CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
APOTEX CORP.

I. PREAMBLE

Apotex Corp. (Apotex) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Apotex is entering into a Settlement Agreement with the United States.

Apotex represents that, prior to the Effective Date (as defined below), Apotex established a compliance program that addresses all seven elements of an effective compliance program and is designed to address compliance with Federal health care program requirements (Compliance Program). Apotex further represents that its Compliance Program includes a Compliance Officer and compliance committee. It also includes a Code of Conduct, written policies and procedures, educational and training initiatives, a disclosure program, a risk management assessment system, and internal auditing procedures. Apotex shall continue the Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. Apotex may modify the Compliance Program as appropriate. However, at a minimum, Apotex 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 Apotex 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) Apotex's final Annual Report; or (2) any additional materials submitted by Apotex pursuant to OIG's request, whichever is later.

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

1. "Covered Persons" includes:

   a. all owners of Apotex 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 Apotex;

   b. all employees of Apotex; and

   c. all contractors, subcontractors, agents, and other persons who perform any of the Pricing and Contracting Functions on behalf of Apotex.

Notwithstanding the above, the term "Covered Persons" does not include: (1) employees of Apotex who work solely at its Indianapolis distribution facility; (2) employees of Apotex who perform only distribution or building and facilities functions (i.e., facilities maintenance, grounds maintenance, and food service functions); and (3) part-time or per diem employees, contractors, subcontractors, agents, or persons who are not reasonably expected to work more than 160 hours during a fiscal year, except that any such persons shall become Covered Persons at the point when they work more than 160 hours during the fiscal year.

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

3. The term "Pricing and Contracting Functions" includes: (a) the setting or establishing of prices (including changes in prices) for Government Reimbursed Products, including but not limited to suggested wholesale prices (SWP), wholesale acquisition costs (WAC), average wholesale price (AWP) and actual prices at which products are sold or offered for sale to customers in the United States, and including all activities, systems, processes, and procedures relating to market research and other pricing-related research and analysis, the development of pricing strategies and policies, and the approval processes and systems relating to the offering and negotiation of pricing terms with customers; and (b) the offering or selling of Government Reimbursed Products to any potential or current customer, including but not limited to all activities, systems, processes, and procedures relating to offering, bidding, negotiating, and contracting with customers or potential customers.

4. The term "Apotex Affiliate" shall mean any entity, including Apotex, that is owned or controlled, directly or indirectly, by Aposherm Delaware Holdings Corp. and whose employees or contractors perform any Pricing and Contracting Functions. All obligations set forth in Section III below shall apply to the Pricing and Contracting Functions performed by any Apotex Affiliate and all references to "Apotex" in the defined terms set forth in this Section II shall mean Apotex and any Apotex Affiliate. In addition, the notice requirements in Section IV and the certification obligations set forth in Section V.C. below shall apply to both Apotex and any Apotex Affiliate.

III. CORPORATE INTEGRITY OBLIGATIONS

Apotex 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, Apotex shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee of Apotex or Apotex,

Inc. (a sister entity to Apotex Corp.) and a member of senior management of Apotex; shall report directly to the Chief Executive Officer of Apotex; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Apotex. 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 requirements;

b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Apotex and the Compliance Officer shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request; and

c. monitoring the day-to-day compliance activities engaged in by Apotex and 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.

Apotex 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, Apotex shall appoint a U.S. 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, regulatory affairs, human resources, finance, and commercial operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Apotex'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.

Apotex 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 of Directors Compliance Obligations*. The Board of Directors (or a committee of the Board) of Apotex (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include an independent (i.e., non-executive) member.

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

a. meeting at least quarterly to review and oversee Apotex'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 Apotex's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

> "The Board of Directors has made a reasonable inquiry into the operations of Apotex'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, Apotex has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."

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 Apotex.

Apotex 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 Apotex employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Apotex division or business unit is in compliance with applicable Federal health care program requirements and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: VP, Sales and Marketing; VP, Commercial Finance, US; VP, Sales; VP, 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 or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Apotex policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department or functional area] of Apotex is in compliance with all applicable Federal health care program 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, Apotex 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.

Within 90 days after the Effective Date, Apotex 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 Apotex's compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this CIA, Apotex shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element in 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 Pricing and Contracting Functions in compliance with all applicable Federal health care program requirements, including but not limited to, the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)), the False Claims Act (codified at 31 U.S.C. §§ 3729-3733), and the Civil Monetary Penalties Law (codified at 42 U.S.C. § 1320a-7a);

b. appropriate interactions with customers and potential customers and with competitors in accordance with all applicable legal requirements and Apotex's policies and procedures; and

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

At least annually (and more frequently, if appropriate), Apotex 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.

C. Training and Education.

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

2. *Board Member Training*. In addition to the training described in Section III.C.1, within 90 days after the Effective Date, each member of the Board of Directors 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 of Directors shall receive the Board Member Training described above within 30 days after becoming a Board member or within 90 days after the Effective Date, whichever is later.

3. *Training Records*. Apotex shall make available to OIG, upon request, training materials and records verifying that Covered Persons and Board members have timely received the training required under this section.

D. Risk Assessment and Mitigation Process.

Within 90 days after the Effective Date, Apotex shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Apotex's Government Reimbursed Products and with applicable Federal health care program requirements (including the requirements of the Federal Anti-Kickback Statute). The risk assessment and internal review process shall require compliance, legal, and department leaders, at least annually, to: (1) identify and prioritize risks associated with Government Reimbursed Products, including risks associated with the Pricing and Contracting Functions, (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. Apotex 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, Apotex shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews referenced 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 Apotex shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports

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

c. *Access to Records and Personnel.* Apotex shall ensure that 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 two components: Systems Review and Transactions Review. The Systems Review shall assess Apotex's systems, processes, policies, and procedures relating to the Pricing and Contracting Functions. If there are no material changes in Apotex's relevant systems, processes, policies, and procedures, the Systems Review shall be performed for the first and fourth Reporting Periods. If Apotex materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendix B.

The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review.

As set forth more fully in Appendix B, the Transactions Review shall include several components. In addition to the items specifically identified in Appendix B, each Transactions Review shall also include a review of up to three additional areas or practices of Apotex identified by OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, OIG will consult with Apotex and may consider internal audit and monitoring work conducted by Apotex, the Government Reimbursed Product portfolio, and other information known to it.

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 A and Appendix B.

4. *Independence and Objectivity Certification*. The IRO shall include in its report(s) to Apotex 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. The IRO's certification shall include a summary of current and prior engagements between Apotex and the IRO.

F. Disclosure Program.

Within 90 days after the Effective Date, Apotex shall establish a Disclosure Program that includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Apotex's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Apotex shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Apotex's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by Apotex. 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, Apotex 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 each disclosure 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 status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

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 any Federal health care program; 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.* Apotex shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Apotex 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. Apotex shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on an annual basis thereafter.

c. Apotex shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

3. *Removal Requirement*. If Apotex has actual notice that a Covered Person has become an Ineligible Person, Apotex shall remove such Covered Person from responsibility for, or involvement with, Apotex'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 Apotex 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, Apotex shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect Apotex's compliance with its obligations under the CIA.

H. Incentive Compensation Restriction and Executive Financial Forfeiture and Recoupment Programs

1. *Incentive Compensation Restriction Program.* Apotex agrees to develop and maintain throughout the term of the CIA policies and procedures that shall: (1) be designed to ensure that financial incentives do not improperly motivate employees to engage in improper sales, marketing, pricing, or contracting for Apotex's products or other improper conduct; and (2) include mechanisms, where appropriate, to exclude from incentive compensation any such employees who have engaged in improper sales, marketing, pricing, or contracting activities or other improper conduct (Incentive Compensation Program). The specific terms and conditions of the Incentive Compensation Program are described in Appendix C to this CIA.

2. *Executive Financial Forfeiture and Recoupment Program.* Apotex agrees to establish and maintain throughout the term of this CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to three years of annual performance pay for certain executives who are discovered to have been involved in any significant misconduct (Executive Financial Forfeiture and Recoupment Program). The specific terms and conditions of the Executive Financial Forfeiture and Recoupment Program are described in Appendix C to this CIA.

I. Notification of Government Investigation or Legal Proceeding.

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

J. 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. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

c. the filing of a bankruptcy petition by Apotex.

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

2. *Reporting of Reportable Events*. If Apotex determines (after a reasonable opportunity to conduct an appropriate review or investigation of the

allegations) through any means that there is a Reportable Event, Apotex shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.J.1.a*. For Reportable Events under Section III.J.1.a, 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; and

d. a description of Apotex's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.J.1.b.* For Reportable Events under Section III.J.1.b, 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 Apotex completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the

Ineligible Persons 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.J.1.c*. For Reportable Events under Section III.J.1.c, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

K. Internal Monitoring and Review Efforts.

Within 90 days after the Effective Date, Apotex shall establish a Monitoring and Auditing Plan to evaluate and monitor the following types of activities: (1) adherence to Apotex's policies relating to certain Pricing and Contracting Functions (Contract Monitoring); and (2) the interactions of Covered Persons who engage in Pricing and Contracting Functions with competitors (Records Review).

1. *Contract Monitoring.*

a. Apotex shall establish Policies and Procedures applicable to pricing and contracting with customers or potential customers of Government Reimbursed Products that are designed to ensure that pricing and contracting decisions are made in compliance with all applicable Federal health care program requirements, including but not limited to the Anti-Kickback Statute. The Policies and Procedures shall require the establishment and implementation of a written review and approval process for contracts with customers for the purchase of Government Reimbursed Products that includes a business review and a legal review and that specifies the documentation required in support of activities relating to Pricing and Contracting Functions.

b. Apotex shall maintain the following records relating to its Pricing and Contracting Functions in one or more centralized

electronic repositories: documentation of decision-making and required approvals relating to list and contract price increases, records relating to all bids submitted to potential customers of Government Reimbursed Products and a comprehensive list of all contracts entered into with customers of Government Reimbursed Products.

c. Apotex shall institute an internal review process under which Apotex compliance or other appropriately trained Apotex personnel who are independent from the functional area being monitored (Monitoring Personnel) shall review four contracts per Reporting Period (Contract Audits). The contracts shall be selected using either a risk-based targeting approach or a random sampling approach. For each contract reviewed, Monitoring Personnel shall review the documentation contained in the central repositories (including documentation relating to decision-making and approvals) and other available records, as needed, to assess whether pricing decisions and approvals relating to the contracts were made in a manner consistent with Apotex's Policies and Procedures.

Apotex shall maintain the controls around pricing and contract negotiations as described above and shall conduct its Contract Audits as described above throughout the term of the CIA.

2. *Records Reviews*. The Records Review component of the Monitoring and Auditing Plan shall be designed to monitor and assess the appropriateness of interactions between Covered Persons who engage in Pricing and Contracting Functions with competitors and to identify potential improper conduct. For purposes of the Records Reviews, all companies that manufacture and sell generic pharmaceutical products shall be considered "competitors." Among other things, Apotex's Monitoring and Auditing Plan includes a review of whether Covered Persons who attend industry events receive antitrust training and a reminder about Apotex's Policies and Procedures prior to their attendance at such events.

a. For each Reporting Period, Apotex shall develop and implement a plan for conducting Records Reviews associated with at least three Covered Persons who are engaged in

establishing or changing the actual prices at which Government Reimbursed Products are sold or offered for sale or who communicate or negotiate with customers or potential customers about actual prices, bids, or offers for Government Reimbursed Products (Reviewed Covered Persons). Monitoring Personnel shall conduct the Records Review described below. The Reviewed Covered Persons shall be selected using either a risk-based targeting approach or a random sampling approach;

b. For each Reviewed Covered Person, the Records Reviews shall include an interview of the Reviewed Covered Person and a review of:

(i) all Apotex records relating to interactions or communications between the Reviewed Covered Person and any competitor, including but not limited to all e-mails and other electronic records of the Reviewed Covered Person;

(ii) all training records of the Reviewed Covered Person; and

(iii) all performance review records and any disciplinary records for the Reviewed Covered Person.

c. Based on the review of the records listed above and the interview, Monitoring Personnel shall prepare a report which includes:

(i) the identity of the Reviewed Covered Person;

(ii) the identity of the Monitoring Personnel;

(iii) an overall assessment of the Reviewed Covered Person's compliance with Apotex Policies and Procedures; and

(iv) the identification of any potential improper conduct by the Reviewed Covered Person.

3. *Reporting and Follow-up*. Results from the Monitoring and Auditing Plan shall be compiled and reported to the Compliance Officer for review and remediation as appropriate. Potential violations of Federal health care program 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 noncompliance with Apotex's Policies and Procedures or legal or compliance requirements, is identified during any portion of the Monitoring and Auditing Plan, Apotex 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.J above, as applicable. Any compliance issues identified during the Monitoring and Auditing Plan and any corrective action shall be recorded in the files of the Compliance Officer.

L. Reporting of Price-Related Information.

1. *Definition of Price-Related Information*. For purposes of this CIA, "Price-Related Information" includes the following:

a. a summary of Apotex's internal decisions and the decision-making process relating to any increase in the: (i) list prices (including but not limited to SWP, WAC, AWP) for Apotex's top ten Government Reimbursed Products[1] and (ii) contract prices at which Apotex's top ten Government Reimbursed Products were sold or offered to customers, that occurred during the prior fiscal quarter. The underlying records reflecting Apotex's internal decisions and the decision-making process (e.g., minutes from pricing committee

1 For each Reporting Period, Apotex shall identify the ten unique product families (by active pharmaceutical ingredient) that generated the largest amounts of sales revenue in the fiscal year preceding the applicable Reporting Period. For each of these ten product families, Apotex shall identify the product (by 11-digit National Drug Code (NDC)) that generated the largest amount of sales revenue in the prior fiscal year. Provided that each such identified drug is a Government Reimbursed Product, the group of such drugs (by 11-digit NDC) that generated the greatest revenue amounts shall be referred to as the "top ten Government Reimbursed Products" for purposes of Sections III.L.1.a-e of the CIA and Appendix B.

meetings, emails, memos, presentations, slide decks, internal reports, and other documentation of projected and actual gross revenue and revenue net of rebates, discounts, chargebacks, and returns for each such Government Reimbursed Product) shall be made available to OIG upon request;

b. documentation of all list prices (*e.g.*, SWP, WAC, AWP) and list price increases during the prior fiscal quarter for each of Apotex's top ten Government Reimbursed Products, as determined pursuant to Section III.L.1.a.n.1 for the Reporting Period. The documentation shall include the names of the Government Reimbursed Products and 11-digit NDC associated with each of the Government Reimbursed Products;

c. documentation of the average net price per unit (e.g., "dead net" prices) at which each of Apotex's top ten Government Reimbursed Products were sold to all customers in the prior fiscal quarter, arranged by name and NDC(s) of each product;

d. pricing trend reports for each of the top ten Government Reimbursed Products, arranged by NDC, which compare the list price and average net price per unit for each product for each quarter beginning 24 months before the date of the pricing trend report through the current fiscal quarter;

e. the initial launch list (i.e., WAC) price and the date of launch for each of the top ten Government Reimbursed Products; and

f. if Apotex is required, pursuant to any state or federal law, to submit to any government agency, or otherwise make public, information about prices or any increase in the price of any of Government Reimbursed Products (including any justification for any price increases), Apotex shall provide to OIG a list of such reports submitted or made public by Apotex. The list shall include the following information: (a) the nature of, and relevant time period for, the pricing or price increase

information, (b) the applicable law under which Apotex was required to submit or make public the information, and (c) the government agency to which and/or the means by which the information was submitted or made public. Copies of the reports shall be made available to OIG upon request.

2. *Reporting of Price-Related Information*. Apotex shall report to OIG each component of the Price-Related Information identified above in Section III.L.1 on a quarterly basis. The first report shall be submitted within 90 days after the end of the first full fiscal quarter following the Effective Date of the CIA. Subsequent reports shall be submitted 45 days after the end of each subsequent fiscal quarter.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Apotex 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 Pricing and Contracting Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any 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. Apotex 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, Apotex 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, Apotex 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, Apotex shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.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 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 written copy of the process to be followed by Certifying Employees in connection with completing the required certifications;

5. a list of the Policies and Procedures required by Section III.B;

6. the Training Plan required by Section III.C.1 and a description of the Board of Directors 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);

7. a description of the risk assessment and internal review process required by Section III.D;

8. 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; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Apotex;

9. a description of the Disclosure Program required by Section III.F;

10. a description of the Ineligible Persons screening and removal process required by Section III.G.;

11. a list of all of Apotex's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers, and the location's Medicare and state Medicaid program provider and/or supplier numbers (if any);

12. a description of Apotex's corporate structure, including identification of any U.S.-based parent and sister companies, subsidiaries, and their respective lines of business; and

13. the certifications required by Section V.C.

B. Annual Reports.

Apotex shall submit to OIG a written report 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. (a) any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; (b) a current list of the Compliance Committee members; (c) a current list of the Board members who are responsible for satisfying the Board of Directors compliance obligations; (d) a current list of the Certifying Employees, along with any changes made during the Reporting Period to the Compliance Committee, Board of Directors, and Certifying Employees; and (e) a description of any changes to the process to be followed by Certifying Employees including the reasons for the changes;

2. 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);

3. 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;

4. a list of any new or revised Policies and Procedures developed during the Reporting Period under Section III.B;

5. a description of any changes to Apotex's Training Plan developed pursuant to Section III.C and a summary of any Board of Directors training provided during the Reporting Period;

6. a description of any changes to the risk assessment and internal review process required by Section III.D, including the reasons for such changes;

7. 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;

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

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

10. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs 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;

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

12. a description of the Incentive Compensation Restriction and Executive Financial Forfeiture and Recoupment Programs required by Section III.H, including any changes to the programs during the Reporting Period, the reasons for any changes, and the annual reports to OIG required under Section E of Appendix C;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. The summary shall include a

description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

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

15. a description of the Internal Monitoring Program and the results of the Monitoring and Auditing Plan required by Section III.K, including a description of any instances in which it was determined that Apotex failed to follow its Policies and Procedures with regard to pricing decisions and approvals relating to the Reviewed Contracts or any Reviewed Covered Persons engaged in improper conduct and a description of the action (s) that Apotex took as a result of such determinations;

16. a listing of the dates on which the Price-Related Information described in Section III.L was submitted to OIG, and a summary of any information reported to OIG in accordance with Section III.L.1.f (relating to prices, price increases, or justifications for price increases) during the Reporting Period;

17. an aggregate pricing trend report reflecting prices for the top ten Government Reimbursed Products offered for sale by Apotex during the Reporting Period. More specifically, the aggregate trend report shall be arranged by product name and it shall include NDC information and shall compare the average list prices and average net prices per unit at which each of the products was offered or sold in the current Reporting Period with the list and average net prices per unit at which each of the products was offered or sold in the prior Reporting Period;

18. a description of all changes to the most recently provided list of Apotex's locations as required by Section V.A.11;

19. a description of any changes to Apotex's corporate structure, including any U.S.-based parent and sister companies, subsidiaries, and their respective lines of business; and

20. the certifications required by Section V.C.

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

C. Certifications.

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

2. *Compliance Officer and 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, Apotex is in compliance with all of the 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;

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

d. to the best of his or her knowledge, Apotex has implemented procedures reasonably designed to ensure that contracts entered into with customers relating to the purchase of Government Reimbursed Products are in compliance with all applicable Federal health care program requirements and Apotex Policies and Procedures.

D. Designation of Information.

Apotex 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. Apotex 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

Apotex:

Elizabeth Gill
Compliance Officer
Apotex Corp.
2400 North Commerce Parkway, Suite 400
Weston FL 33326
Telephone: 416.401.7938
Email: egill@apotex.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, Apotex may be required to provide OIG with an additional copy of each notification or report required by this CIA in the 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 Apotex's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Apotex's locations for the purpose of

verifying and evaluating: (a) Apotex's compliance with the terms of this CIA and (b) Apotex's compliance with the requirements of Federal health care programs. The documentation described above shall be made available by Apotex 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 Apotex'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. Apotex shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Apotex's owners, employees, contractors and directors may elect to be interviewed with or without a representative of Apotex present.

VIII. DOCUMENT AND RECORD RETENTION

Apotex 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 Apotex prior to any release by OIG of information submitted by Apotex pursuant to its obligations under this CIA and identified upon submission by Apotex as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Apotex shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

Apotex 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, Apotex and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Apotex 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 of Directors compliance obligations;

d. the management certification obligations;

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. Incentive Compensation Restriction and Executive Financial Forfeiture and Recoupment Programs;

k. notification of Government investigations or legal proceedings;

l. reporting of Reportable Events;

m. the Monitoring and Auditing Plan; and

n. reporting of Price-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 Apotex fails to engage and use an IRO as required by Section III.E, Appendix A, or Appendix B.

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

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Apotex fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

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

6. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of Apotex 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 Apotex fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.E, and for each day Apotex fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix A.

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

2. *Response to Demand Letter.* Within 10 business days after the receipt of the Demand Letter, Apotex 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 Apotex elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Apotex 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 Apotex 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 Apotex to report a Reportable Event and take corrective action as required in Section III.J;

c. a failure to engage and use an IRO in accordance with Section III.E, Appendix A, or Appendix B; 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 Apotex constitutes an independent basis for Apotex'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 Apotex has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Apotex of: (a) Apotex's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure*. Apotex shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate 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) Apotex has begun to take action to cure the material breach; (ii) Apotex is pursuing such action with due diligence; and (iii) Apotex has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, Apotex fails to satisfy the requirements of Section X.D.3, OIG may exclude Apotex from participation in the Federal health care programs. OIG shall notify Apotex in writing of its determination to exclude Apotex. (This letter shall be referred to 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 Apotex'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, Apotex 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 Apotex 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, Apotex 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 Apotex was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Apotex 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 Apotex to pay Stipulated Penalties, such Stipulated Penalties shall

become due and payable 20 days after the ALJ issues such a decision unless Apotex 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 Apotex was in material breach of this CIA and, if so, whether:

a. Apotex 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 Apotex's receipt of the Notice of Material Breach: (i) Apotex had begun to take action to cure the material breach within that period; (ii) Apotex pursued such action with due diligence; and (iii) Apotex 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 Apotex, only after a DAB decision in favor of OIG. Apotex's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Apotex 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 Apotex 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. Apotex 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 Apotex, Apotex 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

Apotex 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) Apotex's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

D. The undersigned Apotex 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 capacities 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 copies of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF APOTEX CORP.

___/Peter Hardwick/_____ ___September 27, 2021_____
PETER HARDWICK DATE
President and CEO
Apotex Corp.

___/Steven Cherry/_____ ___09/27/2021_____
STEVEN F. CHERRY DATE
Counsel for Apotex Corp.

___/James W. Matthews/_____ __September 27, 2021_____
JAMES W. MATTHEWS DATE
Counsel for Apotex Corp.

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

____/Lisa M. Re/_____ ___September 29, 2021___
LISA M. RE DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

____/Mary E. Riordan/_____ ____September 30, 2021__
MARY E. RIORDAN DATE
MADELINE BAINER
Senior Counsel
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

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. Apotex 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 Apotex in response to a request by OIG, whichever is later, OIG will notify Apotex if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Apotex may continue to engage the IRO.

2. If Apotex 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, Apotex 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 Apotex at the request of OIG, whichever is later, OIG will notify Apotex if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Apotex 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 Pricing and Contracting Functions;

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 inquires 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. Apotex Responsibilities

Apotex 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. Apotex *and IRO*. If Apotex terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Apotex 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. Apotex 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 Apotex in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Apotex 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 Apotex regarding the IRO, OIG determines that the IRO has not met the requirements of

this Appendix, OIG shall notify Apotex in writing that Apotex shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Apotex 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 Apotex to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

INDEPENDENT REVIEW ORGANIZATION REVIEWS

I. Pricing and Contracting Functions Review, General Description

As specified more fully below, Apotex shall retain one or more Independent Review Organizations (IROs) to perform reviews (IRO Reviews) to assist Apotex in assessing and evaluating certain systems, processes, policies, procedures, and practices. The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Apotex 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 Apotex relating to the reviewed Policies and Procedures described below, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Apotex materially changes applicable systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Systems 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. IRO Systems Review

The IRO Systems Review shall be a review of systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) of Apotex relating to Pricing and Contracting Functions and other systems as described below. Where practical, Apotex 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 Apotex in accordance with the preceding sentence.

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

1. Apotex's systems (including any electronic systems), processes, policies, and procedures relating to Pricing and Contracting Functions. This review shall include an assessment of the following:

a. Apotex's organizational structure as it relates to Pricing and Contracting Functions, including:

i. The identification of those individuals, departments, or groups within Apotex responsible for conducting market (and other) research relevant to setting prices and establishing pricing strategies and policies for Government Reimbursed Products, including the individuals, departments, or groups authorized to approve pricing terms and pricing strategies; and

ii. The identification of those individuals, departments, or groups within Apotex responsible for bidding, negotiating, and contracting with customers or potential customers of Government Reimbursed Products, including the individuals, departments, or groups authorized to approve bids submitted to potential customers and contracts (including contract terms and changes in contract terms, including pricing terms) entered with customers;

b. the systems, processes, policies, and procedures that Apotex uses or follows in connection with setting prices (including but not limited to suggested wholesale price (SWP), wholesale acquisition cost (WAC), and average wholesale price (AWP)) and establishing pricing strategies, including i) the information and factors to be considered in connection with setting prices and establishing pricing strategies; and ii) the types and sources of information (both internal and external) used to make decisions about prices and pricing strategies; and

c. the systems, processes, policies, and procedures that Apotex uses or follows in connection with the offering or selling of

Government Reimbursed Products to any potential customer or current customer, including offering, bidding, negotiating, and contracting for the sale of Government Reimbursed Products and the manner and circumstances under which such activities occur.

2. systems, processes, policies and procedures relating to Apotex's review of records relating to interactions between Covered Persons who engage in Pricing and Contracting Functions and competitors including:

a. record-keeping systems relating to records reflecting interactions or communications between Reviewed Covered Persons (as defined in Section III.K of the CIA) and competitors;

b. Apotex's reviews of records relating to interactions and communications between Reviewed Covered Persons and competitors; and

c. records relating to performance review records and any disciplinary records for Reviewed Covered Persons.

3. Apotex's systems, policies, processes, and procedures applicable to the development and review of Apotex processes relating to incentive compensation for Covered Persons engaged in Pricing and Contracting Functions 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 improper sales, marketing, pricing, or contracting activities or other improper conduct relating to Government Reimbursed Products. To the extent that Apotex establishes different methods of compensation for different Government Reimbursed Products or different compensation arrangements based on the type of Pricing and Contracting Function in which the Covered Person engages, the IRO shall review each type of compensation arrangement separately; and

4. Apotex's systems, processes, policies, and procedures relating to its risk assessment and internal review process outlined in Section III.D of the CIA. This review shall assess whether the risk assessment and internal review process identifies and addresses relevant and appropriate risks associated with Government Reimbursed Products, including risks associated with the sales, pricing, and contracting activities relating to such products.

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 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 Apotex;

4. a detailed description of the incentive compensation system for Covered Persons engaged in Pricing and Contracting Functions, including a description of the bases upon which compensation is determined. To the extent that Apotex may establish compensation differently for individual products or based on the type of Pricing and Contracting Function in which the Covered Person engages, the IRO shall report separately on each such type of compensation arrangement;

5. findings relating to whether the risk assessment and internal review processes identify and address relevant and appropriate risks for each Government Reimbursed Product;

6. findings relating to whether the risk assessment and internal review processes result in the implementation of appropriate corrective action plans and appropriate tracking and monitoring of such corrective action plans;

7. findings and supporting rationale regarding any weaknesses in the systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures identified in Section II.A above, if any; and

8. recommendations to improve any of the systems, policies, processes, or procedures relating to any of the Reviewed Policies and Procedures identified in Section II.A above, if any.

III. Transactions Review

As described more fully below, the Transactions Review shall include: (1) a review of benchmark prices (including SWP, AWP, and WAC) for a sample of Government Reimbursed Products; and (2) a review of up to three additional items identified by the OIG in accordance with Section III.E.2 of the CIA (hereafter "Additional Items"). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. IRO Review of Prices for Selected Products.

1. *Selection of Sample*. For the first Reporting Period, the IRO shall review SWP, AWP, WAC, and other benchmark prices set by Apotex for Apotex's top ten Government Reimbursed Products (as defined in Section III.L of the CIA) (Price Review). For the second and subsequent Reporting Periods, the IRO shall review Apotex's top ten Government Reimbursed Products and up to two additional Government Reimbursed Products selected by OIG. The products selected for review shall be referred to as the "Selected Products."

For the second and subsequent Reporting Periods, at least 30 days prior to the end of the applicable Reporting Period, Apotex shall provide OIG with a list of the Government Reimbursed Products sold by Apotex during the Reporting Period and shall identify the top ten Government Reimbursed Products and any Government Reimbursed Products launched to date during the Reporting Period. OIG shall have 15 days to notify Apotex or its IRO regarding whether and which two additional Government Reimbursed Products shall be reviewed along with the top ten Government Reimbursed Products for the applicable Reporting Period.

2. *Materials and Information to be Reviewed:* For purposes of conducting its Price Review, the IRO shall have access to all records and personnel necessary to complete the review described below. This shall include access to internal Apotex documents and information relating to: i) the Selected Product, ii) benchmark prices established for the Selected Product; iii) benchmark pricing decisions for the Selected Product; and iv) prices for the Selected Product reported to the Center for Medicare and Medicaid Services (CMS) for purposes of the Medicaid drug rebate program and the Medicare program, including but not limited to Average Manufacturer Price (AMP), Best Price (if applicable), Average Sales Price (ASP) and Wholesale Acquisition Cost (WAC). In addition, the IRO shall review information available from Apotex and publicly available information relevant to the market for the Selected Product (including information about the number and identity of entities selling products that

compete with the Selected Product, available information about the prices at which such competing products are sold, and information about the Consumer Price Index for All Urban Customers (CPI-U)).

3. *Scope of Review for Selected Products*. For each Selected Product reviewed the IRO shall:

a. identify the SWP, AWP, WAC, and any other benchmark prices established for the Selected Product during the Reporting Period;

b. identify the SWP, AWP, WAC, and any other benchmark prices established for the Selected Product during the prior three Reporting Periods;

c. if the SWP, AWP, WAC, or any other benchmark prices for the Selected Product increased or did not decrease over the time period reviewed, the IRO shall identify Apotex's reasons and rationale for the price increases or price levels;

d. identify the AMP, ASP, and, if applicable, Best Price and WAC reported to CMS for the Selected Product during the current Reporting Period and each of the three prior Reporting Periods;

e. identify the applicable CPI-U during the current and each of the three prior Reporting Periods;

f. identify all third-party entities that sell products that competed with the Selected Product in the current Reporting Period;

g. identify all third-party entities that sold products that competed with the Selected Product during each of the three prior Reporting Periods and identify the time period during which each such entity sold a competing product;

h. for each Selected Product, the IRO shall evaluate whether the SWP, AWP, WAC and other benchmark prices were established in a manner consistent with Apotex's Policies and

Procedures relating to Pricing and Contracting Functions, including whether all required approvals were obtained, whether the decision-making process was consistent with Apotex's Policies and Procedures, and whether all required documentation pertaining to pricing decisions (including price increases) was retained.

B. IRO Review of Additional Items.

As set forth in Section III.E.2 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 Apotex 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 Apotex shall submit an audit work plan to the OIG for review and, absent any objection from the OIG, the IRO shall conduct the review of the Additional Items based on the work plan. 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 Apotex's systems, processes, policies, and procedures based on its review of each Additional Item).

2. Apotex may propose to the OIG that its internal audit(s) and/or review(s) conducted as part of the Monitoring and Auditing Plan described in Section III.K of the CIA and/or other reviews conducted by both internal and outside entities at Apotex's request 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 Apotex's internal audit work or monitoring and/or other reviews conducted by outside entities 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 Apotex's planned monitoring activities and audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Apotex's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Apotex'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, Apotex shall engage the IRO to perform the Review as outlined in this Section III.B.

4. If the OIG agrees to permit certain of Apotex's monitoring, internal audit work, or other reviews for a given Reporting Period to be substituted for a portion of Additional Items review, such 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.

C. 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 Review of Prices for Selected Products. In connection with the review of Prices for Selected Products:

i. a description of each Selected Product reviewed, including the name of the product, a description of the product (including the approved indications for the product), the therapeutic class of the product, a description of when Apotex began to sell the product, and the identities of all entities that sell competing products;

ii. for each Selected Product, a description of the SWP, AWP, WAC and other benchmark prices in effect during the Reporting Period and description of SWP, AWP, WAC, and other benchmark prices over the prior three Reporting Periods, including an identification of changes in the applicable prices over time. The IRO shall identify actual benchmark price changes over time and shall also identify percentage changes in the benchmark prices over time;

iii. for each Selected Product, a comparison of the percentage change in the SWP, AWP, WAC, and other benchmark prices to the changes in the CPI-U during the current Reporting Period and for each of the prior three Reporting Periods;

iv. for each Selected Product, a comparison between the SWP, AWP, WAC, and other benchmark prices and the AMP, ASP, and, if applicable, Best Price and/or WAC reported to CMS for the product during the Reporting Period and for each of the three prior Reporting Periods;

v. the IRO's findings and supporting rationale as to the following:

a. whether the SWP, AWP, WAC, and other benchmark prices for the Selected Product increased over time;

b. if the SWP, AWP, WAC, and other benchmark prices for the Selected Product increased or did not decrease over time, the IRO's findings about Apotex's rationale for the prices;

c. if the SWP, AWP, WAC, and other benchmark prices for the Selected Product increased or did not decrease over time, the IRO's findings relating to any changes in the market conditions

for the applicable product (e.g., changes in the number of competitors for the product, supply chain disruptions);

d. if the SWP, AWP, WAC, and other benchmark prices for the Selected Product increased or did not decrease over time, whether Apotex's rationale for such prices were consistent with changes in market conditions and other relevant factors;

e. whether the SWP, AWP, WAC and other benchmark prices were established in a manner consistent with Apotex's Policies and Procedures relating to Pricing and Contracting Functions, including whether all required approvals were obtained, whether the decision-making process was consistent with Apotex's Policies and Procedures, and whether all required documentation pertaining to pricing decisions (including price increases) was retained;

f. whether the IRO identified any weaknesses in Apotex's systems, processes, policies, procedures and/or practices relating to Pricing and Contracting Functions; and

g. whether the IRO has recommendations for improvements to Apotex's systems, processes, policies, procedures and/or practices relating to Pricing and Contracting Functions.

b. 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 Apotex'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 Apotex's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

Appendix C
Incentive Compensation Restriction and Executive Financial Forfeiture and Recoupment Program

Within 120 days after the Effective Date of the CIA, Apotex shall establish and maintain throughout the term of the CIA two programs relating to compensation. The first shall be an Incentive Compensation Restriction Program as described below in Section A. The second shall be an Executive Financial Forfeiture and Recoupment Program as described below in Section B.

(A) Incentive Compensation Restriction Program

Within 120 days after the Effective Date, Apotex shall develop and maintain throughout the term of the CIA an Incentive Compensation Restriction Program (Incentive Compensation Program), applicable to all employees other than Covered Executives, who are addressed below in Section (B). Apotex's Incentive Compensation Policy (Policy), in connection with its Incentive Compensation Program, shall outline the criteria that Apotex employees must satisfy as a prerequisite to earning incentive compensation. To be eligible for any form of incentive, they generally must adhere to and comply with all applicable laws and with Apotex's rules and policies (including any Code of Conduct, other compliance requirements, and other applicable Apotex policies, procedures, and guidelines). Among other things, incentive compensation shall be designed so that financial incentives do not inappropriately incentivize employees to engage in or tolerate improper conduct in connection with sales, pricing, or contracting for Apotex products. Under the Policy, employees may not be eligible or may have limited eligibility for incentive compensation where they have been found to have committed, directed, or tolerated violations of company rules and policies, or have not completed compliance training. At Apotex's discretion, incentive grants to the individual may be suspended for the current period and an employee may be ineligible to receive all or a portion of future incentive payments for a one-year period. In addition, if Apotex determines that an employee engaged in Significant Misconduct (i.e., a violation of law or regulation or a significant violation of Apotex's Corporate Compliance Program), incentive grants to the individual must be suspended for the current period and must be rescinded for any prior period in which such violations occurred or were discovered. To the extent such an incentive grant was already paid, the employee must promptly repay any incentive already received or the company shall recoup it in accordance with the Policy.

(B) Executive Financial Forfeiture and Recoupment Program

Within 120 days after the Effective Date of the CIA, Apotex shall establish a financial forfeiture and recoupment program applicable to all individuals at the Vice President level or higher who are involved in Pricing and Contracting Functions (as that

term is defined in the CIA) and their superiors (collectively, "Covered Executives") that puts at risk of forfeiture and recoupment an amount equivalent to up to three years of annual performance pay from the Global Apotex Incentive Plan (GAIP), the Apotex Long Term Incentive Plan (LTIP), and any successor incentive plan for any Covered Executive who is the subject of an Affirmative Forfeiture/Recoupment Determination. This program shall be known as the Executive Financial Forfeiture and Recoupment Program. This recoupment program shall apply to employees who were Covered Executives at the time of the violation, including Covered Executives whose employment with Apotex has since been terminated for any reason between the time of the violation and the time of an Affirmative Forfeiture/Recoupment Determination.

Within 120 days after the Effective Date of the CIA, Apotex shall establish policies and procedures (and modify employment and other contracts as necessary) to provide that incentive awards, bonuses, and other similar awards (collectively "Cash Awards") for each Covered Executive is at risk of forfeiture in the event of Significant Misconduct (as defined above) that is discovered by Apotex before the bonus is paid. If Apotex discovers any Significant Misconduct that would implicate the forfeitures described in this Paragraph by a Covered Executive, it shall evaluate the situation in accordance with the process outlined below and make a determination about whether any forfeiture shall be implemented, and if so, the terms of such forfeiture.

Within 120 days after the Effective Date of the CIA, Apotex shall modify and supplement the GAIP and LTIP and any other incentive compensation plan applicable to Covered Executives (and any employment agreements, as appropriate) by imposing the eligibility and repayment conditions described below on future Cash Awards and making the additional remedies discussed below applicable to all Covered Executives. Apotex shall implement policies and procedures and, as necessary, shall modify contracts with Covered Executives so that, beginning no later than fiscal year 2023, Cash Awards may be recouped if an Affirmative Recoupment Determination is made. The forfeiture and recoupment rights described in this Section B shall apply prospectively to Covered Executives beginning no later than the fiscal year 2023 bonus plan year.

(i) Cash Award Eligibility and Repayment Conditions. Apotex shall implement an eligibility and repayment condition on Cash Awards that will allow Apotex, as a consequence of a Triggering Event, to pursue repayment from Covered Executives of all or any portion of Cash Awards paid to the individual in the three years prior to the Affirmative Recoupment Determination, if the Cash Awards were paid during or subsequent to the Triggering Event. These eligibility and repayment conditions shall be designed to survive the payment of the Covered Executive's Cash Award and the separation of the Covered Executive's employment for a period of three years from the payment of the Cash Award. If payment of any portion of a Cash Award is deferred on a mandatory or voluntary basis, the three-year period shall be measured

from the date the bonus would have been paid in the absence of deferral.

If an Affirmative Recoupment Determination is made, Apotex shall endeavor to collect repayment of any Cash Award from the Covered Executive through reasonable and appropriate means according to the terms of its Cash Award plan (or executive contract if applicable), and to the extent permitted by controlling law of the relevant jurisdiction. If necessary and appropriate to collect the repayment, Apotex shall file suit against the Covered Executive unless good cause exists not to do so. For purposes of the Executive Financial Forfeiture and Recoupment Program, good cause shall include, but not be limited to, a financial inability on the part of the Covered Executive to repay any recoupment amount, Apotex's assessment that the costs of collecting repayment under this section would exceed the amount of repayment likely to be collected, and/or Apotex's inability to bring such a suit under the controlling law of the relevant jurisdiction.

(ii) Additional Remedies.

To the extent permitted by controlling law, for the three years during which the Cash Award eligibility and repayment conditions exist, if Apotex reasonably anticipates that a Triggering Event has occurred, and Apotex has recoupment rights remaining under Paragraph B(i), Apotex shall have the right to notify the Covered Executive that those rights shall be tolled and thereby extended for an additional three years or until the Forfeiture/Recoupment Committee determines that a Triggering Event has not occurred, whichever is earlier, to the extent permitted by controlling law of the relevant jurisdiction.

If, after expiration of the time period specified in Paragraph B(i) above, the Forfeiture/Recoupment Committee determines that a Triggering Event has occurred, Apotex shall make a determination as to whether to pursue available remedies (e.g., filing suit against the Covered Executive) existing under statute or common law to the extent available.

(C) Definition of Triggering Events. The forfeiture and repayment conditions described above shall be triggered upon an Affirmative Forfeiture Determination or Affirmative Recoupment Determination that finds either of the following (each, a "Triggering Event"):

(i) Significant Misconduct relating to Pricing and Contracting Functions by the Covered Executive that, if discovered prior to payment, would have made the Covered Executive ineligible for a Cash Award in that plan year or subsequent plan years; or

(ii) Significant Misconduct relating to Pricing and Contracting

Functions by subordinate employees in the business unit for which the Covered Executive had responsibility that does not constitute an isolated occurrence and which the Covered Executive knew or should have known was occurring that, if discovered prior to payment, would have made the Covered Executive ineligible for a Cash Award in that plan year or subsequent plan years.

(D) Administration of Forfeiture/Recoupment Programs. Apotex shall engage in a standardized, formal process to determine whether a Triggering Event has occurred, and, if so, the extent of the Cash Awards that will be subject to forfeiture or repayment by the Covered Executive, and, where applicable, the most appropriate method for securing recoupment of relevant monies previously paid to a Covered Executive. The findings and conclusions resulting from this process shall be referred to as the "Forfeiture Determination" or "Recoupment Determination." A determination that Cash Award amounts shall be forfeited by or recouped from a Covered Executive shall be referred to as an "Affirmative Forfeiture Determination" or "Affirmative Recoupment Determination."

(i) Initiation. Apotex shall initiate the Forfeiture Determination process or Recoupment Determination process upon: (1) discovery of potential Significant Misconduct that may rise to the level of a Triggering Event, or (2) written notification by a United States federal government agency to Apotex's Compliance Officer of a situation that may rise to the level of a Triggering Event and either occurred in the United States or gives rise to liability relating to Federal health care programs. This written notification shall either identify the Covered Executive(s) potentially at issue or provide information (e.g., a description of the alleged Significant Misconduct and the applicable time period) to allow Apotex to identify the Covered Executive.

(ii) Forfeiture/Recoupment Committee. The Forfeiture/Recoupment Determination shall be made by a committee of senior executives representing the Compliance, Legal, Finance and Human Resources groups (Forfeiture/Recoupment Committee). The Forfeiture/Recoupment Committee may also include members of other functional areas or business groups, as it deems necessary. A Covered Executive shall not participate in the Forfeiture/Recoupment Committee while that individual is subject to a Forfeiture/Recoupment Determination. If a Forfeiture/Recoupment Determination involves an Executive Officer of Apotex, a Recoupment Determination for such individual shall be subject to approval by the Board of Directors (or appropriate committee thereof) of Apotex.

(iii) Forfeiture/Recoupment Determination Process. Apotex shall initiate the Forfeiture/Recoupment Determination process within 30 days after discovery by Apotex, or notification pursuant to Paragraph D(i)(2), of a potential Triggering Event.

As part of the Forfeiture/Recoupment Determination process, the Forfeiture/Recoupment Committee or appropriate Delegate (as defined below) shall: i) undertake an appropriate and substantive review or investigation of the facts and circumstances associated with the Triggering Event or any written notifications about potential Triggering Events received pursuant to Paragraph D(i)(2) above; ii) make written findings regarding the facts and circumstances associated with the Triggering Event and any written notifications about potential Triggering Events received pursuant to Paragraph D(i)(2) above; and iii) set forth in writing its determinations (and the rationale for such determinations) about: 1) whether a Triggering Event occurred; 2) the extent of Cash Awards (collectively "performance pay") that will be subject to forfeiture by and/or recoupment from the Covered Executive, if any; 3) the means that will be followed to implement the forfeiture and/or secure the recoupment of performance pay from the Covered Executive; and 4) the timetables under which Apotex will implement the forfeiture and/or attempt to recoup the performance pay.

For purposes of this Paragraph, a "Delegate" shall refer to the Apotex personnel to whom the Forfeiture/Recoupment Committee has delegated one or more of its required tasks in furtherance of the Executive Financial Forfeiture/Recoupment Program.

(E) Reporting. The Forfeiture/Recoupment Committee shall provide annual reports to the Board of Directors (or an appropriate committee thereof) of Apotex about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i)(2) above; ii) a description of any Forfeiture/Recoupment Determinations where a Triggering Event occurred during the preceding year (including information about any decision to require or not require forfeiture/recoupment from any Covered Executives, information about any decision to file or not file a recoupment action against a Covered Executive, the amount and type of any forfeiture/recoupment, the means for collecting any recoupment and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Affirmative Forfeiture/Recoupment Determinations that were not fully completed in prior years.

The Forfeiture/Recoupment Committee shall also provide annual reports to the OIG about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i)(2) above; ii) a summary description of any Forfeiture/Recoupment Determinations where a Triggering Event occurred during the preceding year (including any decision to require or not require forfeiture/recoupment from any Covered Executives, the amount and type of any forfeiture/recoupment, the method for collecting any recoupment, and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior

Affirmative Forfeiture/Recoupment Determinations that were not fully completed in prior years. Apotex shall provide OIG with additional information regarding any Forfeiture/Recoupment Determination where a Triggering Event has occurred upon OIG's request.

Apotex commits, to the extent permitted by controlling law, to maintaining all of the forfeiture and recoupment commitments set forth in Paragraphs B-E above for at least the duration of the CIA, absent agreement otherwise with the OIG.