

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
DUSA PHARMACEUTICALS, INC. AND SUN PHARMACEUTICAL
INDUSTRIES, INC.**

I. PREAMBLE

DUSA Pharmaceuticals, Inc. and Sun Pharmaceutical Industries, Inc. (collectively, SUN) hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, DUSA Pharmaceuticals, Inc. is entering into a Settlement Agreement with the United States.

Prior to the Effective Date, SUN established a compliance program that SUN represents addresses all seven elements of an effective compliance program and that is designed to address compliance with Federal health care program requirements (Compliance Program). SUN shall continue the Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. SUN may modify the Compliance Program as appropriate. However, at a minimum, SUN shall ensure that during the term of this CIA, it shall maintain a compliance program to comply with the obligations set forth in this CIA.

II. TERM AND SCOPE OF THE CIA

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

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

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

1. For purposes of this CIA, the term "Covered Persons" includes: (a) all owners of SUN who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading) and all officers and directors of SUN; (b) all employees of SUN who are engaged in or who supervise personnel who are engaged in Covered Functions (as defined below in Section II.C.6); and (c) all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of SUN and who, in the course of performing Covered Functions, either: (i) interact directly with healthcare professionals (HCPs), healthcare institutions (HCIs), or consumers; or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a SUN employee who is a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term "Covered Persons" does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to perform a Covered Function for SUN more than 160 hours per year, except that any such individual shall become a "Covered Person" at the point when they work more than 160 hours on a Covered Function for SUN during the calendar year.

3. "Government Reimbursed Products" refers to all SUN products that are: (a) marketed or sold by SUN in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

4. "Relevant Government Reimbursed Products" refers to the SUN branded Government Reimbursed Products.

5. The term "Promotional Functions" includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Relevant Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Relevant Government Reimbursed Products, including those functions relating to SUN's

review and approval processes for promotional materials and any applicable review committee(s).

6. The term “Product Related Functions” includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to healthcare professionals (HCPs), and healthcare institutions (HCIs) about Relevant Government Reimbursed Products, including those functions relating to any applicable review committees and those functions relating to medical affairs/medical information services or involved in scientific exchange; (b) contracting with HCPs licensed in the United States or with HCIs to conduct post-marketing clinical trials, Investigator-Sponsored Studies (ISSs), and any other types of post-marketing studies relating to Relevant Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Relevant Government Reimbursed Products; and (d) activities related to the submission of information about Relevant Government Reimbursed Products to Compendia (such as Drugdex or other compendia of information about Government Reimbursed Products).

7. The term “Covered Functions” refers to “Promotional Functions” and “Product Related Functions,” collectively.

8. The term “Third Party Educational Activity” shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by SUN, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations

1. *Compliance Officer.* Within 90 days after the Effective Date, SUN shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Sun Pharmaceutical Industries, Inc.; shall report directly to the Chief Executive Officer of Sun Pharmaceutical Industries, Inc.; and shall not be, or be

subordinate to, the General Counsel or Chief Financial Officer of Sun Pharmaceutical Industries, Inc., or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for SUN. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters in person to the Board of Directors of Sun Pharmaceutical Industries, Inc. (Board) and shall be authorized to report on such matters to the Board at any time. Written documentation of the Compliance Officer's reports to the Board shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by SUN as well as any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

SUN shall report to OIG, in writing, any changes in the identity 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 five business days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, SUN 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 sales, marketing, legal, medical affairs/medical information, regulatory affairs, research and development, human resources, audit, finance, manufacturing, and 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 SUN's risk areas and shall oversee monitoring of internal and external audits and investigations). The

Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

SUN shall report to OIG, in writing, 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 business days after such a change.

3. *Board Compliance Obligations.* The Board of Sun Pharmaceuticals, Inc., shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board must include an independent (i.e., non-employee and non-executive) member.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee SUN's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board, summarizing its review and oversight of SUN's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board has made a reasonable inquiry into the operations of SUN's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the

Board has concluded that, to the best of its knowledge, SUN has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement.”

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

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

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain SUN employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable SUN business unit is in compliance with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Financial Officer, Chief Compliance Officer, business unit leader of Specialty Dermatology I, head of Medical Affairs, and head of Commercial Operations. For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of the department] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Sun Pharmaceutical Industries policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of [Sun Pharmaceutical Industries, Inc. or DUSA Pharmaceuticals, Inc.] is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 90 days after the Effective Date, SUN shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards

1. *Policies and Procedures.* Within 90 days after the Effective Date, SUN shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and SUN's compliance with Federal health care program and FDA requirements (Policies and Procedures). Throughout the term of this CIA, SUN shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons. At a minimum, the Policies and Procedures shall address the following:

- a. appropriate ways to conduct Promotional Functions in compliance with all: (i) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements;
- b. appropriate ways to conduct Product Related Functions in compliance with: (i) all applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements;
- c. the materials and information that may be distributed by SUN sales representatives (including any contract sales force)

about Relevant Government Reimbursed Products and the manner in which SUN sales representatives respond to requests for information about non-FDA approved (or “off-label”) uses of Government Reimbursed Products;

- d. the materials and information that may be distributed by Medical Information and the mechanisms through, and manner in which, Medical Information receives and responds to requests for information from an HCP or another individual or entity about off-label uses of Relevant Government Reimbursed Products; the form and content of information disseminated by SUN in response to such requests; and the internal review process for the information disseminated;
- e. the manner and circumstances under which medical personnel interact with or participate in meetings or events with HCPs or HCIs (either alone or with SUN sales representatives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to requests for information about off-label uses of Relevant Government Reimbursed Products;
- f. the materials and information that may be distributed or made available by SUN through social media and/or direct-to-consumer advertising;
- g. the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other SUN representatives who promote and sell Relevant Government Reimbursed Products;
- h. the development, implementation, and review of all plans for the distribution of samples of, or coupons or vouchers for, Relevant Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples, coupons, or vouchers from

SUN (including, separately, from sales representatives, from Medical Affairs, or through other channels);

- i. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;
- j. programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;
- k. sponsorship or funding of grants (including educational grants) or charitable contributions;
- l. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.7 above;
- m. review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside SUN by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during SUN's review and approval process and are elevated when appropriate;
- n. compensation (including through salaries, bonuses, or other means) for Covered Persons engaged in Promotional Functions;
- o. the submission of information about any Relevant Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal

health care program for the product (hereafter “Compendia”). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (including any changes based on SUN’s discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results.);

- p. sponsorship or other support of post-marketing clinical trials and all other post-marketing studies of Relevant Government Reimbursed Products and support of ISSs (collectively, “Research”), including the decision to provide financial or other support for such Research; the manner in which Research support is provided; the publication of information about the Research (including the publication of information about the Research results and trial outcomes); and uses made of publications relating to Research;
- q. authorship of journal articles or other publications about Relevant Government Reimbursed Products or about therapeutic areas or disease states that may be treated with Relevant Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and SUN or other potential conflicts of interest that might bias the author’s work; the identification of all authors or contributors (including professional writers) associated with a given publication; and the scope and breadth of research results made available to each author or contributor; and
- r. disciplinary policies and procedures for violations of SUN’s Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

At least annually (and more frequently, if appropriate), SUN shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

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

C. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, SUN shall develop a written plan (Training Plan) that outlines the steps SUN will take to ensure that: (a) all Covered Persons receive at least annual training regarding SUN's CIA requirements and compliance program, and (b) all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions and (ii) all SUN Policies and Procedures and other requirements applicable to Covered Functions. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons and required to attend each training session, length of the training session(s), schedule for training, and format of the training. SUN shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Training.* In addition to the training described in Section III.C.1, within 90 days after the Effective Date, each member of the Board shall receive training regarding the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of OIG's guidance on Board member responsibilities.

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

3. *Training Records.* SUN shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided as required.

D. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, SUN shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted annually and shall require SUN to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. SUN shall maintain the risk assessment and internal review process for the term of the CIA.

E. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, SUN shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and SUN shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports

(those exchanged between the IRO and SUN) related to the reviews.

- c. *Access to Records and Personnel.* SUN shall ensure the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E., and that all records furnished to the IRO are accurate and complete.

2. *System, Transaction, and Additional Items Reviews.* As set forth more fully in Appendix B, the IRO reviews shall consist of three components: Systems Reviews and Transactions Reviews relating to the Covered Functions and an Additional Items Review.

- a. *Systems Review.* The Systems Reviews shall assess SUN's systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in SUN's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the first and fourth Reporting Periods. If SUN materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendix B.
- b. *Transactions Review.* The Transactions Reviews shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.
- c. *Additional Items Review.* Each IRO review shall also include a review of up to three additional areas or practices of SUN identified by OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the IRO review for a particular Reporting Period, OIG will consult with SUN and may consider internal

audit and monitoring work conducted by SUN, the Government Reimbursed Product portfolio, the nature and scope of SUN's promotional and other practices, the nature and scope of SUN's arrangements with HCPs and HCIs, and other information known to OIG.

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

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to SUN a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of current and prior engagements between SUN and IRO.

F. Disclosure Program

Within 90 days after the Effective Date, SUN shall establish 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 SUN's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. SUN shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of SUN's Covered Persons shall be expected to report suspected violations of any Federal health care program or FDA requirements to the Compliance Officer or other appropriate individual designated by SUN. 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, SUN 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 and shall record all disclosures, whether or not related to a potential violation of criminal, civil or administrative law related to Federal health care programs or FDA requirements, in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the individual or department responsible for reviewing the disclosure, the status of the review, and any corrective action taken in response to the review.

G. Ineligible Persons

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

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded from participation in the Federal health care programs; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.
- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

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

- a. SUN shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. SUN shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.
- c. SUN shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

3. *Removal Requirement.* If SUN has actual notice that a Covered Person has become an Ineligible Person, SUN shall remove such Covered Person from responsibility for, or involvement with, SUN's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation is paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

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

H. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, SUN shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to SUN conducted or brought by a governmental entity or its agents involving an allegation that SUN 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. SUN also shall provide written notice to OIG within 30 days after the resolution of the matter and describe the findings and/or results of the investigation or proceeding, if any.

I. Reportable Events

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

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- b. a matter that a reasonable person would consider a probable violation of FDA requirements relating to the promotion of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by SUN.

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

2. *Reporting of Reportable Events.* If SUN determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, SUN shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. Sun shall not be required to report as a Reportable Event a matter that is the subject of an

ongoing investigation or legal proceeding by a government entity or its agents if disclosed under Section III.H above.

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

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event, if any;
- d. a statement of the FDA requirements probably violated by the Reportable Event, if any; and
- e. a description of SUN's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.I.1.c.* For Reportable Events under Section III.I.1.c, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that SUN completed before and/or during the Ineligible Person's

employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;

- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

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

J. Notification of Communications with FDA

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

K. Field Force Monitoring and Review Efforts

Within 90 days after the Effective Date, SUN shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: (1) a Speaker Monitoring Program; (2) direct field observations (Observations) of sales personnel; and (3) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.*

- a. SUN shall implement a process to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements regarding the use of SUN approved materials and requirements that speakers may not directly or indirectly promote the product for off-label uses.).
- b. SUN shall establish a centralized, electronic system to initiate and track all speaker programs that includes controls designed to ensure that speaker programs are used for legitimate and lawful purposes in accordance with all applicable Federal health care program and FDA requirements.
- c. SUN shall ensure that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by SUN.
- d. SUN shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, SUN shall use its centralized system to handle all logistics and spending associated with speaker programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs.
- e. SUN shall require certifications by sales representatives or other SUN personnel that a speaker program complied with SUN requirements, or in the event of non-compliance, SUN shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.
- f. SUN shall institute a Speaker Monitoring Program under which SUN compliance or other appropriately trained SUN personnel who are independent from the functional area being

monitored (Monitoring Personnel) shall attend 45 speaker programs during each Reporting Period and conduct live audits of the programs (Speaker Program Audits). The programs subject to Speaker Program Audits shall be selected using either a risk-based targeting approach or a random sampling approach. For each program reviewed, Monitoring Personnel shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and SUN sales representative activities during the program to assess whether the programs were conducted in a manner consistent with SUN's Policies and Procedures.

SUN shall maintain the controls around speaker programs as described above and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations.* As a component of the FFMP, Monitoring Personnel shall conduct observations of field sales representatives for Relevant Government Reimbursed Products (including any contract sales personnel) to assess whether the messages delivered and materials distributed to HCPs and HCIs are consistent with applicable legal requirements and with SUN's Policies and Procedures. These observations shall be full day ride-alongs with field sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs and HCIs during the workday. The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, include a review of each therapeutic area and actively promoted product, and be conducted across the United States.

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Monitoring Personnel who conducted the Observation;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;

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

Monitoring Personnel shall conduct at least 35 Observations during each Reporting Period.

Monitoring Personnel shall have access to all relevant records and information necessary to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

3. *Records Reviews.* As a component of the FFMP, SUN shall also review various types of records to assess Relevant Government Reimbursed Products field sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

- a. For each Reporting Period, SUN shall develop and implement a plan for conducting Records Reviews associated with at least five Relevant Government Reimbursed Products. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate district and/or region (as applicable) who promoted the products under review.
- b. The Records Reviews shall include the monitoring and review of:
 - (i) records and systems associated with field sales representatives' interactions with HCPs and HCIs (including records relating to speaker program activities, samples, travel and entertainment, expense reports, any payments to HCPs or HCIs, and sales communications from managers);
 - (ii) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of representatives interactions with HCPs and HCIs;

- (iii) records relating to requests for medical information about or inquiries relating to, the Relevant Government Reimbursed Products under review;
- (iv) field sales representative call notes;
- (v) field sales representatives' e-mails and other electronic records; and
- (vi) recorded results of the Observations of field sales force representatives, coaching guides, and district manager notes.

4. *Reporting and Follow-up.* Results from the FFMP shall be compiled and reported to the Compliance Officer for review and remediation as appropriate. Potential violations related to improper promotion of a Relevant Government Reimbursed Product or potential violations of Federal health care program or FDA requirements shall be reported to the Compliance Officer for appropriate follow-up activity. In the event that a compliance issue, including but not limited to any potential improper promotion or noncompliance with SUN's Policies and Procedures or legal or compliance requirements, is identified during any portion of the FFMP, SUN shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the investigative procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events pursuant to Section III.I above, as applicable. Any compliance issues identified during the FFMP and any corrective action shall be recorded in the files of the Compliance Officer.

L. Monitoring of Non-Promotional Activities

Within 90 days after the Effective Date, SUN shall develop and implement a monitoring program for consultant arrangement activities. This program shall be referred to as the Non-Promotional Monitoring Program (NPMP).

1. *Consulting Arrangement Activities.* To the extent that SUN engages HCPs for services other than for speaker programs (e.g., as a member of an advisory

board or to attend consultant meetings), such HCPs shall be referred to herein as Consultants.

- a. SUN shall require all Consultants to enter written agreements describing the scope of work to be performed, the consultant fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on an independent fair-market value analysis conducted on behalf of SUN.
- b. Within 90 days after the Effective Date, SUN shall establish a process to develop an annual budgeting plan that identifies the business needs for, and the estimated numbers of, the various Consultant engagements and activities to occur during the following year. The annual Consultant budgeting plan shall also identify the budgeted amounts to be spent on Consultant-related activities. SUN compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and SUN Policies and Procedures.
- c. Within 90 days after the Effective Date, SUN shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs and HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and the type of work product to be generated). Any deviations from the Consultant budgeting plans shall be

documented in the needs assessment form and shall be subject to review and approval by SUN compliance personnel.

- d. Within 90 days after the Effective Date, SUN shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, SUN received the work product generated by the Consultant.
- e. Within 90 days after the Effective Date, SUN shall establish a Consultant Monitoring Program through which it shall conduct audits (Consultant Program Audits) of at least the greater of ten percent or five consultant programs with HCPs during each Reporting Period. The Consultant Monitoring Program shall select Consultant arrangements for review using either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review needs assessment documents, Consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with SUN's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of SUN policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow up as appropriate.

2. *Follow Up Reviews and Reporting.* In the event that a potential violation of SUN's Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, are identified during any aspect of the NPMP, SUN shall investigate the incident consistent with established policies and procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.I above, if applicable.

M. Reporting of Physician Payments

1. *Reporting of Payment Information.* Within 90 days after the Effective Date, SUN shall post on its website a description of the types of Payments it makes to Covered Recipients and include a link to CMS's Open Payments Data website (www.openpaymentsdata.cms.gov). SUN also shall include on its website instructions regarding how to utilize the CMS Open Payments Data search tool to search for information regarding Payments provided to Covered Recipients from SUN.

2. *Definitions.* For purposes of this Section III.M, the terms "Payments" and "Covered Recipient" are defined as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by CMS.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, SUN proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA; or (b) purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any such new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. SUN shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, SUN wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, SUN must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, SUN 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, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the Board members who are responsible for satisfying the Board compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;
5. (a) a copy of the letter (including all attachments) required by Sections II.C.8 and III.B.1 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' responses to SUN's letter;
6. a list of the Policies and Procedures required by Section III.B.1;
7. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);
8. a description of the risk assessment and internal review process required by Section III.D;

9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to SUN that includes a summary of all current and prior engagements between SUN and the IRO;
10. a description of the Disclosure Program required by Section III.F;
11. a description of the Ineligible Persons screening and removal process required by Section III.G;
12. a certification by the Compliance Officer that the notice required by Section III.M was posted in the manner required by Section III.M and a summary of the calls or messages received in response to the notice;
13. a certification from the Compliance Officer that information regarding Payments has been posted on SUN's website as required by Section III.N;
14. a list of all of SUN's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; and the locations' Medicare and state Medicaid provider number and/or supplier number(s) if any;
15. a description of SUN's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
16. the certifications required by Section V.C.

B. Annual Reports

SUN shall submit a written report to OIG on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board compliance obligations; and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, and Certifying Employees;
2. a description of any changes to the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;
3. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);
4. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;
5. (a) a copy of the letter (including all attachments) required by Sections II.C.8 and III.B.1 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' responses to SUN's letter;
6. a list of any new or revised Policies and Procedures required by Section III.B.1 developed during the Reporting Period;
7. a description of any changes to SUN's Training Plan developed pursuant to Section III.C and a summary of any Board training provided during the Reporting Period;
8. a description of any changes to the risk assessment and internal review process required by Section III.D, including the reasons for such changes;
9. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed; (b) internal audits performed; (c) corrective action plans developed in response to internal audits; and (d) steps taken to track the implementation of the corrective action plans.

Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

10. a complete copy of all reports prepared pursuant to Section III.E and SUN's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

11. a certification from the IRO regarding its professional independence and objectivity with respect to SUN, including a summary of all current and prior engagements between SUN and the IRO;

12. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or Government Reimbursed Products, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;

13. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

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

15. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period;

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

17. a summary of the FFMP and the results of the FFMP required by Section III.K, including copies of the Observations for any instances in which it was determined that improper promotion occurred and a description of the action (s) that SUN took as a result of such determinations;

18. a summary of the NPMP and the results of the program described in Section III.L, including detailed description of any identified instances in which it was determined that the activities violated SUN's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) SUN took as a result of such determinations;

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

20. a certification from the Compliance Officer that information regarding Payments has been posted on SUN's website as required by Section III.N;

21. a description of all changes to the most recently provided list of SUN's locations (including addresses) as required by Section V.A.13;

22. a description of any changes to SUN's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and

23. the certifications required by Section V.C.

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

C. Certifications

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

2. *Compliance Officer and Sun Pharmaceutical Industries, Inc. Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

- a. to the best of his or her knowledge, except as otherwise described in the report, SUN has implemented and is in compliance with all requirements of this CIA;
- b. 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

- c. he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

SUN 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. SUN 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

SUN:

Michael Perry
Director, Corporate Compliance
Sun Pharma Corporate Services, North America
Sun Pharmaceutical Industries, Inc.
Taro Pharmaceutical Industries Ltd.
3 Skyline Drive, Hawthorne, NY 10532
Telephone: 914-345-9001 x6829
Email: michael.perry@taro.com

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, SUN may be required to provide OIG with an additional copy of each notification or report required by this CIA in OIG's requested format (electronic or paper).

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 conduct interviews, examine and/or request copies of or copy SUN's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of SUN's locations for the purpose of verifying and evaluating: (a) SUN's compliance with the terms of this CIA and (b) SUN's compliance with Federal health care program requirements and with all applicable FDA requirements. The documentation described above shall be made available by SUN to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of SUN's owners, employees, contractors and directors 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. SUN shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. SUN's owners, employees, contractors and directors may elect to be interviewed with or without a representative of SUN present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify SUN prior to any release by OIG of information submitted by SUN pursuant to its obligations under this CIA and identified upon submission by SUN as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, SUN shall have the rights set forth at 45 C.F.R. § 5.42 (a).

X. BREACH AND DEFAULT PROVISIONS

SUN 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, SUN 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) per obligation for each day SUN fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board compliance obligations;
- d. the management certification obligations and the

development and implementation of a written process for Certifying Employees, as required by Section III.A.4;

- e. written Policies and Procedures;
- f. the development of a written training plan and the training and education of Covered Persons and Board members;
- g. a risk assessment and internal review process;
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements;
- j. notification of Government investigations or legal proceedings;
- k. reporting of Reportable Events;
- l. notification of written communications with FDA;
- m. the FFMP;
- n. the NPMP;
- o. notification to HCPs and HCIs; and
- p. posting of any Payment-related information.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day SUN fails to engage and use an IRO as required by Section III.E and Appendix A.

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 SUN fails to timely submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.

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 SUN fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix A.

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

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of SUN as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$2,500 for each day SUN fails to grant the IRO access to all records and personnel necessary to complete the reviews required by Section III.E and for each day SUN fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix A; and

8. A Stipulated Penalty of \$1,000 for each day SUN fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to SUN stating the specific grounds for its determination that SUN has failed to comply fully and adequately with the CIA obligation(s) at issue and steps SUN shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 business days after the date SUN 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 1-7 of this Section.

B. Timely Written Requests for Extensions

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

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

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that SUN 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. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by SUN to report a Reportable Event and take corrective action as required in Section III.I;
- c. a failure to engage and use an IRO in accordance with Section III.E and Appendix A; or
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by SUN constitutes an independent basis for SUN's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that SUN has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify SUN of: (a) SUN'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.* SUN 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. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) SUN has begun to take action to cure the material breach; (ii) SUN is pursuing such action with due diligence; and (iii) SUN has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, SUN fails to satisfy the requirements of Section X.D.3, OIG may exclude SUN from

participation in the Federal health care programs. OIG shall notify SUN in writing of its determination to exclude SUN (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 SUN’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, SUN 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 SUN 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, SUN 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. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

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 SUN was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. SUN 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 SUN to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless SUN 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 whether SUN was in material breach of this CIA and, if so, whether:

- a. SUN cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following SUN's receipt of the Notice of Material Breach: (i) SUN had begun to take action to cure the material breach within that period; (ii) SUN pursued such action with due diligence; and (iii) SUN provided to OIG within that period a reasonable timetable for curing the material breach.

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

SUN and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

C. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) SUN's responsibility to follow all applicable Federal health care program and FDA requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program or FDA requirements.

D. The undersigned SUN signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically-transmitted signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF SUN

/Abhay Gandhi/
ABHAY GANDHI, CEO
Sun Pharmaceutical Industries, Inc.

August 11, 2020
DATE

/J.P. Ellison/
JAMES P. ELLISON
Hyman, Phelps & McNamara P.C.
Counsel for Sun Pharmaceutical Industries, Inc.

August 11, 2020
DATE

/Michael Schwartz/
MICHAEL A. SCHWARTZ
Troutman Pepper Hamilton Sanders LLP
Counsel for Sun Pharmaceutical Industries, Inc.

August 11, 2020
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. SUN 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 E. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by SUN in response to a request by OIG, whichever is later, OIG will notify SUN if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SUN may continue to engage the IRO.

2. If SUN engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, SUN 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 this information or any additional information submitted by SUN at the request of OIG, whichever is later, OIG will notify SUN if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, SUN may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and in all applicable Federal health care program and FDA requirements relating to the Covered Functions, including but not limited to expertise relating to marketing and promotional activities associated with pharmaceutical products and the Federal Anti-Kickback Statute and False Claims Act.

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

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

C. IRO Responsibilities

The IRO shall:

1. perform each component of the IRO Reviews in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in the IRO Reviews;
3. respond to all OIG inquiries in a prompt, objective, and factual manner; and
4. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. SUN Responsibilities

SUN shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.E of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform each component of the IRO Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

1. *SUN and IRO.* If SUN terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, SUN must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. SUN must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify SUN in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. SUN shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns

identified by OIG. If, following OIG's review of any information provided by SUN regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify SUN in writing that SUN shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. SUN must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require SUN to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

COVERED FUNCTIONS REVIEW

I. Covered Functions Review, General Description

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

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

II. Systems Review

A. Promotional and Product Related Functions Systems Review

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

Specifically, the IRO shall review systems, processes, policies, and procedures of SUN associated with the following (hereafter “Reviewed Policies and Procedures”):

1. SUN’s systems, policies, processes and procedures applicable to the manner in which sales representatives and personnel from Medical Affairs handle requests or inquiries relating to information about the uses of Relevant Government Reimbursed Products (including non-FDA-approved (i.e., off-label) uses of Relevant Government Reimbursed Products) and the dissemination of materials relating to the uses of these products. This review shall include: (a) the manner in which SUN sales representatives handle requests for information about off-label uses of Relevant Government Reimbursed Products, (b) the manner in which Medical Affairs personnel, including those at SUN’s headquarters, handle and respond to requests for information about off-label uses of Relevant Government Reimbursed Products; (c) the form and content of information and materials related to Relevant Government Reimbursed Products disseminated to HCPs, HCIs, payers, and formulary decision-makers by SUN; (d) the systems, processes, policies, and procedures of SUN to track requests to Medical Affairs for information about off-label uses of products and responses to those requests; (e) the manner in which SUN collects and supports information reported in any systems used to track and respond to requests to Medical Affairs for Relevant Government Reimbursed Product information; (f) the processes and procedures by which Medical Affairs or other appropriate individuals within SUN identify situations in which it appears that off-label or other improper promotion may have occurred; and (g) the processes and procedures of SUN for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;

2. SUN’s systems, policies, processes, and procedures applicable to the manner and circumstances under which SUN’s medical personnel participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Relevant Government Reimbursed Products and the role of the medical personnel at such meetings or events;

3. SUN’s systems, policies, processes, and procedures applicable to SUN’s internal review of promotional materials related to Relevant Government Reimbursed Products disseminated to HCPs, HCIs and payers and individuals or entities (e.g., PBMs) acting on behalf of HCPs, HCIs or payers;

4. SUN’s systems, policies, processes, and procedures applicable to the development and review of SUN processes relating to incentive compensation for Covered Persons who are sales representatives and their direct managers, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the

improper promotion, sales, and marketing of Relevant Government Reimbursed Products. To the extent that SUN establishes different methods of compensation for different Relevant Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;

5. SUN's systems, policies, processes, and procedures applicable to the development and review of SUN's call plans for Relevant Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the call plans based on all relevant factors including expected utilization of Relevant Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;

6. SUN's systems, policies, processes, and procedures applicable to the development and review of Sample Distribution Plans (as defined in Section III.B.h of the CIA). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from SUN (including, separately, from SUN sales representatives and other SUN personnel or components). It shall also include a review of whether samples of Relevant Government Reimbursed Products are distributed by SUN through sales representatives or are distributed from a central location and the rationale for the manner of distribution;

7. SUN's systems (including any centralized electronic systems), processes, policies, and procedures relating to SUN's speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;

8. SUN's systems, processes, policies, and procedures relating to the engagement of non-speaker related consultants or other fee-for-service arrangements (including, but not limited to, presentations, advisory boards, preceptorships, mentorships, and ad hoc advisory activities, and any other financial engagement) that SUN entered with HCPs or HCIs and all events and expenses associated with such activities;

9. SUN's systems, processes, policies, and procedures relating to SUN's funding, directly or indirectly, of Third Party Educational Activities (as defined in Section II.C.8 of the CIA) and all events and expenses relating to such activities;

10. SUN's systems, processes, policies, and procedures applicable to the submission of information about any Relevant Government Reimbursed Product to any Compendia (as defined in Section III.B.o of the CIA) such as Drugdex or other

published source of information used in connection with the determination of coverage by a Federal health care program for the product;

11. SUN's systems, processes, policies, and procedures applicable to Research (as defined in Section III.B.p), including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information about the Research results and trial outcomes; and uses made of publications relating to such Research; and

12. SUN's systems, processes, policies, and procedures relating to authorship-related practices (as referenced in Section III.B.q of the CIA), including, but not limited to, the disclosure of all financial relationships between the author and SUN, the identification of all authors or contributors (including professional writers, if any) associated with a given publication, and the scope and breadth of research results made available to each author or contributor.

B. IRO Systems Review Report

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

1. a description of the documentation (including policies) reviewed and any personnel interviewed;
2. a detailed description of systems, policies, processes, and procedures relating to the items identified in Section II.A above, including a general description of the control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Section II.A above are made known or disseminated within SUN;
4. a detailed description of any system(s) used to track and respond to requests for information about Relevant Government Reimbursed Products;
5. a detailed description of the incentive compensation system for Covered Persons who are sales representatives or their direct managers, including a

description of the bases upon which compensation is determined. To the extent that SUN may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

6. findings and supporting rationale regarding any weaknesses in the systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

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

III. Transactions Review

As described more fully below, the Transactions Review shall include: (1) a review of call plans and the call plan review process; (2) a review of records relating to a sample of the Payments referenced in Section III.N of the CIA; and (3) a review of up to three additional items identified by the OIG in accordance with Section III.E.2.c of the CIA (hereafter “Additional Items”). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. Review of Call Plans and Call Plan Review Process. The IRO shall conduct a review and assessment of SUN’s review of its call plans for (i) all products in its Specialty Dermatology Business Unit and (ii) two other Relevant Government Reimbursed Products promoted by SUN during the Reporting Period (Selected Government Reimbursed Products). During each Reporting Period, SUN may propose to the IRO the Selected Government Reimbursed Products. The IRO, at its discretion, may accept or reject SUN’s proposal.

1. For each of the products in its Specialty Dermatology Business Unit promoted by SUN during the Reporting Period and for the Selected Government Reimbursed Products, SUN shall provide the IRO with: i) information about the FDA-approved uses for each such product and ii) the call plans for each such product. SUN shall also provide the IRO with information about the reviews of call plans that SUN conducted during the relevant Reporting Period and any modifications to the call plans made as a result of SUN’s reviews.

2. For each call plan, the IRO shall select a sample of 50 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 SUN in conducting its review and/or modifying the call plan. The IRO shall seek to

determine whether SUN followed its criteria and Policies and Procedures in reviewing and modifying the call plan.

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

B. Review of Physician Payment Listings

1. *Information to be Reviewed.* As set forth in Section III.M of the CIA, SUN reports Payments to Covered Recipients to CMS that are listed on the Open Payments Data website. For purposes of the review described in in this Section III.C, the term "Control Documents" shall include all documents or electronic records associated with each Payment reflected on the Open Payments Data website for the applicable calendar year. For example, the term "Control Documents" includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments; contracts relating to the Payment(s); documents relating to the occurrence of Payment(s); documents reflecting any work product generated in connection with the Payment(s); documents submitted by sales representatives or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

2. *Selection of Sample for Review.* For each Reporting Period, the OIG shall have the discretion to identify up to 50 Covered Recipients who received Payments from SUN during the prior calendar year who will be subject to the review described below. If the OIG elects to exercise this discretion, it shall notify the IRO at least 90 days prior to the end of the Reporting Period of the Covered Recipients subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 Covered Recipients to be included in the review. For each selected Covered Recipient, the IRO shall review Control Documents relating to Payments to the Covered Recipient for all categories reflected on the Open Payments Data website, except for the Food/Beverage and Travel/Lodging categories of Payments.

3. *IRO Review of Control Documents for Selected Covered Recipients.* For each Covered Recipient selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reported to CMS to evaluate the following:

- a. Whether Control Documents are available relating to each Payment for each selected Covered Recipient;

- b. Whether the Control Documents were completed and archived in accordance with the requirements set forth in SUN's policies;
- c. Whether the aggregate value of the Payment(s) as reflected in the information reported to CMS for the selected Covered Recipient is consistent with the value of the Payments(s) reflected in the Control Documents; and
- d. Whether the Control Documents reflect that SUN policies were followed in connection with Payment(s) reflected in the report to CMS (e.g., all required written approvals for the activity were obtained in accordance with all applicable policies).

4. *Identification of Material Errors and Additional Review.* A Material Error is defined as any of the following:

- a. A situation in which all required Control Documents relating to Payments for the selected Covered Recipient do not exist and (i) no corrective action was initiated prior to the selection of the selected Covered Recipient; or (ii) the IRO cannot confirm that SUN otherwise followed applicable policies and procedures relating to the Payment for the selected Covered Recipient, including its policies and procedures relating to any Payment(s); or
- b. Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with SUN's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but SUN has initiated corrective action prior to the selection of the Covered Recipient, or if a Control Document does not exist but the IRO can determine that SUN otherwise followed its policies and procedures with regard to each Payment, 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 Payment 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 Additional Items. As set forth in Section III.E of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter “Additional Items”).

1. No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify SUN of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or SUN shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO’s findings based on its review for each Additional Item; and the IRO’s recommendations for any changes in SUN’s systems, processes, policies, and procedures based on its review of each Additional Item).

2. SUN may propose to the OIG that its internal audit(s) be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow SUN’s internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

3. In making its decision, the OIG agrees to consider, among other factors, the nature and scope of SUN’s planned internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and SUN’s demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies SUN’s request to permit its internal audit work to be substituted for a portion of the IRO’s review of Additional Items in a given Reporting Period, SUN shall engage the IRO to perform the Review as outlined in this Section III.D.

4. If the OIG agrees to permit certain of SUN’s internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such

an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO.

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

1. *General Elements to Be Included in Report*

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

2. *Results to be Included in Report*. The following results shall be included in each Transaction Review Report:

- a. Relating to the Call Plan Reviews.
 - i. a list of products in SUN's Specialty Dermatology Business Unit that were promoted by SUN during the Reporting Period, and the Selected Relevant Government Reimbursed Products, and a summary of the FDA-approved uses for such products;
 - ii. for each product in SUN's Specialty Dermatology Business Unit t which was promoted during the Reporting Period and for each Selected Government Reimbursed Product: i) a description of the criteria used by SUN in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans; ii) a description of all instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are

inconsistent with SUN's criteria relating to the call plan and/or SUN's policies and procedures; and iv) a description of all instances in which it appears that SUN failed to follow its criteria or policies and procedures relating to call plans;

- iii. the findings and supporting rationale regarding any weaknesses in SUN's systems, processes, policies, procedures, and practices relating to call plans, if any; and
- iv. recommendations, if any, for changes in SUN's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to call plans.

b. Relating to the Physician Payment Listing Reviews

- i. a description of the entries on the Open Payments Data website for each selected Covered Recipient and a description of the Control Documents reviewed in connection with each selected Covered Recipient;
- ii. for each selected Covered Recipient, findings and supporting rationale as to whether: (a) all required Control Documents exist; (b) each Control Document was completed in accordance with all of the requirements set forth in the applicable SUN policy; (c) the aggregate value of the Payment(s) as reflected in the report to CMS for the sampled Covered Recipient is consistent with the value of the Payment(s) reflected in the Control Documents; (d) each Control Document reflects that SUN's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (e) disciplinary action was undertaken in those instances in which SUN's policies were not followed;

- iii. for each selected Covered Recipient 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 selection of the Covered Recipient, including a description of the circumstances requiring corrective action and the nature of the corrective action; and
 - iv. if any Material Errors are discovered, 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.
- d. Relating to the Review of Additional Items
- i. for each Additional Item reviewed, a description of the review conducted;
 - ii. for each Additional Item reviewed, the IRO's findings based on its review;
 - iii. for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in SUN's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
 - iv. for each Additional Item reviewed, recommendations, if any, for changes in SUN's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.