CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
TAP PHARMACEUTICAL PRODUCTS INC.

I. PREAMBLE

TAP Pharmaceutical Products Inc. ("TAP") 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 by its officers, directors, employees, contract workers, and agents working at TAP's facilities 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"). All persons identified in the preceding sentence shall collectively be referred to as the "Covered Persons".[1] Contemporaneously with this CIA, TAP is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement. Contemporaneously with this CIA, TAP is also entering into settlement agreements with various States, and TAP's agreement to this CIA is a condition precedent to those agreements.

Prior to the effective date of this CIA, TAP initiated certain voluntary compliance measures, which as represented by TAP, include regular training to all Covered Persons concerning TAP's Code of Conduct and Operational Guidelines and include review and disciplinary procedures aimed, in part, at ensuring that TAP's activities are in compliance with all Federal health care program requirements and meeting TAP's goals of continuing to promote high ethical standards in the conduct of TAP's business practices. TAP agrees to continue the operation of its compliance measures in accordance with the terms set

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[1]Specifically excluded from the definition of "Covered Persons" are the marketing, sales or other personnel of entities with which TAP has agreements to co-promote its products. TAP shall, however, in good faith seek to obtain assurances that such personnel have received appropriate training on proper marketing and sales techniques. The term "Covered Persons" specifically includes all other personnel, apart from those acting under co-promotion agreements, who comprise TAP's contract sales force, if any.

forth below for the term of this CIA. TAP may modify its voluntary compliance measures as appropriate, but, at a minimum, TAP will ensure that during the term of this CIA, it shall comply with the integrity obligations enumerated in this CIA.

II. TERM OF THE CIA

The period of the compliance obligations assumed by TAP under this CIA shall be seven (7) years from the effective date of this CIA (unless otherwise specified). The effective date ("Effective Date") of this CIA shall be the date on which the final signatory of this CIA executes this CIA.

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final Annual Report submissions and any additional materials submitted by TAP pursuant to OIG's request, which review OIG agrees to complete without unreasonable delay.

III. CORPORATE INTEGRITY OBLIGATIONS

TAP hereby agrees to maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* TAP presently has a Compliance Officer and Compliance Committee with responsibility for administering TAP's Compliance Program. TAP shall continue to employ an individual to serve as its Compliance Officer during the term of this CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of TAP, shall make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of TAP, or its designated subcommittee, in such form or manner as the Board of Directors of TAP determines, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by TAP as well as for any reporting obligations created under this CIA.

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

2. *Compliance Committee.* TAP shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of each major department, including the heads of those departments responsible for sales, marketing, and human resources). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of TAP's risk areas and shall oversee monitoring of internal and external audits and investigations).

Any material changes in the composition of the Compliance Committee, or any material actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 15 days of such a change.

B. Written Standards.

1. *Code of Conduct.* To the extent not already accomplished, TAP shall revise and redistribute its Code of Business Conduct (hereafter "Code of Conduct") to all Covered Persons within 120 days of the Effective Date of this CIA. TAP shall revise its Code of Conduct to reflect the items specified below. TAP shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. TAP's commitment to full compliance with all Federal health care program requirements, including its commitment to report prices for and market and sell its pharmaceutical and other products for which the Federal health care programs provide reimbursement ("Government Reimbursed Products") in accordance with Federal health care program requirements;

b. TAP's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program

requirements and with TAP's own Policies and Procedures as implemented pursuant to section III.B.2. (including the requirements of this CIA);

c. the requirement that all of TAP's Covered Persons shall be expected to report to the Compliance Officer or other individual designated by TAP (such as district managers or other supervisory personnel) suspected violations of any Federal health care program requirements or of TAP's own Policies and Procedures;

d. the possible consequences to both TAP and Covered Persons of failure to comply with all Federal health care program requirements and with TAP's own Policies and Procedures or of failure to report such non-compliance; and

e. the right of all individuals to use the Disclosure Program described in section III.F., and TAP's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures made in accordance with the terms of the Disclosure Program.

On or before January 31, 2002, or within 120 days of the Effective Date of this CIA, whichever is later, each Covered Person who has not already done so within 180 days prior to the Effective Date of this CIA shall certify, in writing or electronically, that he or she has received, read, understood, and will abide by TAP's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or by January 31, 2002 or within 120 days of the Effective Date of this CIA, whichever is later.

TAP shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within 60 days of the distribution of such revisions.

2. *Policies and Procedures*. By January 31, 2002, TAP shall implement written Policies and Procedures regarding the operation of TAP's compliance program

and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in section III.B.1.;

b. the calculation and reporting of accurate prices for Government Reimbursed Products to certain entities, including the Centers for Medicare & Medicaid Services ("CMS"), the State Medicaid programs, and drug price reporting services on which government agencies rely (*e.g.*, First DataBank Inc., the Red Book, *etc.*);

c. the proper calculation and reporting of all data and information reported to CMS and/or the State Medicaid programs in connection with the Medicaid Drug Rebate program, codified at 42 U.S.C. § 1396r-8;

d. the proper uses and tracking of drug samples in accordance with all applicable requirements, including, but not limited to, the Prescription Drug Marketing Act, codified in 21 U.S.C. §§ 331, 333 and 353; and

e. measures designed to promote marketing and sales practices that conform with all statutes, regulations and requirements applicable to Government Reimbursed Products. The Policies and Procedures shall specify that TAP shall refrain from violating the Federal anti-kickback statute, codified at 42 U.S.C. §§ 1320a-7b(1) & (2), and other applicable statutes, regulations or requirements.

On or before January 31, 2002, or within 120 days of the Effective Date of this CIA, whichever is later, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), TAP shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be

distributed to all Covered Persons whose job functions are related to those Policies and Procedures.

C. Training and Education.

1. *Training Requirements, General Description.* The training and education required under section III.C. of this CIA may be provided by supervisory employees or outside consultant trainers selected by TAP and/or through electronic means. Persons providing the training must be knowledgeable about the subject areas of their training. TAP may provide the training required under this CIA through appropriate computer-based approaches. In that event, all applicable references to "hours" in this section III.C. shall mean "normative hours" as that term is used in the computer-based training industry. If TAP chooses to provide computer-based training, it shall also make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the Covered Persons who are receiving such training. To the extent a Covered Person is on a leave of absence when the required training is offered, the Covered Person shall receive the training within 60 days of the conclusion of the leave of absence.

New Covered Persons shall receive the training outlined below in sections III.C.2. and III.C.3. within 60 days of the beginning of their employment or becoming Covered Persons or on or before January 31, 2002, whichever is later. A TAP employee who has completed the training shall review a new Covered Person's work, to the extent that the work relates to the promotion, marketing or sales of Government Reimbursed Products; the calculating or reporting of prices for Government Reimbursed Products; or the fulfilment of any responsibilities relating to the Medicaid Drug Rebate program until such time as the new Covered Person completes the applicable training.

2. *Training Provided to Covered Persons.* On or before January 31, 2002, TAP shall provide at least four hours of training to each Covered Person. This training, at a minimum, shall explain:

a. TAP's CIA requirements;

b. TAP's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues);

c. proper methods of promoting, marketing and selling Government Reimbursed Products in accordance with all applicable statutes, regulations and requirements, including, but not limited to, the Federal anti-kickback statute and the Prescription Drug Marketing Act (to the extent such Covered Person's responsibilities involve handling drug samples);

d. the personal obligation of each individual involved in marketing and sales of Government Reimbursed Products to ensure that those products are marketed and sold in accordance with all applicable requirements;

e. all applicable legal rules (including the sanctions for violations) relating to promotion, marketing and sales of Government Reimbursed Products (including, but not limited to, the Federal anti-kickback statute; the Civil Monetary Penalties law, 42 U.S.C. § 1320a-7a; the civil False Claims Act, 31 U.S.C. §§ 3729-3733; the Medicaid Drug Rebate statute, and the Prescription Drug Marketing Act (to the extent such Covered Person's responsibilities involve handling drug samples); and

f. examples of proper and improper promotion, marketing and sales practices.

After receiving the initial training described above, each Covered Person shall receive at least three hours of training on the topics outlined above each calendar year.

3. *Additional Training for Certain Covered Persons*. In addition to the training outlined in section III.C.2. above, on or before January 31, 2002, TAP shall provide ninety (90) minutes of additional training (the "Additional Training") to those Covered Persons: 1) whose job responsibilities include responsibility for complying with any requirements of the Medicaid Drug Rebate program; or 2) who are involved in the calculation or reporting of any pricing data or other related information for Government Reimbursed Products. To the extent that TAP has provided training that satisfies the Additional Training requirements set forth below within 180 days prior to the Effective Date of this CIA, the OIG shall credit that training for purposes of satisfying TAP's Additional Training obligations for the first year of the CIA.

This Additional Training shall include a discussion of:

a. the calculation and reporting of accurate pricing data and other information to CMS, the State Medicaid programs and drug price reporting services for Government Reimbursed Products;

b. the calculation and reporting of accurate pricing data and other information as required by the Medicaid Drug Rebate program;

c. the personal obligation of each individual involved in the calculation or reporting of drug pricing data or other information to ensure that prices are accurately calculated and reported;

d. all applicable legal rules (including the sanctions for violations) relating to proper price and information calculation and reporting for Government Reimbursed Products (including, but not limited to, the Federal anti-kickback statute; the Civil Monetary Penalties law; the civil False Claims Act; and the Medicaid Drug Rebate statute); and

e. examples of proper and improper drug price calculation and reporting practices.

After receiving the initial training described in this section, every Covered Person required to receive Additional Training shall receive at least one hour of Additional Training each calendar year.

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

D. Reporting Requirements.

1. *General Statement of Purpose and Intent.*

On a quarterly basis, TAP shall report to the entities identified below in section III.D.2.b. certain pricing information, as specified below in section III.D.2.a., for the

purpose of furnishing those entities with true pricing information that accurately reflects prices at which actual purchasers buy the Government Reimbursed Products sold by TAP. Such information shall be provided to the OIG subject to section IX and other conditions of this CIA, and TAP shall comply with section V.D. in providing the data. The OIG agrees that if, and when, it shares the confidential pricing information with government agencies other than the OIG, it will encourage that the information not be used in a way that would competitively disadvantage TAP in relation to any of its competitors.

2. *Specific Reporting Requirements.*

a. *Average Sale Price Defined.*

For purposes of this CIA, "Average Sale Price" means, with respect to each dosage form, strength and volume of the Government Reimbursed Product (without regard to any special packaging, labeling, or identifiers on the dosage form or product or package) the average of all final sales prices charged by TAP for the product in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of "Best Price" for Medicaid Drug Rebate purposes, pursuant to 42 U.S.C. § 1396r-8, and excluding direct sales to hospitals. (Those purchasers for which the sales are included in the calculation of Average Sale Price are hereafter referred to as the "Relevant Purchasers".) The prices identified in the calculation of the Average Sale Price should be net of all the following: volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates;[2] and all other price concessions provided by TAP to any Relevant Purchaser that result in a reduction of the ultimate cost to the purchaser. Notwithstanding the foregoing, the Average Sale Price shall not include the value of bona fide charity care or grants.

TAP shall report the Average Sale Price by National Drug Code ("NDC") for each Government Reimbursed Product identified by TAP's NDC. The Average Sale Price reported shall be properly weighted to reflect the volume of sales at each sale price, *i.e.,* for each NDC, the price reported shall be an average per unit price determined by dividing the sum of all final prices charged by TAP to a Relevant Purchaser, net of all price reductions identified above, for a Government Reimbursed Product in a quarter by the total number of units of that product sold in that quarter.

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[2] The term "rebate" as used in this paragraph does not include any payments made by TAP to the States pursuant to the Medicaid Drug Rebate program (42 U.S.C. § 1396r-8).

b. *Reporting Obligations for Government Reimbursed Products.*

Except as otherwise noted below, thirty (30) days after the last day of each calendar quarter, TAP shall report, in accordance with section III.D.2.a. above, the Average Sale Prices of each of its Government Reimbursed Products identified by TAP's NDC to: 1) the Medicaid programs of those States who have executed a state settlement agreement with TAP; 2) to First DataBank Inc.[3] solely for the purpose of reporting pricing information based on those Average Sale Prices to the Medicaid programs of those States that have executed a state settlement agreement; 3) to CMS; and 4) to the OIG. The first report of Average Sale Prices shall be made no later than 30 days after the end of the first full calendar quarter following the Effective Date of the CIA.

c. *Certification Requirement.*

In connection with each report of Average Sale Price, TAP shall also provide the OIG, CMS, and the applicable States a detailed description of the methodology used to calculate the Average Sale Prices. An appropriate employee or agent of TAP will certify that the Average Sale Prices reported are calculated in accordance with the described methodology. Said certifications shall be made in the form attached hereto as Attachment A. TAP agrees that this certification by an appropriate employee or agent of TAP constitutes a certification by TAP. To the extent that TAP's methodology involves accruing for the impact of future events, TAP shall include a description of its accrual methodology, including underlying assumptions, with its certification, and shall, on a quarterly basis, evaluate such accrual methodology in light of its actual experience and make any appropriate adjustments.

d. *Confidentiality and Use of Reported Information.*

TAP and the OIG (on behalf of itself and CMS) acknowledge that the pricing information provided by TAP is considered to be confidential commercial information and proprietary trade secrets that if disclosed may cause substantial injury to the competitive position of TAP. On behalf of itself and CMS, the OIG agrees to afford the pricing information disclosed by TAP the maximum degree of confidentiality permitted

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[3] If appropriate to reflect changes in the sources from which the State Medicaid programs receive their pricing information, TAP agrees that, upon the receipt of a written request by any of the States, it will report the required information to a drug pricing reporting source other than, and in addition to, First DataBank Inc., subject to reasonable provisions equivalent to those agreed to by First DataBank Inc. to ensure the confidentiality of that information.

by law. CMS has been advised by the OIG of the purpose and use of the pricing information provided by TAP. The parties acknowledge that this information may be relied upon by CMS in establishing reimbursement rates for TAP products, provided however that CMS will not change reimbursement rates for any TAP product based on this information without conducting meaningful review for all government-reimbursed therapeutically similar products. Similarly, the parties acknowledge that the pricing information may be relied upon by State Medicaid programs in establishing reimbursement rates for TAP's products, subject to the provisions of the settlement agreements entered between TAP and various States as referenced in the Preamble to this CIA.

e. *Document Retention.*

TAP shall retain all supporting work papers and documentation relating to the Average Sale Price of its Government Reimbursed Products for eight years after the Effective Date of this CIA and, to the extent not protected by appropriately asserted privileges, shall make such documentation available for inspection by the OIG or its duly authorized representative(s) in accordance with the provisions set forth more fully below in section VII of this CIA.

E. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization and Consultant.

TAP shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "IRO" or "Consultant"), to perform procedures to assist TAP in assessing and evaluating its drug price reporting practices, sales and marketing systems, policies and practices and compliance practices required pursuant to this CIA. Each IRO or Consultant must have expertise in auditing and the requirements of the Federal health care programs as they relate to the reporting for, reimbursement of and marketing/sales of Government Reimbursed Products. The IRO(s) or Consultant(s) must be retained to conduct the engagements described below for the first year within 120 days of the Effective Date of this CIA. Each IRO or Consultant shall assess, along with TAP, whether it can perform the engagements in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.

b. Types of Engagements.

The IRO(s) and, as appropriate, Consultant(s) will conduct three separate engagements.[4] One engagement shall address TAP's drug price reporting practices ("Drug Price Reporting Engagement"). The second engagement shall address TAP's systems, policies and practices with regard to sales and marketing activities ("Sales and Marketing Engagement"). The third engagement shall address TAP's compliance with the obligations assumed under this CIA ("Compliance Engagement").

c. Frequency of Engagements.

The Drug Price Reporting and the Sales and Marketing Engagements shall each be performed by the IRO and, as appropriate, Consultant, for each of the seven years of the CIA and cover each of the one-year periods beginning with the Effective Date of the CIA. However, after the IRO and Consultant performs the Drug Price Reporting and Sales and Marketing Engagements for the fourth year of the CIA, TAP, at its option, may request the OIG to permit that the two Engagements be conducted internally and subject only to verification by the IRO and Consultant for the remainder of the term of the CIA. The OIG retains sole discretion over whether to permit the Drug Price Reporting and Sales and Marketing Engagements to be conducted internally by TAP and subject to validation by the IRO and Consultant after the fourth year of the CIA. In making its decision, the OIG will consider, among other factors, the results of the Drug Price Reporting and Sales and Marketing Engagements during the first four years of the CIA and TAP's demonstrated audit capabilities to perform the Engagements internally. If the OIG denies TAP's request to shift the audit responsibilities, TAP agrees to engage the IRO and Consultant to complete the remaining Drug Price Reporting and Sales and Marketing Engagements in accordance with the CIA. The Compliance Engagement shall be performed by the IRO for the first one-year period beginning with the Effective Date of the CIA.

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[4] As explained below, one component of both the Drug Price Reporting Engagement and the Sales and Marketing Engagement shall be a systems review conducted pursuant to a consulting engagement. TAP may engage a separate Consultant to perform each systems review. Alternatively, at its discretion, TAP may engage a single entity (an IRO) to perform the systems reviews and the other components of the Drug Price Reporting Engagement and the Sales and Marketing Engagement.

d. Retention and Submission of Records.

For each year of the CIA, a complete copy of the IRO's and/or Consultant's Drug Price Reporting Engagement and Sales and Marketing Engagement Reports (including the Systems Review Consulting Engagement Reports referenced in Attachments B and C to this CIA) and, for the first year of the CIA only, the IRO's Compliance Engagement Report, shall be included in TAP's Annual Reports to OIG. The IRO and/or, as appropriate, Consultant and TAP shall retain and make available to the OIG upon request (to the extent not protected by appropriately asserted legal privileges) all supporting work papers and documentation, correspondence, and draft reports (those that are exchanged between the IRO or Consultant and TAP) relating to the Engagements.

2. *Drug Price Reporting Engagement.*

The Drug Price Reporting Engagement shall be composed of two separate reviews, a "Reported Prices Engagement" and a "Systems Review Consulting Engagement," both of which are described in detail in Attachment B to the CIA. Prior to conducting the Reported Prices Engagement, the IRO shall submit its Agreed Upon Procedures workplan(s) to the OIG for approval. Prior to conducting the Systems Review Consulting Engagement, the IRO or Consultant may submit its workplan(s) to the OIG for comment. However, any comments or recommendations made by the OIG in connection with a review of the submitted workplan(s) will not preclude the OIG from making further comments or recommendations for future workplan(s) after reviewing the Drug Price Reporting Engagement Report or the Systems Review Consulting Engagement Report.

3. *Sales and Marketing Engagement*

The Sales and Marketing Engagement shall consist of two separate reviews, a "Systems Review Consulting Engagement" and a "Documentation Review," both of which are described in detail in Attachment C to the CIA. Prior to conducting the Systems Review Consulting Engagement, the IRO or Consultant may submit its workplan(s) to the OIG for comment. Prior to conducting the Documentation Review, the IRO shall submit its Agreed Upon Procedures workplan(s) to the OIG for approval. However, any comments or recommendations made by the OIG in connection with a review of the submitted workplan(s) will not preclude the OIG from making further comments or recommendations for future workplan(s) after reviewing the Systems Review Consulting Engagement Report or the Documentation Review Report.

4. *Compliance Engagement.*

The IRO shall conduct an engagement regarding TAP's compliance activities under which it shall review TAP's adherence to the obligations set forth in sections III through V and section VIII of this CIA ("Compliance Engagement"). The IRO shall prepare a report based upon the Compliance Engagement performed (the "Compliance Engagement Report"), which shall include the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding TAP's compliance with the terms of sections III through V and section VIII of the CIA, as applicable.

5. *Verification/Validation.*

In the event that the OIG has reason to believe that: (a) any of TAP's IRO or Consultant Engagements (or internal audits, if permitted under section III.E.1.c.) fails to conform to the requirements of this CIA, or (b) the findings of the reports from these Engagements or audits are inaccurate, the OIG may, at its sole discretion, conduct its own review ("Validation Review") to determine whether the Engagement or audit in question complies with the requirements of the CIA and/or the reported findings for the Engagement are inaccurate. TAP agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the submission the final Annual Report submission or any additional materials requested by the OIG as described in section II.

Prior to initiating a Validation Review, the OIG shall notify TAP of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, and upon request by TAP, the OIG agrees to meet with TAP representatives to discuss the results of any Engagement or audit submissions or findings; present any additional or relevant information to clarify the results of the Engagement or audit or to correct any inaccuracies; and/or propose alternatives to the proposed Validation Review. To the extent the information is not protected by appropriately asserted legal privileges, TAP agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any IRO or Consultant Engagement or audit issues with TAP prior to conducting a Validation Review. However, the final determination as to whether to proceed with a Validation Review shall be made at the sole discretion of the OIG.

6. *Independence Certification.*

Within 120 days from the Effective Date of this CIA, the IRO(s) and, as appropriate, the Consultant(s) shall provide to TAP a certification or sworn affidavit that it has evaluated its professional independence with regard to the Drug Price Reporting, Sales and Marketing and Compliance Engagements and that it has concluded that it is, in fact, independent. Such certification(s) shall be included in TAP's Implementation Report submission.

F. Disclosure Program.

TAP presently has a disclosure program designed to facilitate communications relating to compliance with law and TAP's policies. During the term of the CIA, TAP shall maintain its Disclosure Program, which 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 TAP'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. TAP shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall continue to include a reporting mechanism for anonymous, confidential communications. 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, TAP shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

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

G. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense that is governed by 42 U.S.C. §1320a-7(a) related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible. For purposes of this section III.G., "Relevant Covered Person" shall be any Covered Persons: 1) whose job responsibilities include responsibility for complying with any requirements of the Medicaid Drug Rebate program; 2) who are involved in the calculating or reporting of any pricing data or other related information for Government Reimbursed Products; and 3) who are involved in the promotion, marketing or sales of Government Reimbursed Products.

2. *Screening Requirements.* TAP shall not hire or engage as Relevant Covered Persons any Ineligible Person in connection with TAP's business operations related to Federal health care programs. To prevent hiring or engaging any Ineligible Person, TAP shall screen all prospective Relevant Covered Persons prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* On or before January 31, 2002, TAP shall review its list of current Relevant Covered Persons against the Exclusion Lists. Thereafter, TAP shall review the list annually. In addition, TAP shall require Relevant Covered Persons to disclose immediately any debarment, exclusion or other event that makes the individual an Ineligible Person.

If TAP has notice that a Relevant Covered Person has become an Ineligible Person, TAP shall remove such person from responsibility for, or involvement with, TAP's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until

such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If TAP has notice that a Relevant Covered Person is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, TAP shall take all appropriate actions to ensure that the Relevant Covered Person's continued performance of his or her responsibilities shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

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

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date of this CIA, TAP establishes or acquires new business units engaged in the contracting for, marketing, sales or price reporting of Government Reimbursed Products, TAP shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of the establishment or acquisition. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding contractor's name and address that has issued each provider number. All new Covered Persons at such business units shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date of this CIA, TAP shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number, position description, and summary of other non-compliance job responsibilities of the Compliance Officer required by section III.A.1.;

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

3. a copy of TAP's Code of Conduct required by section III.B.1.;

4. a copy of all compliance-related Policies and Procedures required by section III.B.2. and a summary of all other Policies and Procedures required by section III.B.2.;

5. a copy of all training materials used or to be used for the training required by section III.C., a description of such training programs and a summary of the activities undertaken in furtherance of these programs, including a schedule, topic outline and a description of the audiences for the training sessions held;

6. a certification by the Compliance Officer that:

   a. the Policies and Procedures required by section III.B.2. have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;

   b. all Covered Persons have completed the Code of Conduct certification required by section III.B.1.;

   c. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C.; and

   d. in the event that the Compliance Officer cannot certify to these items in their entirety, the Compliance Officer shall provide an explanation of any deficiencies and a timetable for when the deficiencies will be remedied.

The documentation supporting this certification shall be available to OIG, upon request.

7. a description of the Disclosure Program required by section III.F.;

8. the identity of the IRO(s) and Consultants(s); a summary/description of all current engagements between TAP and the IRO or Consultant; and a description of all engagements between TAP and the IRO or Consultant relating to the work of or issues examined by the IRO or Consultant in connection with the Engagements required by this CIA; and the proposed start and completion dates of the first Engagements;

9. a certification from the IRO and, as appropriate, Consultant regarding its professional independence from TAP;

10. a summary of personnel actions (other than hiring) taken pursuant to section III.G.;

11. a list of all of TAP's locations (including locations and mailing addresses) except for home offices, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, and, if applicable, each location's Federal health care program provider identification number(s) and the contractor's name and address that issued each provider identification number;

12. to the extent not already furnished to OIG, or if modified, a description of TAP's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and

13. the certification required by section V.C.

B. Annual Reports. TAP shall submit to OIG Annual Reports with respect to the status of, and findings regarding, TAP's compliance activities for each of the seven one-year periods beginning on the Effective Date of the CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period.")

Each Annual Report shall include:

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

2. a certification by the Compliance Officer that:

   a. all Covered Persons have completed any Code of Conduct certifications required by section III.B.1.;

   b. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C.;

   c. TAP has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs; and

   d. TAP's Policies and Procedures, including its Operational Guidelines and Standard Operating Procedures (relating to drug samples), and the templates for the Control Documents (as the term is defined in Attachment C) have been reviewed by competent legal counsel and have been found to be in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed.

The documentation supporting this certification shall be available to OIG, upon request.

3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.B. and the reasons for such changes (e.g., change in Federal health care program requirements) and copies of any Policies and Procedures;

4. a copy of all training materials used for the training required by section III.C. (to the extent it has not already been provided), a description of such training conducted during the Reporting Period, including a list of attendees, a topic outline of training sessions, and a schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the IRO's and/or Consultant's Engagements required by this CIA, including, to the extent not already provided, a copy of the methodology used, along with a copy of the IRO's and/or Consultant's engagement letter;

6. TAP's response and corrective action plan(s) related to any issues raised by the IRO(s) or Consultant(s);

7. a revised summary/description of all engagements between TAP and the IRO or Consultant, as described in section V.A.8., if different than what was submitted as part of the Implementation Report;

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

9. a description of any personnel actions (other than hiring) taken by TAP as a result of the obligations in section III.G., and the name, title, and responsibilities of any person that falls within the ambit of section III.G.4., and the actions taken in response to the obligations set forth in that section;

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

11. a description of all changes to the most recently provided list (as updated) of TAP's locations except home offices as required by section V.A.11., the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, and, if applicable, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number; and

12. the certification required by section V.C.

The first Annual Report shall be submitted to the OIG no later than 120 days after the end of the first Reporting Period except for TAP's response to any issues raised by the IRO(s) or Consultant(s), which shall be submitted to the OIG no later than 150 days after the end of the first Reporting Period. Each subsequent Annual Report shall be submitted to OIG no later than 120 days after the end of each subsequent Reporting Period except for TAP's response to any issues raised by the IRO(s) or Consultant(s), which shall be submitted to the OIG no later than 150 days after the end of each subsequent Reporting Period.

C. Certifications.

The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, TAP is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information therein is accurate and truthful.

D. Designation of Information.

TAP shall clearly identify any portions of any of its submissions under this CIA 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. TAP 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 of this CIA, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Civil Recoveries Branch - Compliance Unit
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, SW
Washington, DC 20201
Phone: 202-619-2078
Fax: 202-205-0604

TAP:

Compliance Officer
TAP Pharmaceutical Products Inc.
675 North Field Drive
Lake Forest, IL 60045
Phone: 800-621-1020
Fax: 847-582-5006

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

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of TAP's books, records, and other documents and supporting materials (to the extent such items are not protected under appropriately asserted legal privileges) and/or conduct on-site reviews of any of TAP's locations for the purpose of verifying and evaluating: (a) TAP's

compliance with the terms of this CIA; and (b) TAP's compliance with the applicable requirements of the Federal health care programs. The documentation described above shall be made available by TAP to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of TAP's Covered Persons 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. TAP's employees shall have the right to be represented by counsel and any such employee may, at his or her option, be accompanied by counsel for TAP and/or their personal counsel at any interview by the OIG. TAP agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Notwithstanding such agreement, the OIG recognizes that individuals have the right to refuse to submit to interviews, and TAP shall not be obligated to require such individuals to submit to interviews. If any individual decides not to submit to an interview, such refusal shall not constitute a breach of this CIA. TAP's employees may elect to be interviewed with or without a representative of TAP present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

The OIG shall follow all applicable Federal laws concerning privacy and confidentiality, including the Federal Privacy Act, 5 U.S.C. §552a, to the greatest extent allowed by law. Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify TAP prior to any release by OIG of information submitted by TAP pursuant to its obligations under this CIA and identified upon submission by TAP as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, TAP shall have the rights set forth at 45 C.F.R. § 5.65(d). The OIG shall provide the pre-disclosure notice required pursuant to 45 C.F.R. §5.65(d) to the Compliance Officer at the address provided in section VI. Nothing in this CIA or any communication or report made pursuant to this CIA shall constitute or be construed as a waiver by TAP of TAP's

attorney-client, work product or other applicable privileges. Except as otherwise stated herein, the existence of any such privilege does not affect TAP's obligation to comply with the provisions of the CIA.

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, TAP and OIG hereby agree that failure to comply with certain obligations 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 TAP fails to have in place any of the obligations described in section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. a requirement that Covered Persons be trained; and

f. a Disclosure Program.

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 TAP fails to retain an IRO or Consultant, as required in section III.E.1.a.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day TAP fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue 10 days after the date failure to comply began) for each day TAP engages as a Relevant Covered Person an Ineligible Person and that person: (i) has responsibility for, or involvement with, TAP's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which TAP can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.G.) as to the status of the person).

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

6. A Stipulated Penalty of $1,000 for each day TAP fails to comply substantially with any other obligation of this CIA. (A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-5 of this section.) In its notice to TAP, OIG shall state the specific grounds for its determination that TAP has failed to comply substantially and adequately with the CIA obligation(s) at issue and steps that TAP must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to TAP of the failure to comply.)

B. Timely Written Requests for Extensions.

TAP may, in advance of the due date, submit a timely written request for an extension of time to perform any act or submit 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 TAP 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 submit the notification or report shall not begin to accrue until three business days after TAP 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 TAP 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 TAP in writing of: (a) TAP's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter"). Such Demand Letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, TAP 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 TAP elects to request an ALJ hearing and does not prevail, the Stipulated Penalties shall continue to accrue until TAP cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.D.

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

4. *Independence from Material Breach Determination.* Except as set forth in section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that TAP has materially breached this CIA,

which decision shall be made at OIG's discretion and shall be governed by the provisions in section X.D, below.

D. Exclusion for Material Breach of this CIA

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

a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A.;

b. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C.; or

c. a failure to retain and use an IRO or Consultant in accordance with section III.E.

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

3. *Opportunity to Cure.* TAP shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. TAP is not in material breach of this CIA;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) TAP has begun to take action to cure the material breach; (ii) TAP is pursuing such action with due diligence; and (iii) TAP has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, TAP fails to satisfy the requirements of section X.D.3., OIG may exclude TAP from participation in the Federal health care programs, subject to TAP's rights set forth in section X.E. OIG will notify TAP in writing of its determination to exclude TAP (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E., below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, TAP wishes to apply for reinstatement, TAP must submit 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 TAP 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, TAP 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 business days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether TAP was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. TAP shall have the burden of proving its full and timely compliance with the obligations at issue and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders TAP to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless TAP 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 Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether TAP was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30 day period, but that:

(i) TAP had begun to take action to cure the material breach within that period;

(ii) TAP has pursued and is pursuing such action with due diligence; and

(iii) TAP provided to OIG within that period a reasonable timetable for curing the material breach and TAP has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for TAP, only after a DAB decision in favor of OIG. TAP's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude TAP upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that TAP 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. TAP agrees that receipt of the ALJ or DAB decision constitutes notice of exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB.

XI. EFFECTIVE AND BINDING AGREEMENT

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

A. This CIA shall be binding on the successors, assigns, and transferees of TAP; however, the CIA shall not apply to the individuals or products of an acquiring company or a company merging with TAP except to the extent the individuals associated with that company become involved in the sales, marketing or pricing of, or Medicaid Drug Rebate program obligations associated with, TAP's Government Reimbursed Products (as defined in this CIA);

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

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA and the CIA will be subject to modifications if so required by any change in Federal health care program requirements as referenced in the Preamble to this CIA;

D. The undersigned TAP signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF TAP PHARMACEUTICALS PRODUCTS INC.

H. Thomas Watkins
President
TAP Pharmaceutical Products Inc.

September 28, 2001
DATE

Kenneth D. Greisman
Senior Counsel and Assistant Secretary
TAP Pharmaceutical Products Inc.

September 28, 2001
DATE

Daniel E. Reidy, Esq.
Jones, Day, Reavis & Pogue

DATE

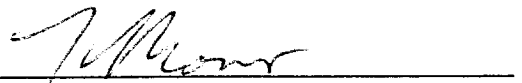
Joseph F. Savage, Jr., Esq.
Testa, Hurwitz & Thibeault, LLP

DATE

ON BEHALF OF TAP PHARMACEUTICALS PRODUCTS INC.

H. Thomas Watkins President TAP Pharmaceutical Products Inc.	DATE
Kenneth D. Greisman Senior Counsel and Assistant Secretary TAP Pharmaceutical Products Inc.	DATE
Daniel E. Reidy, Esq. Jones, Day, Reavis & Pogue	9/26/01 DATE
Joseph F. Savage, Jr., Esq. Testa, Hurwitz & Thibeault, LLP	9/28/01 DATE

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



Lewis Morris
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

9/28/01
DATE

Attachment A To CIA
TAP Pharmaceutical Products Inc.

CERTIFICATION

In accordance with the Corporate Integrity Agreement ("CIA") entered between TAP Pharmaceutical Products Inc. ("TAP") and the OIG, the undersigned hereby certifies that the attached Average Sale Price information has been communicated to First DataBank Inc. (and/or other price reporting entity as specified in the CIA); to the State Medicaid programs of those States which executed settlement agreements with TAP, as required; to the OIG; and to the Centers for Medicare & Medicaid Services and that it has been calculated in accordance with the methodology described generally in the CIA and more specifically in the attached document.

_____
Signature

_____
Title

_____
Date

Attachment B to CIA for TAP Pharmaceutical Products Inc.

Drug Price Reporting Engagement

I. Drug Price Reporting Engagement

Each year during the term of the CIA, an Independent Review Organization ("IRO") or Consultant, as explained below, shall review TAP's systems, policies and practices relating to the calculation and reporting of Average Sale Price and Best Price during each one year period covered by the Drug Price Reporting Engagement ("the Reporting Period"). Consistent with section III.E.1.c. of the CIA, after the fourth Reporting Period, the OIG may, at its discretion and upon request of TAP, permit TAP to perform the engagement described in this Attachment B (subject to validation by the IRO or Consultant, as appropriate). The Drug Price Reporting Engagement shall consist of two separate components: 1) a Reported Prices Engagement, and 2) a Systems Review Consulting Engagement. TAP may engage, at its discretion, a single entity to perform the Systems Review Consulting Engagement and the Reported Prices Engagement, provided that the entity has the necessary expertise and capabilities to perform both.

Prior to performing the Reported Prices Engagement, the IRO and TAP shall design agreed upon procedures as defined in the AICPA "attest standards" for Agreed Upon Procedures Engagements (hereafter "Agreed Upon Procedures") outlining the specific work to be performed by the IRO, and the Agreed Upon Procedures shall be submitted to the OIG for approval. Prior to performing the Systems Review Consulting Engagement, the Consultant and TAP shall design a workplan outlining the specific work to be performed by the Consultant. The Consultant's workplan may be submitted to the OIG for comment. The Engagements are described in general terms below.

A. Reported Prices Engagement

The Reported Prices Engagement shall be designed to allow for evaluation of whether TAP is reporting Average Sale Price and Best Price in accordance with its obligations under the CIA and the requirements of the Medicaid Drug Rebate program (codified at 42 U.S.C. § 1396r-8), respectively. The Reported Prices Engagement shall consist of two parts, "Reported Prices Procedures for Average Sale Price" and "Reported Prices Procedures for Best Price."

1. Reported Prices Procedures for Average Sale Price

For each Reporting Period, the IRO shall conduct Reported Prices Procedures for Average Sale Price to determine whether TAP calculated and reported Average Sale Price in accordance with the CIA requirements. The Procedures shall require the IRO to select and test samples of transactions (consisting of sales and sales-related activities, for individual Government Reimbursed Products to individual purchasers or other entities, that are specifically included in or excluded from the Average Sale Price (as defined in section III.D.2.a. of the CIA) (hereafter "Transactions")). The IRO will also select and test samples of Estimated Transactions (as defined below) used in the calculation of Average Sale Prices in order to perform procedures regarding TAP's accrual methodologies as described in the certification referenced in section III.D.2.c. of the CIA.

a. Grouping and Testing of Transactions

The IRO shall begin its Agreed Upon Procedures by selecting and testing samples of Transactions (as grouped by TAP) from the Reporting Period. All Transactions that were finalized at the time of sale shall be grouped by transaction type (hereafter "Like-Kind Transactions")[1]. All transactions that were estimated (based on TAP's accrual methodology) during at least one quarter of the Reporting Period and were finalized during the Reporting Period shall also be grouped together (hereafter "Estimated Transactions"). The sum of all grouped Like-Kind Transactions and Estimated Transactions shall be deemed to be all Transactions that occurred during the Reporting Period. Each group of Like-Kind Transactions and the Estimated Transactions will be considered a separate universe from which the IRO will test a probe sample and, if required as set forth below, a statistically valid random sample of Transactions.

With regard to all grouped Like-Kind Transactions, the IRO will test for the following attributes: 1) whether the Transaction prices are supported by source

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[1] Examples of the Like-Kind Transactions to be tested may include, but not be limited to: sales; volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; replacement goods; cash disbursements to purchasers; and other price concessions or incentives provided by TAP.

documents; and 2) whether TAP properly included or excluded each Transaction in the calculation of Average Sale Price under the definition of that term as set forth in section III.D.2.a. of the CIA.

With regard to the Estimated Transactions, the IRO shall test for the following attributes: 1) whether the recorded Estimated Transaction amounts were supported by commercial arrangements or other source documentation; 2) whether the Estimated Transactions were properly included or excluded in the calculation of Average Sale Price; 3) whether after the transactions became final, TAP reviewed the Estimated Transaction amounts in light of actual experience (including TAP's contract(s) with the customer, the customer's purchasing history, TAP's rebate policy or other relevant information); 4) whether the actual experience (as reviewed in Item 3 above) supported the recorded Estimated Transaction amount(s); and 5) if the actual experience did not support the recorded Estimated Transaction amounts, whether TAP adjusted the amounts during the Reporting Period.

b. Sampling of Transactions

The IRO shall initially test a probe sample of Transactions from each group of Like-Kind Transactions and Estimated Transactions. If the error rate for any of the probe samples falls below an identified threshold error rate, no further testing of the universe of Like-Kind Transactions or Estimated Transactions shall be required. If the error rate in any of the probe samples exceeds an identified threshold error rate, the IRO shall test a statistically valid random sample of Transactions or Estimated Transactions from that universe of Transactions. The size of the probe samples, the size of any required statistically valid random sample(s), the allocation of Transactions into universes, and the threshold error rate shall be agreed upon by TAP, the OIG and the IRO as an element of the Agreed Upon Procedures.

The probe samples and, if necessary, any subsequent statistically valid random samples shall be generated through the use of the OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS" (which is available through the Internet at www.hhs.gov/oas/ratstat.html) or through the use of another method of random sampling acceptable to the OIG.

2. Reported Prices Procedures for Best Price

For each Reporting Period, the IRO shall conduct the Reported Prices Procedures for Best Price to determine whether TAP calculated and reported Best Price to CMS for Government Reimbursed Products in accordance with the applicable requirements of the Medicaid Drug Rebate program. The Procedures shall require the IRO to select and test samples of transactions (consisting of sales and sales-related activities, for individual Government Reimbursed Products to individual purchasers or other entities, that are specifically included in or excluded from the calculation of Best Price, (hereafter "Best Price Transactions")).

a. Grouping and Testing of Like-Kind Best Price Transactions

The IRO shall begin its Agreed Upon Procedures by selecting and testing samples of like-kind Best Price Transactions [2] (as grouped by TAP) from the Reporting Period. The sum of all Best Price Transactions in all the like-kind Best Price Transaction groups combined shall equal the sum of all Best Price Transactions that occurred during the Reporting Period. Each group of like-kind Best Price Transactions will be considered a separate universe from which the IRO will review a probe sample and, if required as set forth below, a statistically valid random sample of Best Price Transactions.

With regard to all grouped like-kind Best Price Transactions, the IRO will test whether: 1) the Medicaid Rebate Transaction prices are supported by source documents; and 2) TAP properly included or excluded each Best Price Transaction in the calculation of Best Price in accordance with 42 U.S.C.§ 1396r-8(c)(1)(C) or other applicable Medicaid Drug Rebate program requirements. The IRO shall also identify those instances in which TAP reported adjusted Best Price amounts to CMS based on the IRO's

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[2] Examples of like-kind Best Price Transactions to be tested may include, but not be limited to: sales; volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates paid to customers or credited to customers' accounts; replacement goods; cash disbursements to purchasers; and all other price concessions or incentives provided by TAP.

Reported Prices Procedures for Best Price and shall report the amounts of any adjustments to the reported Best Prices.

b. Sampling of Like-Kind Best Price Transactions

The IRO shall initially test a probe sample of Best Price Transactions from each group of like-kind Best Price Transactions. If the error rate for any of the probe samples falls below an identified threshold error rate, no further testing of the universe of like-kind Best Price Transactions shall be required. If the error rate in any of the probe samples exceeds an identified threshold error rate, the IRO shall test a statistically valid random sample of Best Price Transactions from that universe of like-kind Best Price Transactions. The size of the probe sample, the size of any statistically valid random sample, and the threshold error rate shall be agreed upon by TAP, the OIG and the IRO as an element of the Agreed Upon Procedures.

The probe samples and, if necessary, any subsequent statistically valid random samples shall be generated through the use of the OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS" (which is available through the Internet at www.hhs.gov/oas/ratstat.html) or through the use of another method of random sampling acceptable to the OIG.

II. Systems Review Consulting Engagement

For each Reporting Period, TAP will retain a Consultant to review its price calculation and reporting systems as they relate to Government Reimbursed Products ("the Systems Review Consulting Engagement"). This Systems Review Consulting Engagement shall provide for a review of the following:

1. TAP's systems and operations relating to the calculation and reporting of Average Sale Price as required by section III.D. of the CIA;

2. TAP's systems and operations relating to the identification and correction of any inaccurate pricing information (*e.g.* Average Sale Prices), if any, provided to the

State Medicaid programs, CMS, the OIG, and drug price reporting services to which TAP reports prices;

3. TAP's systems and operations relating to the calculation and reporting of Best Price as required under the Medicaid Drug Rebate program; and

4. TAP's systems and operations relating to the identification and correction of any inaccurate pricing information relating to the Medicaid Drug Rebate program, if any, provided to CMS or the State Medicaid programs in accordance with all applicable requirements of the Medicaid Drug Rebate program.

III. Drug Price Reporting Engagement Report

The IRO shall annually prepare a report based upon the Drug Price Reporting Engagement. Each report shall include the following information:

A. Elements to Be Included:

1. Engagement Objectives: A statement of the objectives intended to be achieved by the Drug Price Reporting Engagement;

2. Review Protocol: A detailed narrative description of the procedures performed and a description of each sampling unit and universe utilized in performing the procedures; and

3. Sources of Data: A full description of the documentation relied upon by the IRO when performing the Drug Price Reporting Engagement.

B. Results to Be Included:

The following results shall be included in each Drug Price Reporting Engagement Report:

1. for each universe of Like-Kind Transactions and Estimated Transactions tested, the IRO shall describe the procedures performed and state its findings and supporting evidence as to whether the Transactions and Estimated Transactions tested satisfied the corresponding criteria outlined in section I.A.1. above;

2. for each universe of Like-Kind Transactions and Estimated Transactions, the IRO shall state the percentage error rate discovered;

3. for each universe of Like-Kind Transactions or Estimated Transactions for which the error rate exceeded the identified threshold error rate, and the IRO tested a statistically valid random sample, the IRO shall state its findings and supporting evidence based upon the testing of the larger sample;

4. for each universe of like-kind Best Price Transactions, the IRO shall describe the procedures performed and state its findings and supporting evidence as to whether the Best Price Transactions tested satisfied the criteria outlined in section I.A.2. above;

5. for each universe of like-kind Best Price Transactions, the IRO shall state the percentage error rate discovered, describe any instances in which Best Price adjustments were reported to CMS as a result of the IRO's Reported Prices Procedures for Best Price and the amounts of any adjustments to the reported Best Prices; and

6. for each universe of like-kind Best Price Transactions for which the error rate exceeded the identified threshold error rate, and the IRO tested a statistically valid random sample, the IRO shall state its findings and supporting evidence based upon the testing of the larger sample.

IV. Systems Review Consulting Engagement Report

For each Reporting Period, the Consultant shall prepare a report based upon the Systems Review Consulting Engagement ("Systems Review Consulting Engagement Report"). Each Report shall include the following:

a) a description of the Systems Review Consulting Engagement performed (including a description of the documentation reviewed);
b) a description of any identified weaknesses in TAP's systems and operations relating to the calculation and reporting of Average Sale Price and Best Price;
c) a description of any identified weaknesses in TAP's systems and operations relating to the identification and correction of any inaccurate pricing information (including, but not limited to, Average Sale Price or Best Price), if any, provided to the State Medicaid programs, CMS, the OIG and to any drug price reporting services to which TAP reports in connection with reimbursement under Federal health care programs;
d) a description of any recommendations the Consultant may have to improve any of TAP's systems and operations relating to the calculation and reporting of Average Sale Price or Best Price;
e) a description of any recommendations the Consultant may have to improve any of TAP's systems and operations relating to the identification and correction of any inaccurate pricing information provided to the State Medicaid programs, CMS, the OIG and to any drug price reporting services to which TAP reports.

The Consultant's Systems Review Consulting Engagement Report will be restricted solely to use by TAP management, and TAP will provide the final Report to the OIG as part of the Annual Report submission.

Attachment C to CIA for TAP Pharmaceutical Products Inc.
Sales and Marketing Engagement

I. Sales and Marketing Engagement

Each year during the term of the CIA, an Independent Review Organization ("IRO") or Consultant, as explained below, shall review TAP's systems, policies and practices relating to the sales and marketing of Government Reimbursed Products (as defined in section III.B.1 of the CIA) for the one year period covered by the Sales and Marketing Engagement ("the Reporting Period"). Consistent with section III.E.1.c. of the CIA, after the fourth Reporting Period, the OIG may, at its discretion and upon request of TAP, permit TAP to perform the engagements described in this Attachment C (subject to validation by the IRO or Consultant). TAP may engage, at its discretion, a single entity to perform the Systems Review Consulting Engagement and the Documentation Review, explained below, provided that the entity has the necessary expertise and capabilities to perform both. The two Engagements are described in general terms in sections I.A. and I.B. below.

The Sales and Marketing Engagement shall consist of two separate components. The first (the "Systems Review Consulting Engagement") shall be a review by a Consultant of TAP's sales and marketing systems, policies and practices (including the controls on those systems, policies and practices) as they relate to several specified types of activities. Prior to performing the Systems Review Consulting Engagement, the Consultant and TAP shall design a workplan outlining the specific work to be performed by the Consultant. The workplan may be submitted to the OIG for comment.

The second component of the Sales and Marketing Engagement (the "Documentation Review") shall be a review by an IRO of samples of control documentation used in connection with TAP's sales and marketing related practices during the Reporting Period. Prior to performing the Documentation Review, the IRO and TAP shall design agreed upon procedures as defined in the AICPA "attest standards" for Agreed Upon Procedures Engagements (hereafter "Agreed Upon Procedures") outlining the specific work to be performed by the IRO, and the Agreed Upon Procedures shall be submitted to the OIG for approval.

A. Sales and Marketing Systems Review Consulting Engagement

For each Reporting Period, the Consultant shall review TAP's sales and marketing related systems, policies and practices pertaining to the following types of activities engaged in with purchasers or prescribers:

a) retention of physicians and other purchasers and/or prescribers of Government Reimbursed Products for consulting, speaking and other advisory fee-for-service arrangements;
b) sponsorship of speaking engagements, meetings or other events (*e.g.*, TAP Speakers Programs, Local Event Programs, *etc.*);
c) awarding or payment of educational grants;
d) awarding or payment of clinical and research grants;
e) expenditures for third party advice about reimbursement or claims submissions for Government Reimbursed Products;
f) provision of gifts;
g) provision of or payment for business courtesies;
h) provision of or payment for customer assistance programs;
i) provision of debt forgiveness, debt reduction, or other like assistance to customers; and
j) provision of drug samples.

This list of activities shall hereafter be referred to as the "Sales and Marketing Related Activities" or the "Activities."

1. Review of Sales and Marketing Related Systems, Policies and Practices

For each Reporting Period, the Consultant shall review TAP's systems, policies and practices in connection with each of the Sales and Marketing Related Activities.

In general terms, the Consultant shall review the following for each of the Sales and Marketing Related Activities:

a) whether TAP has instituted control and accountability systems (*e.g.*, documentation and approval requirements) and written policies regarding the Activity;
b) the manner in which the control and accountability systems and the written policies are made known or disseminated within TAP;
c) what disciplinary measures TAP has established for failure to comply

with the control and accountability systems and written policies; and

d) the number of instances and the circumstances in which TAP took disciplinary actions for failure to comply with the systems and policies.

To conduct the review, the Consultant shall review appropriate corporate documentation and may also interview TAP personnel (*e.g.*, the Compliance Officer) as appropriate to allow it to report the findings identified in section I.A.2. below.

2. Systems Review Consulting Engagement Report

For each Reporting Period, the Consultant shall prepare a report based upon the Systems Review Consulting Engagement performed ("Systems Review Consulting Engagement Report"). Each Report shall include the following items for each of the Sales and Marketing Related Activities:

a) a description of the documentation reviewed and any personnel interviewed;
b) a general description of TAP's control and accountability systems and written policies and actual practices;
c) a description of the manner in which the control and accountability systems and written policies are disseminated or made known within TAP;
d) a general description of the disciplinary measures TAP has established for failure to comply with the control and accountability systems and written policies;
e) a description of the number of instances and a description of the circumstances in which TAP undertook disciplinary actions for failure to comply with the systems and policies;
f) the findings and supporting rationale regarding the weaknesses in TAP's sales and marketing related systems, policies and practices; and
g) any recommendations to improve any of TAP's sales and marketing related systems, policies or practices.

The Consultant's Systems Review Consulting Engagement Report will be restricted solely to use by TAP management, and TAP will provide the final Report to the OIG as part of the Annual Report submission.

B. Sales and Marketing Documentation Review

1. General Description of Documentation Review

TAP's Policies and Procedures (referenced in section III.B.2. of the CIA), including TAP's Operational Guidelines and Standard Operating Procedures (hereafter collectively "TAP's Policies"), set forth certain requirements relating to control documents used in connection with the Sales and Marketing Related Activities.

a. Control Documents to Be Reviewed

For purposes of this Sales and Marketing Documentation Review, the following categories of control documents ("Control Documents") shall be reviewed:

1. Speakers Agreements and related documentation (*e.g.,* Speaker Information Forms and Speaker Expense Forms);
2. Form agreements for consultation or other non-speaking arrangements;
3. Letters of Agreement (used for educational grants);
4. Agreements relating to clinical or research grants;
5. Administrative Check Requests; and
6. Expense Reports (used for gifts, business courtesies, customer assistance programs, *etc.*).

b. Attributes to Be Tested

During each Reporting Period, the IRO shall follow the Agreed Upon Procedures and test samples of Control Documents for the following attributes:

1. whether the Control Documents were completed in accordance with the requirements set forth in the TAP's Policies;
2. whether the Control Documents reflect that all required written approvals were obtained in accordance with TAP's Policies; and
3. for each Control Document reviewed, whether all supporting documentation (*e.g.,* receipts) and follow-up documentation (*e.g.,* progress and final reports produced in connection with grants) exists in appropriate files in accordance with TAP's Policies.

The IRO shall conduct an attribute test of the samples of Control Documents using the three criteria set forth above and shall identify errors in the Control Documents in accordance with the protocols contained in the Agreed Upon Procedures. The IRO and TAP, in consultation with the OIG, will define what constitutes a material error for purposes of triggering the additional review as set forth in section I.B.3. below. Specifically, if the IRO calculates an overall material error rate of five percent (5%) or greater for any universe of Control Documents reviewed, it shall conduct the additional review explained below.

2. Sampling of Control Documents

For each Reporting Period, the IRO shall follow the Agreed Upon Procedures to test a total of 800 Control Documents, half of which shall relate to Sales and Marketing Related Activities for Lupron Depot® ("Lupron") and the other half of which shall relate to Sales and Marketing Related Activities for Prevacid® ("Prevacid"). The IRO shall select the Control Documents to be reviewed in the following manner.

a. Review of Control Documents Relating to Lupron Sales and Marketing

1. The IRO shall select 320 (eighty percent (80%)) of the Control Documents to be reviewed from those Control Documents reflecting transactions involving the largest volume purchasers of Lupron during the Reporting Period (the "Large Volume Purchasers").

2. The IRO, with assistance from TAP, shall identify the Large Volume Purchasers and rank them in descending order according to purchase volume, with the purchaser of the largest volume of Lupron (the "Largest Volume Purchaser") being ranked first.

3. The IRO shall identify all the Control Documents reflecting transactions between TAP and the Largest Volume Purchaser during the Reporting Period.

4. The IRO shall identify all the Control Documents reflecting transactions between TAP and each of the next successive Large Volume Purchasers, in turn, until the IRO has identified a total of 320 Control Documents. (For instance, if transactions involving the Largest Volume Purchaser were

reflected in twenty Control Documents, the IRO would then select and review a total of 300 Control Documents relating to transactions with other Large Volume Purchasers.)

5. The remaining 80 (twenty percent (20%)) of the Control Documents to be reviewed shall be selected from among those Control Documents reflecting transactions with purchasers who had the largest percentage increase in the volume of Lupron purchased during the Reporting Period (as compared to the immediately preceding Reporting Period) ("Large Percentage Increase Purchasers").

6. The IRO, with assistance from TAP, shall list the Large Percentage Increase Purchasers and rank them in descending order of percentage volume increase, with the purchaser having the largest percentage volume increase being ranked first ("Largest Percentage Increase Purchaser").

7. The IRO shall identify all the Control Documents reflecting transactions between TAP and the Largest Percentage Increase Purchaser during the Reporting Period.

8. The IRO shall then identify all the Control Documents reflecting transactions between TAP and each of the next successive Large Percentage Increase Purchasers, in turn, until the IRO has identified a total of 80 Control Documents.

9. Each set of Control Documents reviewed (those for the Large Volume Purchasers and those for the Large Percentage Increase Purchasers) shall be considered a separate universe for purposes of calculating an error rate.

10. After selecting the two universes of Control Documents to be evaluated, the IRO shall review the Control Documents using the criteria set forth in section I.B.1. and determine an error rate for each universe.

b. Review of Control Documents Relating to Prevacid Sales and Marketing

For each Reporting Period, the IRO shall follow Agreed Upon Procedures to test 400 Control Documents relating to the sales of Prevacid in a manner similar to that in which the Lupron-related Control Documents were tested.

1. The IRO shall select 320 (eighty percent (80%)) of the Control Documents to be reviewed from those Control Documents reflecting transactions involving the largest volume prescribers of Prevacid during the Reporting Period (the "Large Volume Prescribers").

2. The IRO, with assistance from TAP, shall identify the Large Volume Prescribers and rank them in descending order according to the volume of Prevacid prescribed, with the largest volume prescriber (the "Largest Volume Prescriber") being ranked first.

3. The IRO shall identify all the Control Documents reflecting transactions between TAP and the Largest Volume Prescriber during the Reporting Period.

4. The IRO shall identify all the Control Documents reflecting transactions between TAP and each of the next successive Large Volume Prescribers, in turn, until the IRO has identified a total of 320 Control Documents.

5. The remaining 80 (twenty percent (20%)) of the Control Documents to be reviewed shall be selected from among those Control Documents reflecting transactions involving prescribers who had the largest percentage increase in the amount of Prevacid prescribed during the Reporting Period (as compared to the immediately preceding Reporting Period) ("Large Percentage Increase Prescribers").

6. The IRO, with assistance from TAP, shall list the Large Percentage Increase Prescribers and rank them in descending order of percentage volume increase, with the prescriber having the largest percentage volume increase being ranked first ("Largest Percentage Increase Prescriber").

7. The IRO shall identify all the Control Documents reflecting transactions between TAP and the Largest Percentage Increase Prescriber during the Reporting Period.

8. The IRO shall then identify all the Control Documents reflecting transactions between TAP and each of the next successive Large Percentage Increase Prescribers, in turn, until the IRO has identified a total of 80 Control Documents.

9. Each set of Control Documents reviewed (those for the Large Volume Prescribers and those for the Large Percentage Increase Prescribers) shall be considered a separate universe for purposes of calculating an error rate.

10. After selecting the two universes of Control Documents to be evaluated, the IRO shall review the Control Documents using the criteria set forth in section I.B.1. and determine an error rate for each universe.

3. Additional Review if Material Error Rates Are Five Percent or Greater

If the IRO finds a material error rate in any of the four universes of reviewed Control Documents of five percent (5%) or greater, the IRO shall conduct an additional review of the transactions reflected in the erroneous Control Documents for that universe. The IRO will conduct this additional review by performing Agreed Upon Procedures designed to determine the cause of the errors. As referenced in section 1.B.1.b. when establishing the Agreed Upon Procedures, the IRO and TAP, in consultation with the OIG, shall agree what constitutes a material error for purposes of calculating the five percent error rate and shall agree, depending on the nature of the material error, what additional review should be conducted by the IRO to determine the cause of the identified errors. For instance, where necessary, the IRO may need to review additional documentation and/or conduct interviews to identify the cause of the errors.

4. Documentation Review Report

The IRO shall annually prepare a report based upon each Documentation Review performed ("Documentation Review Report"). Each Documentation Review Report shall include the following:

a. Elements to Be Included:

1. Engagement Objectives: A statement of the objectives intended to be achieved by the Documentation Review;

2. Review Protocol: A detailed narrative description of the procedures performed and a description of each sampling unit and universe utilized in performing the procedures; and

3. Sources of Data: A full description of documentation relied upon by the

IRO when performing the Documentation Review.

b. Results to Be Included

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

1. for each universe of Control Documents reviewed, the IRO shall describe the procedures performed and state its findings and supporting rationale as to whether: a) the Control Documents were completed in accordance with all requirements set forth in the TAP's Policies; b) the Control Documents reflect that all written approvals were obtained in accordance with TAP's Policies; and c) for each Control Document reviewed, all supporting documentation and follow-up documentation exists in accordance with TAP's Policies;

2. for each universe of Control Documents reviewed, the IRO shall state the percentage material error rate discovered; and

3. if the material error rate for any universe is five percent or greater, the IRO shall describe the material errors discovered and the additional procedures it performed and shall state its findings as to the cause of the material errors.