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

I. PREAMBLE

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

Prior to the investigation of InterMune by the United States, InterMune established a comprehensive voluntary compliance program (Compliance Program), which includes a corporate Compliance Officer and Compliance Committee, a Code of Conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program, and internal review procedures designed, as represented by InterMune, to promote compliance with applicable laws and the promotion of high ethical standards.

InterMune shall continue the operation of the Compliance Program in accordance with the terms set forth below for the term of this CIA. InterMune may modify its Compliance Program as appropriate, but, at a minimum, InterMune shall ensure that during the term of this CIA, it shall comply with the integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by InterMune under this CIA shall be 5 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) InterMune's final Annual Report; or (2) any additional materials submitted by InterMune 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 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 InterMune; and

b. all contractors, subcontractors, agents, and other persons who perform sales, marketing, promotional, pricing, government contract, and research and development activities (except preclinical researchers and clinical investigators) on behalf of InterMune.

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

2. "Relevant Covered Persons" includes all Covered Persons of InterMune whose job responsibilities relate to the provision of information about or services relating to InterMune's products; distribution of Actimmune or other InterMune products; research and development (except preclinical researchers and clinical investigators); or the sales, marketing, or promotion of InterMune's products (hereafter collectively referred to as "Product Services Related Functions.") This includes, but is not limited to, Medical Science Liaisons, and any individuals who work in the following areas: Clinical Affairs, Medical Affairs, Regulatory, Legal Affairs, Corporate Compliance, Corporate Administration, and Commercial Operations.[1]

3. "Third Party Personnel" shall mean personnel of the entities with whom InterMune has or may, in the future, enter agreements to distribute and purchase its products, joint venture agreements and/or other agreements to co-market its products. InterMune has represented that: 1) Third Party Personnel are employed by other independent entities; 2) InterMune does not control Third Party Personnel; and 3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. However, InterMune agrees to use its best efforts to promote compliance by Third Party Personnel with Federal health care program and FDA requirements as set forth below in Sections III.B and V.

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

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[1] If there are future changes in the organizational structure of InterMune, individuals who undertake the functions of the specific groups enumerated in the preceding sentence shall be considered Relevant Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

To the extent not already accomplished, InterMune shall maintain a Compliance Program throughout the term of this CIA that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* InterMune presently has a Compliance Officer with responsibility for administering InterMune's Compliance Program. InterMune shall continue to employ an individual to serve as its 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 InterMune, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of InterMune, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall also have the option of reporting any matter directly to the CEO. 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 InterMune as well as for any reporting obligations created under this CIA.

InterMune 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, InterMune established a Compliance Committee, and InterMune shall maintain the 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 Clinical Affairs, Medical Affairs, Regulatory, Legal Affairs, Corporate Compliance, Corporate Administration, and Commercial Operations.) The Compliance Officer shall chair the Compliance Committee. The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

InterMune 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, InterMune established a written Code of Conduct applicable to all Covered Persons. InterMune shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. InterMune's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, and advertise its products in accordance with such requirements;

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

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

d. the possible consequences to both InterMune and Covered Persons of failure to comply with Federal health care program and FDA requirements and with InterMune'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 InterMune'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, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by InterMune's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, InterMune shall send a letter to all entities which employ Third Party Personnel. The letter shall outline InterMune's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of InterMune's Compliance Program. InterMune shall attach a copy of its Code of Conduct to the letter and shall ask that the other entity either: (a) make a copy of InterMune's Code of Conduct and the description of InterMune's Compliance Program available to all relevant personnel within its organization; or (b) represent to InterMune that it has and enforces a substantially comparable Code of Conduct and Compliance Program for relevant persons within its organization.

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

Distribution may include publishing the Code of Conduct on InterMune's intranet or other internal web site available to all employees. If InterMune uses such an electronic method of distribution, it must notify the individuals receiving the Code of Conduct that the Code of Conduct will be distributed in such a manner and InterMune must monitor the distribution to ensure that all appropriate individuals received the Code of Conduct.

2. *Policies and Procedures.* To the extent not already accomplished, within 90 days after the Effective Date, InterMune shall implement written Policies and Procedures regarding the operation of InterMune's Compliance Program and its compliance with Federal health care program and FDA requirements. At a minimum, the Policies and Procedures shall address:

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

b. selling, marketing, and promoting InterMune products in compliance with all applicable Federal health care program requirements, including, but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1320a-7b(b);

c. selling, marketing, promoting, advertising, and disseminating information about InterMune's products in compliance with all applicable FDA requirements, including procedures governing the response to requests for information about off-label uses;

d. compensation (including salaries and bonuses) for Covered Persons that are designed to ensure that financial incentives do not inappropriately motivate sales and marketing personnel to engage in the improper promotion, sales, and marketing of InterMune's products;

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

f. appropriate mechanisms by which Medical Affairs receives and responds to requests for information about off-label uses of InterMune's products, including but not limited to, the following: the form and content of information disseminated by Medical Affairs in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that InterMune develop a database (the Medical Affairs Inquiries Database) that includes the following items of information for each unique inquiry (Inquiry) received for information about InterMune's products: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of the requesting health care professional (HCP); 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 InterMune (including a record of the materials provided to the

HCP in response to the request); 7) the name of the InterMune representative who called on or interacted with the HCP; and 8) the status and findings of any follow-up review conducted by InterMune in situations in which it appears that the Inquiry may have related to improper off-label promotion;

g. speaker programs, advisory board programs, focus group programs, and all other consultant arrangements. These policies shall be designed to ensure that the consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The policies shall include requirements about the uses, content, and circumstances of such arrangements and events;

h. funding of, or participation in, any Educational or Informational Activity as defined in Section II.C.4 above (e.g., third party educational grants or sponsorship for CME or other third-party educational programs or events). These Policies and Procedures shall be designed to ensure that InterMune's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements related to the sponsorship of any Educational or Informational Activity.

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

i. funding of charitable grants or sponsorships in a manner that is designed to ensure that InterMune's funding complies with all applicable Federal health care program requirements and FDA requirements; and

j. sponsorship or funding of research activities (including clinical trials, market research, or authorship of articles or other publications) by InterMune in a manner that is designed to ensure that InterMune's funding or sponsorship of such activities complies with all applicable Federal health care program and FDA requirements. In addition, such Policies and Procedures shall ensure that sales and marketing activities are separate from clinical trial enrollment.

To the extent not already accomplished, within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

Distribution may include publishing such Policies and Procedures on InterMune's intranet or other internal web site available to all employees. If InterMune uses such an electronic method of distribution, it must notify the individuals receiving the Policies and Procedures that the Policies and Procedures will be distributed in such a manner and InterMune must monitor the distribution to ensure that all appropriate individuals received the Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

C. Training and Education.

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

a. CIA requirements;

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

c. in general, the proper methods of promoting, marketing, selling, conducting research (including clinical trials), and disseminating information about InterMune's products in accordance with Federal health care program and FDA requirements.

To the extent that General Training provided to Covered Persons during the 90 days immediately prior to the execution of this CIA satisfies the requirements of Sections III.C.1.b-c, above, the OIG shall credit the training toward the training requirements set forth in this Section III.C.1 for the first Reporting Period. InterMune may satisfy its remaining General Training obligation for those Covered Persons who received training as described above by notifying the Covered Persons of the fact that InterMune entered a CIA and notifying them of InterMune's requirements and obligations under the CIA.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

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

a. all Federal health care program requirements relevant to the proper methods for selling, marketing, promoting, and providing information about

InterMune's products, including, but not limited to, the requirements of the Federal anti-kickback statute; the Civil Monetary Penalties Law; the civil False Claims Act; and the Medicaid Drug Rebate statute;

b. all applicable FDA requirements relevant to promotion, marketing, research (including clinical trials), and dissemination of information about InterMune's products including but not limited to, the requirements of the Federal Food, Drug, and Cosmetic Act and FDA regulations;

c. the personal obligation of each Relevant Covered Person involved in Product Services Related Functions to comply with all applicable legal requirements;

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

e. examples of proper and improper practices relating to Product Services Related Functions.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. An InterMune employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to Product Services Related Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

To the extent that Specific Training provided to Relevant Covered Persons during the 90 days immediately prior to the execution of this CIA satisfies the requirements of this Section III.C.2, the OIG shall credit the training toward the Specific Training requirements for the first Reporting Period.

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.

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

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

5. *Update of Training.* InterMune shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program or FDA

requirements, any issues discovered during internal audits or any of the IRO Reviews, and any other relevant information.

6. *Computer-based Training.* InterMune may provide the training required under this CIA through appropriate computer-based training approaches. If InterMune 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, InterMune shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a Promotional and Product Services Engagement. Each IRO engaged by InterMune shall have expertise in Federal health care program and FDA requirements applicable to the Promotional and Product Services Engagement. Each IRO shall assess, along with InterMune, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

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

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

If there are no material changes in InterMune's systems, processes, policies, and practices relating to Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for two Reporting Periods to be selected by the OIG. As set forth in Appendix B, if InterMune materially changes its systems, processes, policies, and practices relating to Product Services Related Functions, then the IRO shall perform a Promotional and Product Services Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the two Reporting Periods selected by the OIG.

The OIG will select the Reporting Periods in which the Systems Reviews shall be conducted based, in part, on information provided by InterMune about the

size of InterMune, the nature of the functions undertaken by InterMune employees *e.g.* sales and marketing activities, research activities, *etc.*), the number of products that InterMune is actively marketing, and other aspects of InterMune's business. InterMune shall report such information to the OIG 90 days prior to the end of each Reporting Period. The OIG shall review the information submitted and shall notify InterMune at least 30 days prior to the end of each Reporting Period whether InterMune shall be required to retain an IRO to conduct a Systems Review in the next upcoming Reporting Period. The OIG will not require a Systems Review in the first Reporting Period.

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

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

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

Prior to initiating a Validation Review, OIG shall notify InterMune 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, InterMune may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the Review in question or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. InterMune agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with InterMune prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. Independence/Objectivity Certification. The IRO shall include in its report(s) to InterMune a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the applicable Review and that it has concluded that it is, in fact, independent and/or objective.

E. Disclosure Program.

Prior to the Effective Date, InterMune established a disclosure program designed to facilitate communications relating to compliance with Federal health care program and FDA requirements and with InterMune's policies (Disclosure Program). During the term of this CIA, InterMune shall continue to maintain a Disclosure Program that includes a mechanism e.g. the toll-free Code of Conduct Ethics Helpline) 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 InterMune's policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. InterMune shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall continue to emphasize a nonretribution, nonretaliation policy, and shall continue to 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, InterMune 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 continue to maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

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

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

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

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

b. "Exclusion Lists" include:

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

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

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

2. *Screening Requirements.* InterMune has a policy to not hire or engage as a Covered Person any Ineligible Person, and it shall maintain that policy during the term of the CIA. InterMune shall continue to ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

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

c. InterMune 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) InterMune to refrain (if applicable) from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. InterMune understands that items or services furnished by excluded persons are not payable by Federal health care programs and that InterMune may be liable for overpayments and/or criminal, civil and administrative sanctions for employing or contracting with an excluded person regardless of whether InterMune meets the requirements of Section III.F.

3. *Removal Requirement.* If InterMune has actual notice that a Screened Person has become an Ineligible Person, InterMune shall remove such Screened Person from responsibility for, or involvement with, InterMune'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 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 InterMune 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, InterMune shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

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

H. Notification of Reportable Event.

1. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program, and/or applicable to any FDA requirements relating to the promotion of prescription drugs for which penalties or exclusion may be authorized. A Reportable Event may be the result of an isolated event or a series of occurrences.

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

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

b. a description of InterMune's actions taken to correct the Reportable Event; and

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

I. Notification of Communications with FDA.

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

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

InterMune has represented that, as of the Effective Date, it does not currently have employees or agents engaged in the direct promotion of any product. If, in the future, InterMune reestablishes a sales force for the direct promotion of Actimmune or any other product, InterMune agrees to obtain non-InterMune records (*e.g.*, Verbatims or similar records) generated by an independent entity (Survey Entity) reflecting the purported content and subject matter of detailing interactions between sales representatives and HCPs for up to three InterMune products. In order to satisfy its obligations under this Section III.J, InterMune may propose that it obtain an alternative type of survey record (*e.g.*, message recall studies) rather than the records of the detailing sessions. The OIG will consider InterMune's proposal, and, after considering InterMune's proposal, shall, in its discretion, identify the type of survey records to be obtained.

Prior to the re-establishment of any sales force, InterMune shall notify the OIG of this development and provide specific information about the sales staff and InterMune's products to the OIG. After reviewing the information provided by InterMune and engaging in a dialogue with InterMune about the issue, the OIG shall provide more specific information to InterMune about the requirements of this Section III.J. The OIG shall have the discretion to establish the specific requirements of this Section III.J consistent with the provisions set forth herein. However, in general terms, this Section III.J will require InterMune to contract with a Survey Entity to conduct inquiries into the content and subject matter of the detailing interactions (or alternate types of inquiries as proposed by InterMune) between InterMune sales personnel and HCPs for each Reporting Period in which InterMune has such a sales force. For each product designated by the OIG (Covered Product), InterMune shall obtain records reflecting the purported content and subject matter of detailing sessions (or alternate types of records) in all regions across the United States.

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

IV. NEW BUSINESS UNITS OR LOCATIONS

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