any FDA requirements relating to the promotion of prescription drugs for which penalties or exclusion may be authorized; or
- b. the filing of a bankruptcy petition by CTI.

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

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

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program and/or FDA authorities implicated;
- b. a description of CTI’s actions taken to correct the Reportable Event; and

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

d. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program 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 CTI and the FDA that materially discusses CTI's or a Covered Person's unlawful or improper promotion of CTI's products (including any improper dissemination of information about off-label indications), CTI shall provide a copy of the report, correspondence, or communication to the OIG. CTI shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

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

For each Reporting Period, CTI shall obtain non-CTI records (e.g., Verbatims or similar records) generated by an independent entity (Survey Entity) reflecting the purported content and subject matter of detailing interactions between sales representatives and HCPs for up to three Covered Products (as defined below in this Section III.J.) For each Covered Product, CTI shall contract with a Survey Entity to conduct inquiries into the content and subject matter of the detailing interactions. The OIG shall select and notify the Survey Entity of a one week period within every quarter in the Reporting Period for which the surveys shall be conducted, beginning in the second full quarter after the Effective Date. For each Covered Product, CTI shall obtain records reflecting the purported content and subject matter of detailing sessions during the identified week in all regions across the United States.

Prior to start of the second Reporting Period and every Reporting Period thereafter, based on information provided by CTI and other information known to it, and after consultation with CTI, the OIG shall select up to three CTI products to be the basis for the review outlined in this Section III.J and shall notify CTI of its selection. The identified

products shall be known as the “Covered Products.” The parties have already identified the Covered Products for the first Reporting Period.

CTI shall review the records obtained from the Survey Entity and shall identify any instances in which the records appear to indicate that Covered Persons may have discussed and/or disseminated information about off-label uses of the Covered Products. CTI shall make findings based on its review (Off-Label Findings) and shall take any responsive action it deems necessary. If necessary for purposes of its review, CTI shall endeavor to gather additional factual information about the circumstances relating to any Off-Label Findings. As part of each Annual Report, CTI shall provide the OIG with copies of the underlying records of the detailing interactions, a copy of CTI’s Off-Label Findings, and a description of the action(s), if any, CTI took in response to the Off-Label Findings.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, CTI changes locations or sells, closes, purchases, or establishes a new business unit or location, CTI shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, any Federal health care program provider identification number and/or supplier number, and any corresponding contractor’s name and address that has issued each Federal health care program provider number. Each new business unit or location shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

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

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. the names and positions of the members of the Compliance Committee required by Section III.A;

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

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

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

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

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

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

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

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

8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between CTI and the IRO; and (d) the proposed start and completion dates of each Review;

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

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

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

12. a list of all of CTI's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which CTI currently submits claims (if applicable);

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

14. the certifications required by Section V.C.

B. Annual Reports. CTI shall submit to OIG annually a report with respect to the status of, and findings regarding, CTI's compliance activities for each of the 5 Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

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

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

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

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

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

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

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

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

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

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

9. a summary of all internal reviews, audits, or analyses related to Product Services Related Functions (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;

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

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

12. any changes to the process by which CTI fulfills the requirements of

Section III.F regarding Ineligible Persons;

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

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

15. a copy of all information required by Section III.J;

16. a list and description of all actively promoted CTI products; the FDA-approved uses of the products; and information about the estimated relative usage (e.g., the percentage) of the CTI products for off-label purposes;

17. 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;

18. a description of all changes to the most recently provided list of CTI's locations (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which CTI currently submits claims (if applicable); and

19. the certifications required by Section V.C.

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

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

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

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

3. CTI has complied with its obligations under the Settlement Agreement not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims;

4. CTI's: 1) Policies and Procedures as referenced in Section III.B.2 above; 2) templates for the standardized contracts and other similar documents; 3) training materials used for purposes of Section III.C, above; and 4) promotional or educational materials containing claims or information about CTI's products have been reviewed by competent legal counsel and have been found to be in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws. 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

5. CTI's call plans were reviewed at least once during the Reporting Period (consistent with the requirements of Section III.B.2.1) and, the call plans were found to be consistent with CTI's policy objectives as referenced above in Section III.B.2.1.

D. Designation of Information. CTI 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. CTI 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

CTI:

Jack Singer, M.D.
Compliance Officer
Cell Therapeutics, Inc.
501 Elliott Avenue West, Suite 400
Seattle, WA 98119
Phone: 206.282.7100
Facsimile: 206.284.6206

With a copy to:

Harold Malkin, Esq.
Yarmuth Wildson Calfo PLLC
925 Fourth Avenue, Suite 2500
Seattle, WA 98104
Telephone: 206.516.3800
Facsimile: 206.516.3888

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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

VIII. DOCUMENT AND RECORD RETENTION

CTI shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for 6 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 CTI prior to any release by OIG of information submitted by CTI pursuant to its obligations under this CIA and identified upon submission by CTI as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, CTI shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

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

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

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons;
- f. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements;
- h. notification of Government investigations or legal proceedings;
- i. notification of communications regarding off-label related matters; and
- j. a review of records reflecting the content of detailing sessions.

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 CTI fails to engage an IRO, as

required in Section III.D and Appendices A and B.

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

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day CTI fails to submit the annual Report associated with any of the Reviews in accordance with the requirements of Section III.D and Appendix B.

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

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

7. A Stipulated Penalty of \$1,000 for each day CTI fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to CTI, stating the specific grounds for its determination that CTI has failed to comply fully and adequately with the CIA obligation(s) at issue and steps CTI shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after CTI 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. CTI 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 CTI 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 CTI 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 CTI 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 CTI of: (a) CTI'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, CTI 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 CTI elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until CTI cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

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

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by CTI to report a Reportable Event, and take corrective action, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.D and Appendices A and B.

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

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

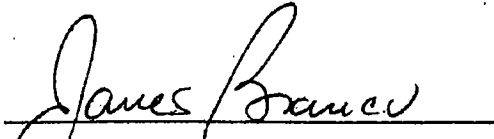
4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for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

XI. EFFECTIVE AND BINDING AGREEMENT

CTI and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of CTI;
- 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 CTI 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; and
- 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.

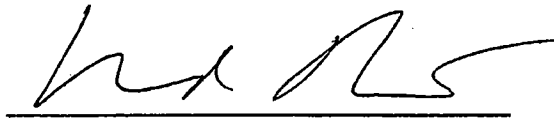
ON BEHALF OF CELL THERAPEUTICS, INC.



James Bianco, M.D.
Chief Executive Officer
Cell Therapeutics, Inc.

SEPT 18, 2007

DATE



Harold Malkin, Esq.
Counsel for Cell Therapeutics, Inc.

9/19/07

DATE

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



Gregory E. Demske
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

10/2/07

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.

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

If CTI 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, CTI shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify CTI if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, CTI may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Promotional and Product Services Engagement who have expertise in the Federal health care program and FDA requirements applicable to Product Services Related Functions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which CTI products are reimbursed;

2. assign individuals to design and select the Promotional and Product Services Engagement samples 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 Promotional and Product Services Engagement in accordance with the specific requirements of the CIA, including Appendix B;
2. follow all applicable Federal health care program and FDA requirements in making assessments in Promotional and Product Services Engagement;
3. if in doubt about the application of a particular Federal health care program or FDA requirement, request clarification from the appropriate authority (e.g., CMS, 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 Appendices A and B.

D. IRO Independence/Objectivity.

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

E. IRO Removal/Termination.

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

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

Prior to requiring CTI to engage a new IRO, OIG shall notify CTI 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, CTI may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. CTI shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with CTI prior to requiring CTI to terminate the IRO. However, the final determination

as to whether or not to require CTI to engage a new IRO shall be made at the sole discretion of OIG.

Appendix B to CIA for Cell Therapeutics, Inc.

Promotional and Product Services Engagement

I. Promotional and Product Services Review, General Description

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

If there are no material changes in CTI's systems, processes, policies, and procedures relating to Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. If CTI materially changes its systems, processes, policies, and procedures relating to Product Services Related Functions, the IRO shall perform a Promotional and Product Services 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 reviewed and reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Promotional and Product Services Transactions Review for each Reporting Period of the CIA.

II. Promotional and Product Services Systems Review

A. Description of Reviewed Policies and Procedures

The Promotional and Product Services Systems Review shall be a review of CTI's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Product Services Related Functions. Specifically, the IRO shall review CTI's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1) CTI's systems, policies, processes, and procedures applicable to the manner in which CTI representatives (including sales representatives and/or medical personnel) handle requests or inquiries relating to information about the uses of CTI products (including the off-label uses of the products) and the dissemination of materials relating to off-label uses of products. This review includes:

- a) the manner in which field personnel and/or headquarters personnel (including medical affairs or medical information personnel) receive and respond to requests for information about off-label uses of CTI products;
- b) the form and content of product-related information disseminated by CTI;
- c) CTI's internal review and approval process for the information disseminated by its field and headquarters personnel;
- d) CTI's systems, processes, and procedures (including its Inquiries Database) to track requests for information about the uses of CTI products and responses to those requests;
- e) the manner in which CTI collects and supports data reported in its Inquiries Database;
- f) the processes and procedures by which the Compliance Officer (and other appropriate individuals within CTI) identify situations in which it appears that off-label promotion may have occurred; and
- g) CTI's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving off-label promotion;

2) CTI's policies and procedures applicable to the manner and circumstances under which its medical personnel (including medical science liaisons (MSLs)) participate in meetings or events with physicians, pharmacists, or other health care professionals (collectively "HCPs") or health care institutions (HCIs), either alone or with sales representatives, and the role of medical personnel at such meetings or events;

3) CTI's systems, policies, processes, and procedures relating to the retention of HCPs or HCIs as consultants or under fee-for-service arrangements (e.g., including as members of advisory boards, focus

groups, clinical research project teams or as speakers or preceptors.)
This shall include a review of:

- a) the criteria used to determine whether, how many, and under what circumstances (including the venue for the performance of any services) CTI will enter such arrangements and the business rationale for entering such arrangements;
- b) the processes and criteria used to identify and select HCPs and HCIs with whom CTI enters arrangements, including the role played by sales representatives or field personnel in the process (if any). This includes a review of CTI's internal review and approval process for such arrangements, and the circumstances under which there may be exceptions to the process;
- c) CTI's tracking or monitoring of the services provided or the work performed under such arrangements (including the receipt of the work product received from the HCPs or HCIs, if any);
- d) CTI's policies and procedures related any requirement that the HCPs or HCIs (or their agents) disclose the existence of their arrangements with CTI and any financial relationship the HCP or HCI has with CTI;
- e) the uses made of work product received from the HCPs or HCIs, if any;
- f) CTI's processes for establishing the amounts paid to HCPs or HCIs under such arrangements and the reasons or justifications for any differentials in the amounts paid to different HCPs and HCIs;
- g) the criteria used to determine under what circumstances entertainment, travel, lodging, meals, and/or other items or reimbursements are provided to the HCPs or HCIs in connection with the arrangements, and CTI's processes for establishing the amounts paid or reimbursed for such items;
- h) whether and in what manner CTI tracks or monitors the prescribing habits or product use of individuals or entities with whom it enters consulting or fee-for-service arrangements, if any; and
- i) the budget funding source within CTI (e.g., department or division) for the consulting or fee-for-service arrangements;

4) CTI's systems, policies, processes, and procedures relating to funding or sponsorship of any Educational or Informational Activity. This review shall include a review of the following items:

- a) the processes and procedures used to approve the funding or sponsorship of an Educational or Informational Activity;
- b) the criteria used to determine whether and under what circumstances the funding or sponsorship will be provided;
- c) the processes and criteria used to select recipients of the funding or sponsorships, including the role played by sales representatives or field personnel in the processes (if any), and the circumstances under which there may be exceptions to the processes;
- d) CTI's policies and procedures relating to any requirement that the recipient of the funding or sponsorship (or the recipient's agent) disclose CTI's funding or sponsorship and any financial relationship CTI may have with the recipient;
- e) CTI's policies or procedures for determining and memorializing the amounts paid to recipients of the funding or sponsorship and the purpose or justifications for the amounts paid;
- f) CTI's policies and procedures relating to the independence of any programs funded or sponsored by CTI;
- g) CTI's policies and procedures relating to the content and nature (e.g., promotional, non-promotional) of any programs sponsored through the funding or sponsorships;
- h) whether and in what manner CTI tracks or monitors the prescribing habits or product use of individuals or entities receiving the funding or sponsorship, if any; and
- i) the budget funding source within CTI (e.g., department or division) from which the funding or sponsorships are provided;

5) CTI's systems, policies, processes, and procedures relating to funding or sponsorship of, or participation in, research agreements, grants, and/or research collaborations (including clinical trials and

independent research) (collectively “Research Activities”). This review shall include a review of the following items:

- a) the processes and procedures used to approve the funding or sponsorship of, or participation in, Research Activities;
 - b) the criteria used to determine whether and under what circumstances CTI will fund or otherwise participate in Research Activities;
 - c) the processes and criteria used to select recipients of the funding for the Research Activities, including the role played by field personnel or sales representatives in the processes (if any), and the circumstances under which there may be exceptions to the processes;
 - d) CTI’s policies and procedures relating to any requirement that the recipient of the funding or participant in the Research Activities disclose CTI’s funding and any financial relationship CTI may have with the recipient;
 - e) CTI’s policies or procedures for determining and memorializing the amounts paid in connection with the Research Activities and the purpose or justifications for the amounts paid;
 - f) CTI’s policies and procedures relating to the independence of the Research Activities funded by CTI;
 - g) whether and in what manner CTI tracks or monitors the prescribing habits or product use of individuals or entities receiving the funding or otherwise participating in the Research Activities, if any; and
 - h) the budget funding source within CTI (e.g., department or division) for the Research Activities;
- 6) CTI’s systems, policies, processes, and procedures relating to the provision of, or payment for, any gifts, meals, receptions, travel, exhibit fees, or other items (collectively “Expenses”) to HCPs or HCIs. This shall include a review of:
- a) the criteria used to determine whether, how many, and under what circumstances CTI will provide or reimburse for Expenses;
 - b) the processes and criteria used to identify and select HCPs or HCIs to whom CTI provides or reimburses

for Expenses. This includes a review of CTI's internal review and approval process for such Expenses, the circumstances under which there may be exceptions to the processes, and the role played by sales representatives or field personnel in the process;

- c) CTI's policies and procedures relating to any requirement that the recipient of the Expenses disclose CTI's payment and any financial relationship CTI may have with the recipient;
- d) CTI's tracking or monitoring of any services provided or work performed by HCPs or HCIs in connection with the Expenses;
- e) the uses made of the work product (if any) generated by those HCPs or HCIs receiving Expenses from CTI;
- f) CTI's processes for establishing the amounts paid to HCPs or HCIs for Expenses and the reasons or justifications for any differentials in the amounts paid to different HCPs or HCIs;
- g) whether and in what manner (if any) CTI tracks or monitors the prescribing habits or product use of HCPs or HCIs receiving Expenses from CTI; and
- h) the budget funding source within CTI (e.g., department or division) for the Expenses;

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

- a) the processes and procedures used to approve charitable contributions;
- b) the criteria used to determine whether and under what circumstances CTI will make charitable contributions;
- c) the processes and criteria used to select recipients of charitable contributions, including the role played by field personnel or sales representatives in the processes (if any), and the circumstances under which there may be exceptions to the processes;
- d) CTI's policies and procedures relating to any requirement that the recipient of the charitable contributions (or the recipient's agent) disclose CTI's contribution and any financial relationship CTI may have with the recipient;

- e) CTI's policies or procedures for determining and memorializing the amounts paid to recipients of the charitable contribution and the purpose or justifications for the amounts paid;
 - f) CTI's policies and procedures relating to the independence of any programs funded through the charitable contributions;
 - g) CTI's policies and procedures relating to the content and nature (e.g., promotional, non-promotional) of any programs funded through the charitable contributions;
 - h) whether and in what manner CTI tracks or monitors the prescribing habits or product use of individuals or entities receiving the charitable contributions, if any; and
 - i) the budget funding source within CTI (e.g., department or division) for the charitable contributions;
- 8) CTI's systems, policies, processes, and procedures relating to CTI's internal review and approval of materials disseminated by CTI to external recipients (including HCPs, HCIs, Federal health care programs, and Federal health care program contractors);
- 9) CTI's systems, policies, processes, and procedures for tracking expenditures (individual and aggregate) associated with the Reviewed Policies and Procedures referenced in Sections II.A.3-7, above;
- 10) CTI's policies, processes, and procedures relating to disciplinary actions that CTI may undertake in the event a Covered Person violates a CTI policy or procedure relating to Product Services Related Functions;
- 11) CTI's systems, policies, processes, and procedures relating to compensation arrangements (including salaries and bonuses) for Covered Persons, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not motivate such individuals to engage in Product Services Related Functions in an improper manner. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance; and

12) CTI's systems, processes, policies, and procedures relating to the development and review of call plans for CTI's sales and medical personnel. This shall include a review of the extent to which HCPs belonging to specified medical specialties and HCIs are included in, or excluded from, the call lists based on their expected utilization of the CTI products for FDA-approved uses or non-FDA-approved uses.

B. Promotional and Product Services 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 CTI's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-12 above, including a general description of CTI's control and accountability systems (e.g., documentation and approval requirements, 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.1-12 above are made known or disseminated within CTI;
- 4) a detailed description of any system used to track and respond to requests for information about CTI's products;
- 5) a description of CTI's systems, policies, processes, and procedures for tracking any expenditures associated with the Reviewed Policies and Procedures referenced in Sections II.A.3-7, above;
- 6) a general description of CTI's disciplinary measures applicable for a failure to comply with its policies and procedures relating to Product Services Related Functions;
- 7) a detailed description of CTI's compensation system (including salaries and bonuses) for Covered Persons, 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 CTI may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

8) findings and supporting rationale regarding any weaknesses in CTI's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

9) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

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

III. Promotional and Product Services Transaction Review

As described more fully below in Sections III.A-C, the Promotional and Product Services Transactions Review shall include a review of a sample of Inquires reflected in CTI's Inquiries Database, a review of a sample of Control Documents associated with Reviewed Activities, and a review of CTI's call plan assessments. As described in Section III.D below, the IRO shall report on all aspects of its reviews in the Promotional and Product Services Transactions Review Reports.

A. Review of Inquiries Reflected in Inquiries Database

1) Information Contained in Inquiries Database

As set forth in Section III.B.2.f of the CIA, CTI shall establish a database to track data relating to Inquiries about CTI's products. Specifically CTI shall document and record all Inquiries received from HCPs or HCIs regarding CTI products in a database (the "Inquiries Database"). CTI 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, etc.); 3) name of requesting HCP or HCI; 4) nature and topic of request (including exact language of the inquiry if made in writing); 5) an evaluation of whether the inquiry relates to information about an off-label use of the product; 6) nature/form of the response from CTI

(including a record of the materials provided in response to the request); 7) the name of the CTI representative who called on or interacted with the HCP or HCI; and 8) the status and findings of any follow-up review conducted by CTI in situations in which improper off-label promotion is suspected.

2) Internal Review of the Inquiries Database

On a semi-annual basis, the Compliance Officer or other appropriate personnel 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 (the "Inquiry Report"). The Compliance Officer 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 Compliance Officer, in consultation with other appropriate CTI personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, the Compliance Officer 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 60 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. 45 of the Inquiries reviewed by the IRO shall be Inquiries for which CTI conducted an Off-Label Review, and the other 15 shall be Inquiries for which CTI did not conduct an Off-Label Review.

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 Compliance Officer 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 Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by CTI based on the Compliance Officer's findings.

B. IRO Sampling and Review of Control Documents for Reviewed Activities

1) Background on Policies and CTI Activities

CTI has developed policies and procedures relating to programs with HCPs and HCIs that may be initiated by sales representatives, field personnel, and/or headquarters (home office) personnel. These programs include some or all of the following which shall be collectively referred to hereafter as the “Reviewed Activities”:

- a) Informational programs initiated by CTI (including meals associated with the programs);
- b) Speaker programs;
- c) Speaker training programs;
- d) Fee-for-service or consulting arrangements with HCPs or HCIs other than the retention of HCPs as speakers (e.g., for advisory boards, preceptorships, research agreements);
- e) Expenses (as defined above in Section II.A.6) provided to HCPs or HCIs;
- f) Grants provided to HCPs or HCIs; and
- g) Promotional activities involving exhibits, displays, and Educational or Informational Activities.

2) Description of Reviewed Activities Control Documents and Sample Sizes

Reviewed Activities Control Documents shall include all documents or electronic records (collectively “documents”) associated with each set of Reviewed Activities. These documents include, but are not limited to, all documents submitted by field or headquarters personnel to request approval for the Reviewed Activity; all business rationale or justification forms; all written contracts relating to the Reviewed Activity; all documents relating to the occurrence of the Reviewed Activity (e.g., attendance sheets, receipts); and all documents reflecting any work product generated in connection with the Reviewed Activity.

No later than 60 days prior to the end of each Reporting Period, the CTI shall notify the OIG about the number of each type of Reviewed Activity that occurred during the course of the Report Period. The OIG in its sole discretion, but after consultation with CTI, shall determine the number of each type of Reviewed Activity (e.g., 30 speaker programs, 50 Expenses, 100 grants) that shall form the basis for the IRO’s testing of the Control Documents associated with the

Reviewed Activities. No later than 30 days prior to the end of the Reporting Period, the OIG shall notify CTI how many occurrences of each type of Reviewed Activity shall be reviewed by the IRO.

Using the sample sizes provided by the OIG, the IRO shall randomly select the OIG-specified number of each type of Reviewed Activity. For each Reviewed Activity selected, the IRO shall review all Control Documents associated the Reviewed Activity.

3) IRO Review of Selected Control Documents

For each selected Reviewed Activity, the IRO shall review the Control Documents associated with each selected sample to evaluate the following:

- a) Whether all required Control Documents exist in appropriate files in accordance with CTI's policies;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in CTI's policies; and
- c) Whether the Control Documents reflect that CTI's policies were followed in connection with the underlying activities (e.g., all required written approvals for the activity were obtained in accordance with CTI's policies.)

4) Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) All required Control Documents relating to a Reviewed Activity do not exist and:
 - i. no corrective action was initiated prior to the IRO's selection of the Reviewed Activity for review; or
 - ii. the IRO cannot confirm that CTI otherwise followed its policies and procedures relating to the Reviewed Activity;
- b) Information or data is omitted from any key fields in a particular Control Document that prevents the IRO from assessing compliance with CTI's policies and procedures and the IRO cannot obtain this information or data from reviewing other Control Documents associated with the same Reviewed Activity.

If a Control Document does not exist, but CTI has initiated corrective action prior to the IRO's selection of the Reviewed Activity, or if a Control Document does not exist but the IRO can determine that CTI otherwise followed its policies and procedures with regard to the Reviewed Activity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Reviewed Activities associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

C. IRO Review of CTI's Call Plan Assessments

The IRO shall conduct a review and assessment of CTI's review of its call plans for all products as set forth in Section III.B.3.1 of the CIA. CTI shall provide the IRO with: i) a list of the products promoted by CTI during the Reporting Period; ii) information about the FDA-approved uses for the products; and iii) the call plans for each product. CTI shall also provide the IRO with information about the reviews of call plans that CTI conducted during the Reporting Period and any modifications to the call plans made as a result of CTI's reviews.

For each call plan, the IRO shall select a sample of 30 of the HCPs and HCIs included on the call plan. For each call plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (*e.g.*, medical specialty or practice area) used by CTI in conducting its review and/or modification of the call plan in order to determine whether CTI 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 CTI's criteria relating to the call plan and/or CTI's Policies and Procedures. The IRO shall also note any instances in which it appears that CTI failed to follow its criteria or Policies and Procedures.

D. Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Promotional and Product Services Transactions Review. 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 Promotional and Product Services Transactions Review.

- 2) Results to be Included in Report:

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

- 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 reviewed (*i.e.*, 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 contained in the Inquiries Database about the Inquiry;
- c) for each Inquiry sample unit, the IRO shall state its findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the Inquiries Database for each reviewed Inquiry; and (ii) for each Inquiry for which the Compliance Officer 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 Compliance Officer as a result of the Off-Label Review; and any follow-

up actions taken by CTI as a result of the Compliance Officer's findings;

- d) the findings and supporting rationale regarding any weaknesses in CTI's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;
- e) recommendations for improvement in CTI's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;
- f) for the Reviewed Activities, a description of each type of sample unit reviewed for each Reviewed Activity, including the number of each type of sample units reviewed (e.g., Control Documents associated with each of the various types of Reviewed Activities) and an identification of the types of Control Documents reviewed for each type of sample unit;
- g) for each sample unit, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed and archived in accordance with all of the requirements set forth in the applicable CTI policy; (iii) each Control Document reflects that CTI's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (iv) any disciplinary action was undertaken relating to the Reviewed Activities in those instances in which CTI policies were not followed;
- h) for each sample unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the IRO review, including a description of the circumstances requiring corrective action and the nature of the corrective action;
- i) if any Material Errors are discovered in the sample unit reviewed, a description of the error, the Additional Review procedures performed, and a statement of findings as to the root cause(s) of the Material Error;

- j) the findings and supporting rationale regarding any weaknesses in CTI's systems, processes, policies, procedures, and practices relating to the Reviewed Activities, if any;
- k) recommendations for changes in CTI's systems, processes, policies, and procedures to correct or address any weaknesses or deficiencies relating to the Reviewed Activities;
- l) a list of the products promoted by CTI during the Reporting Period and a summary of the FDA-approved uses for such products;
- m) for each CTI product, i) a description of the criteria used by CTI in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans for the product; ii) a description of the review conducted by CTI of the call plans and an indication of whether CTI reviewed the call plans as required by Section III.B.3.1; 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 the CTI's criteria relating to the call plan and/or CTI's Policies and Procedures; and iv) a description of all instances in which it appears that CTI failed to follow its criteria or Policies and Procedures relating to call plans;
- n) the findings and supporting rationale regarding any weaknesses in CTI's systems, processes, policies, procedures, and practices relating to CTI's call plans, if any; and
- o) recommendations, if any, for changes in CTI's systems, processes, policies, and procedures to correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to call plans.