CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
OTSUKA AMERICA PHARMACEUTICAL, INC.

I. PREAMBLE

Otsuka America Pharmaceutical, Inc. (Otsuka) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, Otsuka is entering into a Settlement Agreement with the United States. Otsuka will also enter into settlement agreements with various States (Related State Settlement Agreements) and Otsuka's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date, Otsuka established a comprehensive compliance program (Compliance Program), which includes a corporate compliance officer and a compliance committee, a code of business conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a disclosure program, and internal review procedures designed, as represented by Otsuka, to promote compliance with the laws, regulations, and requirements applicable to its business activities.

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

II. TERM AND SCOPE OF THE CIA

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

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

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

1. "Covered Persons" includes:

   a. all owners of Otsuka who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading"), officers, directors, and employees of Otsuka; and

   b. all contractors, subcontractors, agents, and other persons who perform Promotional and Product Services Related Functions (as defined below in Section II.C.4) on behalf of Otsuka.

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

2. "Relevant Covered Persons" includes all Covered Persons whose job responsibilities relate to Promotional and Product Services Related Functions.

3. "Government Reimbursed Products" refers to all products that are promoted by Otsuka and reimbursed by Federal health care programs.

4. The term "Promotional and Product Services Related Functions" includes the promotion, marketing, sales, and the development or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products.

5. The term "Third Party Educational Activity" shall mean any continuing medical education (CME), independent medical education (IME), disease awareness, or other scientific, educational, or professional program, meeting, or event, including but not limited to, sponsorship of symposia at medical conferences.

III. CORPORATE INTEGRITY OBLIGATIONS

Otsuka shall maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

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

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

2. *Compliance Committee.* Prior to the Effective Date, Otsuka established a Compliance Committee, and Otsuka shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as legal, medical affairs/information, sales, marketing, human resources, audit, and operations). 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 the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Otsuka developed, implemented, and distributed a written code of conduct (known as its "Business Conduct Policy") to all Covered Persons. Otsuka has made and shall continue to make the promotion of, and adherence to, the Business Conduct Policy an element in evaluating the performance of all employees.

The Business Conduct Policy sets forth and shall continue to set forth, at a minimum, the following:

a. Otsuka's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to comply with all Federal health care program and FDA requirements relating to Promotional and Product Services Related Functions;

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

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

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

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

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

2. *Policies and Procedures.* Prior to the Effective Date, Otsuka established and implemented written Policies and Procedures regarding the operation of the Compliance Program and its compliance with Federal health care program and FDA requirements (Policies and Procedures). To the extent not already accomplished, within 120 days after the Effective Date, Otsuka shall ensure that the Policies and Procedures address or shall continue to address:

a. the subjects relating to the Business Conduct Policy identified in Section III.B.1;

b. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. 3729-3733);

c. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all FDA requirements, including procedures governing the handling and/or response to requests for information about non-FDA approved (off-label) uses;

d. the mechanisms through and manner in which Otsuka receives and responds to request for information about off-label uses of Otsuka's products; the form and content of information disseminated by Otsuka in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that, for products other than Abilify, Otsuka develop one or more databases to track requests for information about Otsuka's products that are made to Otsuka's medical information (or medical affairs) department. Collectively these databases shall be referred to as the "Inquiries Database." The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Otsuka's products: 1) date of Inquiry; 2) form of Inquiry (*e.g.*, fax, phone, etc.); 3) name of the requesting health care professional (HCP) or health care institution (HCI); 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label indication for the product; 6) nature/form of the response from Otsuka (including a record of

the materials provided to the HCP or HCI in response to the request); 7) the name of the Otsuka representative who called on or interacted with the HCP or HCI; and 8) the status and findings of any follow-up review conducted by Otsuka in situations in which it appears that the Inquiry may have related to improper off-label promotion. The requirements of this subsection (d) shall not apply to products owned by third parties with whom Otsuka has co-promotion agreements that specify that the owner of the product is solely responsible for responding to medical inquiries. The Inquiries Database for Abilify is currently maintained by Bristol-Myers Squibb Company (BMS). If, during the term of this CIA, Otsuka assumes responsibility for maintaining all or any portion of the Inquiries Database for Abilify, Otsuka will, within 90 days thereafter, amend its Policies and Procedures to require compliance with this Section III.B.2.d with respect to Abilify;

e. development of sales call plans for Government Reimbursed Products. For each product, the Policies and Procedures shall require that Otsuka review the call plans for the product and the bases upon which specified physician specialties and institutional provider types are included in, or excluded from, the call plans. The Policies and Procedures shall also require that Otsuka modify the call plans as necessary to ensure that Otsuka is promoting its products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;

f. consultant engagements or fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, speaker programs, speaker trainings, advisory boards, or any similar relationship with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These policies shall be designed to ensure that the engagements or arrangements and related events are used for legitimate and lawful purposes in

accordance with applicable Federal health care program and FDA requirements;

g. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that Otsuka's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;

h. funding of or participation in, any Third Party Educational Activity as defined in Section II.C.5 above. These Policies and Procedures shall be designed to ensure that Otsuka's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements.

The Policies and Procedures shall require that: 1) to the extent feasible consistent with subsection 5 below, Otsuka disclose its financial support of the Third Party Educational Activity and any financial relationships with faculty, speakers, or organizers at such Activity; 2) as a condition of funding, the third party shall agree to disclose Otsuka's financial support of the Third Party Educational Activity and any financial relationships that Otsuka might have with faculty, speakers, or organizers at such Activity; 3) as a condition of funding, the third party shall require any faculty, speakers, or organizers at the Third Party Educational Activity to disclose any financial relationship with Otsuka; 4) any Third Party Educational Activity have an educational focus; 5) the content, organization, and operation of the Third Party Educational Activity be independent of Otsuka control; 6) Otsuka support only Third Party Educational Activity that is non-promotional in tone/nature; and 7) Otsuka support of a Third Party Educational Activity be contingent on the provider's commitment to provide information at the Educational Activity that is fair, balanced, accurate and not misleading;

i. review of promotional materials by legal and medical personnel and the review of other materials and information intended to be

disseminated outside Otsuka in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Otsuka's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information, when finally approved, comply with all applicable Federal health care program and FDA requirements;

j. sponsorship or funding of research or related activities. These Policies and Procedures shall be designed to ensure that Otsuka's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;

k. compensation (including salaries and bonuses) for Covered Persons. These Policies and Procedures shall be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Otsuka's products;

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

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

C. Training and Education.

1. *General Training*. Within 120 days after the Effective Date Otsuka shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Otsuka's:

a. CIA requirements; and

b. Otsuka's Compliance Program (including the Business Conduct Policy and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

To the extent that General Training provided to Covered Persons during the 180 days prior to the Effective Date satisfies the requirements of Section III.C.1.b above, the OIG shall credit the training toward the training requirements set forth in this Section III.C.1 for the first Reporting Period. In such an instance, Otsuka may satisfy its remaining General Training obligation for those Covered Persons who receive training as described above by notifying the Covered Persons in writing of the fact that Otsuka entered a CIA and notifying them of Otsuka's requirements and obligations under the CIA.

2. *Specific Training*. Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of Specific Training in addition to the General Training required above.

This Specific Training shall include a discussion of:

a. all applicable Federal health care program requirements relating to Promotional and Product Services Related Functions;

b. all applicable FDA requirements relating to Promotional and Product Services Related Functions;

c. all Otsuka policies, procedures, and other requirements applicable to Promotional and Product Services Related Functions;

d. the personal obligation of each individual involved in Promotional and Product Services Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;

e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and

f. examples of proper and improper practices related to Promotional and Product Services Related Functions.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. An Otsuka employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to Promotional and Product Services Related Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

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

To the extent that Otsuka provided Specific Training to Relevant Covered Persons during the 180 days immediately prior to the Effective Date that satisfied the requirements set forth in Section III.C.2 above, the OIG shall credit that training for purposes of satisfying Otsuka's Specific Training obligations as described in this Section III.C.2 for the first Reporting Period.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date

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

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

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

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

D. Review Procedures.

1. *General Description.*

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

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

The IRO(s) shall conduct reviews that assess Otsuka's systems, processes, policies, procedures, and practices relating to Promotional and Product Services Related Functions (Promotional and Product Services Review).

b. *Frequency and Brief Description of Review.* As set forth more fully in Appendix B, the Promotional and Product Services Review shall consist of two components - a Systems Review and a Transactions Review. If there are no material changes in Otsuka's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the Promotional and Product Services Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If Otsuka materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods.

Based on information provided, and representations made, to the OIG about the products actively promoted by Otsuka as of the Effective Date of the CIA and the manner in which the promotion is conducted, Otsuka shall not be required to perform Promotional and Product Services Transactions Reviews unless Otsuka changes the products it actively promotes and/or its manner of promoting the products. Prior to beginning to actively promote any additional products and/or prior to changing the manner in which it promotes any products, Otsuka shall notify the OIG and provide specific information about the products and/or manner of promotion to be changed. After reviewing the information provided by Otsuka and engaging in a dialogue with Otsuka about the issue, the OIG shall determine whether to require a Promotional and Product Services Transaction Review in any remaining Reporting Period(s) of the CIA. If the OIG determines that such Reviews are appropriate, Otsuka shall retain an IRO to perform the Promotional and Product

Services Transaction Review(s) annually in a manner consistent with Appendix B.

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

2. *IRO Review Reports.* The IRO(s) shall prepare a report based upon each Review performed. The information and content to be included in the report is described in Appendix B, which is incorporated by reference.

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

Prior to initiating a Validation Review, OIG shall notify Otsuka of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Otsuka may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. Otsuka agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with Otsuka prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

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

to the applicable Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

To the extent not already accomplished, within 90 days after the Effective Date, Otsuka shall establish a Disclosure Program that includes a mechanism (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 Otsuka'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. Otsuka 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 nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Otsuka shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

F. Ineligible Persons.

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

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).

c. "Screened Persons" include: prospective and current owners of Otsuka (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading); and prospective and current officers, directors, employees, and contractors and agents of Otsuka.

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

a. Otsuka shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons.

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

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

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

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

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

G. Notification of Government Investigation or Legal Proceedings.

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

H. Reporting.

1. *Reportable Events.*

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

i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or applicable to any FDA requirements relating to the promotion of Otsuka products for which penalties or exclusion may be authorized; or

ii. the filing of a bankruptcy petition by Otsuka.

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

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

i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program and/or FDA authorities implicated;

ii. a description of Otsuka's actions taken to correct the Reportable Event; and

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

iv. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities and/or FDA authorities implicated.

I. Notification of Communications with FDA.

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

J. Field Force Monitoring.

Otsuka currently has a field visit monitoring program to evaluate and monitor sales representatives' interactions with HCPs. Under this program, each District Manager annually conducts 8 to 10 field visits with each sales representative in the District Manager's region. Field visits may extend over a two-day period, depending on the territory. During each field visit, the District Manager conducts a compliance review (for which District Managers receive training) and, following each visit, completes a Compliance Checklist. The District Manager records on the Checklist whether the physician who was visited treats patients with the approved indications for the product. If not, the District Manager must notify the Vice President, Sales and request that the physician be removed from the call list, and must instruct the sales representative to discontinue calling on the physician. The District Manager also records on the Checklist whether the District Manager reviewed the importance of promotional compliance with the representative prior to the physician visit.

Otsuka shall continue this field visit monitoring program during the term of the CIA except that the program shall be revised such that, where a District Manager finds

that a physician who was visited does not treat patients with the approved indication(s) for the product, the District Manager shall notify the Compliance Officer in addition to the Vice President, Sales. In addition, the Compliance Officer shall develop and implement a sales representative compliance observation program under which Otsuka Compliance staff will accompany a sales representative and observe all of his or her visits with HCPs during a full workday. During each Reporting Period, the Compliance Officer will randomly select at least ten Otsuka sales representatives across the U.S. for full-day compliance observation, at least six of which shall be sales representatives who detail Abilify. The other four sales representatives shall be representatives who detail other products. At the completion of each compliance observation, Otsuka Compliance staff shall prepare a report which includes: (1) the name of the sales representative; (2) the name of the Compliance staff person; (3) the date and duration of the compliance observation; (4) the product(s) promoted during the compliance observation; (5) an overall assessment of the sales representatives' compliance with Otsuka compliance policy; and (6) the identification of any potential off-label promotional activity by the sales representative. Otsuka shall include a summary of the compliance observations in each Annual Report.

In the event that a compliance issue, including potential off-label promotion, is identified during a compliance observation or by a District Manager during a field visit, Otsuka will investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken. The Compliance Officer shall disclose Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during a compliance observation and any corrective action shall be recorded in the records of the Compliance Department.

As part of each Annual Report, Otsuka shall provide the OIG with copies of the compliance observation reports or District Manager field visit reports in any instances in which it was determined that improper promotion occurred and a description of the action(s) that Otsuka took as a result of such determinations. Otsuka shall make the reports for all other compliance observations and District Manager field visits reports available to the OIG upon request.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Otsuka changes locations or closes a business unit or location related to Promotional and Product Services Related Functions, Otsuka shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Otsuka purchases or establishes a new business unit or location related to Promotional and Product Services Related Functions, Otsuka shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider or supplier number (if applicable), and the name and address of the contractor that issued each number (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Otsuka proposes to sell any or all of its business units or locations that are subject to this CIA, Otsuka shall notify OIG of the proposed sale at least 30 days prior to the sale of such business unit or location. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

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

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

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

3. a copy of Otsuka's Business Conduct Policy required by Section III.B.1;

4. to the extent not already provided to the OIG, a copy of all Policies and Procedures required by Section III.B.2;

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

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

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

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

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

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

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

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

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

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

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

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

14. the certifications required by Section V.C.

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

Each Annual Report shall include, at a minimum:

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

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

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

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

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

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

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

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

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

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

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

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

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

11. any changes to the process by which Otsuka fulfills the requirements of Section III.F regarding Ineligible Persons;

12. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by Otsuka in response to the

screening and removal obligations set forth in Section III.F;

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

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

15. all information required by Section III.J;

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

17. the certifications required by Section V.C.

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

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

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

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

3. to the best of his or her knowledge, Otsuka has complied with its

obligations under the Settlement Agreement: (a) 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; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

4. Otsuka's: 1) Policies and Procedures as referenced in Section III.B.2 above; 2) templates for the standardized contracts and other similar documents; and 3) training materials used for purposes of Section III.C, above 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 and legal requirements. In addition, Otsuka's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Otsuka have been reviewed by competent legal counsel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed and elevated when required, and that the materials and information when finally approved are in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other applicable laws and legal requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

5. Otsuka's call plans for those Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.2.e) and, the call plans were found to be consistent with Otsuka's policy objectives as referenced above in Section III.B.3.e.

D. Designation of Information. Otsuka shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Otsuka shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

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

OTSUKA: Sheila A. Cleary
Chief Compliance Officer
Otsuka America Pharmaceutical, Inc.
2440 Research Blvd.
Rockville, MD 20850
Telephone: 240.683.3049
Facsimile: 301.721.7049

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract,

OIG or its duly authorized representative(s) may examine or request copies of Otsuka's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Otsuka's locations for the purpose of verifying and evaluating: (a) Otsuka's compliance with the terms of this CIA; and (b) Otsuka's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Otsuka 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 Otsuka's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Otsuka shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Otsuka's employees may elect to be interviewed with or without a representative of Otsuka present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Otsuka and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Otsuka fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. the training of Covered Persons;

f. a Disclosure Program;

g. Ineligible Persons screening and removal requirements;

h. notification of Government investigations or legal proceedings;

i. notification of communications with FDA regarding promotion matters; and

j. the Field Force Monitoring obligations described in Section III.J.

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 Otsuka fails to engage an IRO, as

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

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

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Otsuka fails to submit the annual IRO Review Report(s) in accordance with the requirements of Section III.D and Appendices A-B.

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

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

7. A Stipulated Penalty of $1,000 for each day Otsuka fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Otsuka, stating the specific grounds for its determination that Otsuka has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Otsuka shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Otsuka receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. Otsuka may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Otsuka fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the

notification or report shall not begin to accrue until three business days after Otsuka 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 Otsuka 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 Otsuka of: (a) Otsuka's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Otsuka 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 Otsuka elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Otsuka 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 Otsuka has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

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

a. a failure by Otsuka to report a Reportable Event and take corrective action, as required in Section III.H;

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

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

d. a failure to engage and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Otsuka constitutes an independent basis for Otsuka's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Otsuka has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Otsuka of: (a) Otsuka'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.* Otsuka 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. Otsuka is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Otuska fails to satisfy the requirements of Section X.D.3, OIG may exclude Otsuka from participation in the Federal health care programs. OIG shall notify Otsuka in writing of its determination to exclude Otsuka (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 Otsuka's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Otsuka may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Otsuka 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, Otsuka shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Otsuka was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Otsuka shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Otsuka to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Otsuka

requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether Otsuka 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) Otsuka had begun to take action to cure the material breach within that period; (ii) Otsuka has pursued and is pursuing such action with due diligence; and (iii) Otsuka provided to OIG within that period a reasonable timetable for curing the material breach and Otsuka 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 Otsuka, only after a DAB decision in favor of OIG. Otsuka's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Otsuka upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Otsuka 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. Otsuka shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Otsuka, Otsuka shall be reinstated effective on the date of the original exclusion.

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

XI. EFFECTIVE AND BINDING AGREEMENT

Otsuka and OIG agree as follows:

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

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

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

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

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

ON BEHALF OF OTSUKA AMERICA PHARMACEUTICAL, INC.

吉川博己

March 24, 2008

Name: Hiromi Yoshikawa
Title: Chairman & CEO/President & COO
Otsuka America Pharmaceutical Inc.

Date

Sheila A. Cleary

March 24, 2008

Sheila A. Cleary
Chief Compliance Officer
Otsuka America Pharmaceutical, Inc.

Date

Alan M. Kirschenbaum
Douglas Farquhar
Counsel for Otsuka America Pharmaceutical, Inc.

Date

ON BEHALF OF OTSUKA AMERICA PHARMACEUTICAL, INC.

_____ _____

Name: Date
Title:
Otsuka America Pharmaceutical Inc.

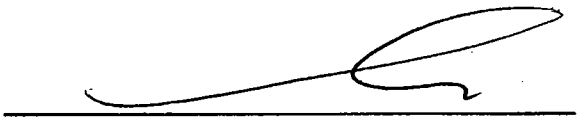
_____ _____

Sheila A. Cleary Date
Chief Compliance Officer
Otsuka America Pharmaceutical, Inc.

_____ March 20, 2008

Alan M. Kirschenbaum Date
Douglas Farquhar
Counsel for Otsuka America Pharmaceutical, Inc.

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



3/25/08

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

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

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

If Otsuka engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Otsuka shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Otsuka if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Otsuka may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

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

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

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

C. IRO Responsibilities.

The IRO shall:

1. perform each Promotional and Product Services Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in each Promotional and Product Services Review;

3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy, or regulation, request clarification from the appropriate authority (e.g., CMS or FDA);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity.

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

E. IRO Removal/Termination.

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

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

Prior to requiring Otsuka to engage a new IRO, OIG shall notify Otsuka of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Otsuka may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Otsuka shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Otsuka prior to requiring Otsuka to terminate the

IRO. However, the final determination as to whether or not to require Otsuka to engage a new IRO shall be made at the sole discretion of OIG.

Appendix B to CIA for Otsuka America Pharmaceutical, Inc.
Promotional and Product Services Review

I. Promotional and Product Services Review, General Description

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

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

As set forth in Section III.D.1.b of the CIA, based on information provided, and representations made, to the OIG about the products actively promoted by Otsuka as of the Effective Date of the CIA and the manner in which the promotion is conducted, Otsuka shall not be required to perform Promotional and Product Services Transactions Reviews unless Otsuka changes the products it actively promotes and/or its manner of promoting the products. Prior to beginning to actively promote any additional products and/or prior to changing the manner in which it promotes any products, Otsuka shall notify the OIG and provide specific information about the products and/or manner of promotion to be changed. After reviewing the information provided by Otsuka and engaging in a dialogue with Otsuka about the issue, the OIG shall determine whether to require a Promotional and Product Services Transaction Review in any remaining Reporting Period(s) of the CIA. If the OIG determines that such Reviews are appropriate, the IRO shall

perform the Promotional and Product Services Transaction Review(s) annually in a manner consistent with Section III of this Appendix B.

II. Promotional and Product Services Systems Review

A. Description of Reviewed Policies and Procedures

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

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

1) Otsuka's systems, policies, processes, and procedures applicable to the manner in which Otsuka representatives (including sales representatives and/or medical personnel (*e.g.*, personnel from Otsuka's medical affairs or medical personnel offices)) handle requests or inquiries relating to information about the uses of Otsuka products (including non-FDA-approved (*i.e.*, off-label) uses) and the dissemination of materials relating to off-label uses of products. This review includes:

a) the manner in which Otsuka sales representatives and marketing personnel handle requests for information about off-label uses of Otsuka products (*i.e.*, by referring all such requests to medical personnel at Otsuka, or, in the case of Abilify, to Bristol-Meyers Squibb Company (BMS));

b) the manner in which medical personnel, including those at Otsuka's headquarters, handle and respond to requests for information about off-label uses of Otsuka products (including tracking the requests and using pre-approved materials for purposes of responding to the request);

c) the form and content of information and materials disseminated by Otsuka;

d) Otsuka's systems, processes, and procedures (including the Inquiries Database) to track requests for information about off-label uses of products and responses to those requests;

e) the manner in which Otsuka collects and supports information reported in any database(s) including its Inquiries Database;

f) the processes and procedures by which the Compliance Officer (and other appropriate individuals within Otsuka) identify situations in which it appears that improper off-label promotion may have occurred; and

g) Otsuka's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving off-label promotion;

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

3) Otsuka's systems, policies, processes, and procedures relating to Otsuka's internal review and approval of information and materials disseminated by Otsuka;

4) Otsuka's systems, polices, processes and procedures relating to incentive compensation for Covered Persons who are sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Otsuka's products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance; and

6) Otsuka's systems, processes, policies, and procedures relating to the development and review of call plans for Otsuka's sales personnel. This shall include a review of the bases upon which HCPs belonging to specified medical specialties are included in, or

excluded from, the call plans based on expected utilization of the Otsuka products for FDA-approved uses or non-FDA-approved uses.

B. Promotional and Product Services Systems Review Report

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

1) a description of the documentation (including policies) reviewed and any personnel interviewed;

2) a detailed description of Otsuka's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-6 above, including a general description of Otsuka's control and accountability systems (*e.g.*, documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-6 above are made known or disseminated within Otsuka;

4) a detailed description of any system(s) used to track and respond to requests for information about Otsuka's products (including the Inquiries Database);

5) a detailed description of Otsuka's incentive compensation system for Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Otsuka may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

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

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

III. Promotional and Product Services Transaction Review

As described more fully below in Sections III.A-B, the Promotional and Product Services Transactions Review shall include a review of a sample of Inquiries reflected in Otsuka's Inquiries Database and a review of Otsuka's call plan assessments. The IRO shall report on all aspects of its reviews in the Promotional and Product Services Transactions Review Reports.

A. Review of Inquiries and Inquiries Information

1) Information Contained in Inquiries Database

As set forth in Section III.B.2.d of the CIA, Otsuka shall establish a database to track information relating to requests for information received by Otsuka about its products (hereafter "Inquiries"). Specifically, Otsuka shall document and record all Inquiries received from HCPs or HCIs regarding Otsuka's products in a database (the "Inquiries Database"). Otsuka shall record in the Inquiries Database the following information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (*e.g.*, fax, phone, medical information request form); 3) name of requesting HCP or HCI; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label use of the product; 6) nature/form of the response from Otsuka (including a record of any materials provided in response to the request); 7) the name of the Otsuka representative who called upon or interacted with the HCP or HCI; and 8) the status and findings of any follow-up review conducted by Otsuka in situations in which improper off-label promotion is suspected.

2) Internal Review of Inquiries Database

On a semi-annual basis, the Compliance Officer or other appropriate personnel shall review the Inquiries Database and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters ("Inquiry Report"). The Compliance Officer shall review the Inquiry Reports to assess whether the information contained in the report suggests that improper off-label promotion may have occurred in connection with any Inquiry (ies). If the Compliance Officer, in consultation

with other appropriate Otsuka personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, the Compliance Officer shall undertake a follow-up review of the Inquiry (Off-Label Review), make specific findings based on his/her Off-Label Review, and take all appropriate responsive action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.H of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of 60 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. 45 of the Inquiries reviewed by the IRO shall be Inquiries for which Otsuka conducted an Off-Label Review, and the other 15 shall be Inquiries for which Otsuka did not conduct an Off-Label Review. For each Inquiry reviewed, the IRO shall determine:

a) Whether each item of information listed above in Section III.A.1 is reflected in the Inquiries Database for each reviewed Inquiry; and

b) For each Inquiry for which the Compliance Officer conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by Otsuka based on the Compliance Officers' findings.

B. IRO Review of Otsuka's Call Plan Assessments

The IRO shall conduct a review and assessment of Otsuka's review of its call plans for Government Reimbursed Products as set forth in Section III.B.3.e of the CIA. Otsuka shall provide the IRO with: i) a list of products promoted by Otsuka during the Reporting Period; ii) information about the FDA-approved uses for each Otsuka product; and iii) the call plans for each product. Otsuka shall also provide the IRO with information about the reviews of call plans that Otsuka conducted during the Reporting Period and any modifications to the call plans made as a result of Otsuka's reviews.

For each call plan, the IRO shall select a sample of 30 of the HCPs and HCIs included on the call plan. For each call plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (*e.g.*, medical specialty or practice

area) used by Otsuka in conducting its review and/or modification of the call plan in order to determine whether Otsuka followed its criteria and Policies and Procedures in reviewing and modifying the call plan.

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

C. Promotional and Product Services Transactions Review Report

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

1) General Elements to Be Included in Report

   a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;

   b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and

   c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Promotional and Product Services Transactions Review.

2) Results to be Included in Report

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

   a) in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (*e.g.,* the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;

b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the Inquiries Database;

c) for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the Inquiries Database; and (ii) for each Inquiry for which the Compliance Officer conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by Otsuka as a result of the Compliance Officer's findings;

d) the findings and supporting rationale regarding any weaknesses in Otsuka's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

e) recommendations for improvement in Otsuka's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

f) a list of the products promoted by Otsuka during the Reporting Period and a summary of the FDA-approved uses for such products;

g) for each Otsuka product: i) a description of the criteria used by Otsuka in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans; ii) a description of the review conducted by Otsuka of the call plans and an indication of whether Otsuka reviewed the call plans as required by Section III.B.3.e of the CIA; iii) a description of all instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are inconsistent with Otsuka's criteria relating to the call plan and/or Otsuka's Policies and Procedures; and iv) a description of all instances in which it appears that Otsuka failed to follow its criteria or Policies and Procedures relating to call plans; and

h) the findings and supporting rational regarding any weaknesses in Otsuka's systems, processes, policies, procedures, and practices relating to Otsuka's call plans, if any; and

i) recommendations, if any, for changes in Otsuka's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect call plans.