UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

July 13, 2007
Date of Report (Date of earliest event reported)

JAZZ PHARMACEUTICALS, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**001-33500**	**05-0563787**
(State or Other Jurisdiction of Incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

3180 Porter Drive, Palo Alto, California 94304
(Address of principal executive offices, including zip code)

(650) 496-3777
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry into a Material Definitive Agreement.

On July 13, 2007, Jazz Pharmaceuticals, Inc. entered into (i) a civil settlement agreement (the "Civil Settlement Agreement") with the United States of America, acting through the United States Department of Justice, the United States Attorney's Office for the Eastern District of New York, the Office of Inspector General of the Department of Health and Human Services ("HHS-OIG"), the United States Office of Personnel Management and the United States Department of Defense TRICARE Management Activity to resolve the previously-disclosed governmental investigation related to the promotion of Xyrem® (sodium oxybate) and (ii) a non-prosecution agreement with the United States Attorney's Office for the Eastern District of New York (the "Non-prosecution Agreement") under which the United States Attorney's Office agreed that Jazz Pharmaceuticals would not be prosecuted for the matters that were the subject of the investigation. Orphan Medical, Inc., which was acquired by Jazz Pharmaceuticals in June 2005, entered into (i) a plea agreement with the United States Attorney's Office for the Eastern District of New York (the "Plea Agreement"), under which Orphan Medical pled guilty, on July 13, 2007, to one felony count of introducing a misbranded drug into interstate commerce and (ii) the Civil Settlement Agreement. Jazz Pharmaceuticals expects that it and Orphan Medical will also enter into agreements with Medicaid participating states.

Pursuant to the Civil Settlement Agreement and the Plea Agreement, payments totaling approximately $20.0 million will be made over the period from July 20, 2007 through January 15, 2012. This amount includes payments to Federal healthcare programs and Medicaid participating states, as well as restitution and fines. In addition, under the Non-prosecution Agreement, Jazz Pharmaceuticals has agreed to guarantee payment by Orphan Medical of the amounts due under the Plea Agreement. The total payments due under the Civil Settlement Agreement and the Plea Agreement are payable as follows: $1.0 million in 2007; $2.0 million in 2008; $2.5 million in 2009; $3.0 million in 2010; $3.0 million in 2011 and $8.5 million in 2012. All remaining amounts due under the Civil Settlement Agreement could be accelerated if Jazz Pharmaceuticals is acquired, or in the event of an uncured default resulting from the failure to make payments when due. In addition, all or a portion of the remaining amounts due under the Civil Settlement Agreement could be accelerated if Jazz Pharmaceuticals has net income in any year. Orphan Medical, which no longer directly markets products, may be excluded from participation in Federal healthcare programs as a result of the settlement.

Jazz Pharmaceuticals has also entered into a five-year corporate integrity agreement with HHS-OIG (the "Corporate Integrity Agreement") pursuant to which Jazz Pharmaceuticals has agreed, among other things, to keep in place and continue its current compliance program, including a compliance committee, a compliance officer, a code of conduct, comprehensive compliance policies, training and monitoring, a compliance hotline, an open door policy and a disciplinary process for compliance violations. Jazz Pharmaceuticals will provide periodic reports to HHS-OIG and its compliance program will be reviewed by an independent review organization.

The settlement is neither an admission of liability by Jazz Pharmaceuticals nor a concession by the United States that its claims are not well founded. Participation in Federal healthcare programs by Jazz Pharmaceuticals, which was not prosecuted, will not be affected by the settlement. In the event of an uncured material breach or deliberate violation, as the case may be, of the Civil Settlement Agreement, the Corporate Integrity Agreement or the Non-prosecution Agreement, Jazz Pharmaceuticals could be excluded from participation in Federal healthcare programs and/or subject to prosecution.

The Plea Agreement was approved by the United States District Court for the Eastern District of New York on July 13, 2007.

The foregoing description of the Civil Settlement Agreement, the Non-prosecution Agreement, the Plea Agreement and the Corporate Integrity Agreement is qualified in its entirety by the text of those agreements, which are attached hereto as Exhibits 10.57A, 10.57B, 10.57C and 10.57D, respectively, and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
10.57A	Civil Settlement Agreement, dated July 13, 2007, among the United States of America acting through the entities named therein, Jazz Pharmaceuticals, Inc., and Orphan Medical, Inc.
10.57B	Non-prosecution Agreement, dated July 13, 2007, between the United States Attorney's Office for the Eastern District of New York and Jazz Pharmaceuticals, Inc.
10.57C	Plea Agreement, dated July13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc.
10.57D	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and Jazz Pharmaceuticals, Inc.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

JAZZ PHARMACEUTICALS, INC.

By: /s/ Carol A. Gamble
Carol A. Gamble
Senior Vice President, General Counsel
and Corporate Secretary

Date: July 17, 2007

EXHIBIT INDEX

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10.57C	Plea Agreement, dated July13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc.
10.57D	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and Jazz Pharmaceuticals, Inc.

Exhibit 10.57A

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (the "Agreement") is entered into among the United States of America, acting through its Department of Justice and the United States Attorney's Office for the Eastern District of New York, the Office of Inspector General of the Department of Health and Human Services ("HHS-OIG"), the United States Office of Personnel Management ("OPM"), and the United States Department of Defense TRICARE Management Activity ("TMA") (collectively the "United States"); Jazz Pharmaceuticals, Inc. ("JPI") and Orphan Medical, Inc. ("Orphan") (JPI and Orphan are collectively referred to as "Defendants"); and Shelley Lauterbach (the "Relator"); through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. WHEREAS, at all relevant times, Orphan and JPI distributed, marketed and sold pharmaceutical products in the United States, including a drug it sold under the trade name Xyrem (registered as sodium oxybate);

B. WHEREAS, on or about January 24, 2005, Relator, an individual resident of Alabama and former sales representative for Orphan, filed a qui tam action in the United States District Court for the Eastern District of New York captioned United States of America and the States of California, Delaware, Florida, Hawaii, Illinois, Massachusetts, Nevada, New Mexico, Tennessee, Texas, Virginia, and the District of Columbia ex rel. Lauterbach v. Orphan Medical Inc. and Dr. Peter Gleason, Civil Action No. CV 05-0387 (Feurstein, J.) (Matsumoto, M.J.) (hereinafter "the Civil Action");

C. WHEREAS, on or about June 24, 2005, JPI acquired Orphan, and on or about January 1, 2006, Orphan employees became employees of JPI;

D. WHEREAS, Orphan has agreed to enter into a plea agreement with the United States Attorney for the Eastern District of New York (the "Plea Agreement"), under which, if the Plea Agreement is approved by the Court, Orphan will enter a plea of guilty, pursuant to Fed. R. Crim. P. 11, to an Information to be filed in United States of America v. Orphan Medical Inc. (the "Federal Criminal Action") that will allege that Orphan, together with others, did knowingly and intentionally introduce into interstate commerce, and cause the introduction into interstate commerce of, with the intent to defraud and mislead, a drug, to wit: Xyrem, that was misbranded within the meaning of 21 U.S.C. § 352(f), in that Xyrem was being marketed for medical indications that were not approved by FDA when, as Orphan knew and believed, Xyrem's labeling lacked adequate directions for such uses and adequate warnings against such uses where such uses could be dangerous to the user's health.

E. WHEREAS, JPI has agreed to enter into a non-prosecution agreement with the United States Attorney for the Eastern District of New York;

F. WHEREAS, Defendants have entered into or will be entering into separate settlement agreements, described in Paragraph 1 below, (hereinafter referred to as the "Medicaid State Settlement Agreements") with the states (hereinafter referred to as the "Medicaid Participating States") in settlement of the Covered Conduct;

G. WHEREAS, the United States and the Medicaid Participating States allege that Orphan employees caused claims for payment for Xyrem to be submitted to the Medicaid Programs, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the "Medicaid Program"). The United States further alleges that Orphan employees caused claims for payment

for Xyrem to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg ("Medicare"), the TRICARE program, 10 U.S.C. §§ 1071-1110, which is administered by the Department of Defense through TMA ("TRICARE"), and the Federal Employees Health Benefits Program ("FEHBP"), and caused purchases of Xyrem by the Department of Veterans Affairs ("DVA");

H. WHEREAS, the United States and the Medicaid Participating States contend that they have certain civil claims against Defendants, as specified in Paragraph 2 below, for engaging in the following conduct concerning the marketing, promotion, and sale of Xyrem (hereinafter referred to as the "Covered Conduct"):

> Between January 1, 2003 and December 31, 2005, Orphan employees knowingly and willfully promoted the sale and use of Xyrem for certain uses for which the Food and Drug Administration ("FDA") had not approved Xyrem (i.e., "unapproved" uses). These employees continued this conduct from January 1, 2006 through March 31, 2006. The promotion of Xyrem for these unapproved uses violated the Food Drug and Cosmetic Act, 21 U.S.C. § 331(a), and these unapproved uses were not medically accepted indications for which the United States and State Medicaid programs reimbursed and as a result, Orphan and JPI knowingly caused false and/or fraudulent claims to be submitted to the Medicare, Medicaid, TriCare, and FEHB Programs, and to be purchased by the VA.

I. WHEREAS, the United States contends that it has certain administrative claims against Defendants as specified in Paragraphs 4 through 6 below, for engaging in the Covered Conduct;

J. WHEREAS, this Agreement is neither an admission of facts nor liability by either Defendant (with the exception of such admissions that are made in connection with any guilty plea by Orphan made in connection with the Federal Criminal Action) nor a concession by the United States that its claims are not well founded.

K. WHEREAS, to avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, the Parties reach a full and final settlement pursuant to the Terms and Conditions below.

III. TERMS AND CONDITIONS

1. Defendants agree to pay to the United States and the Medicaid Participating States the sum of $3.75 million plus four percent interest annually pursuant to the payment schedule annexed hereto as Schedule A (the "Settlement Amount").

a. Defendants' payments to the United States (the "Federal Settlement Amount") shall be made by electronic funds transfer in accordance with written instructions provided by the U.S. Attorney's Office, Eastern District of New York

b. Defendants' payments to the Medicaid Participating States (the "State Settlement Amount") shall be made by electronic funds transfer in accordance with the Medicaid State Settlement Agreement that Defendants will enter into with the Medicaid Participating States. In the event that the Medicaid State Settlement Agreement is not finalized when a payment to the Medicaid Participating States becomes due, Defendants shall place that sum in an interest bearing escrow account.

c. Payments by the United States and the Medicaid Participating States to Relator, as provided for by 31 U.S.C. § 3730(d)(1) and any analogous state statutes, are not included in this Agreement, and will be the subject of separate agreements. If the United States and Relator are unable to reach an agreement regarding Relator's share of the Settlement Amount, such disagreement will be resolved by proceedings in the United States District Court

for the Eastern District of New York. Payments made to Relator pursuant to 31 U.S.C. § 3730(d)(1) are contingent upon the United States and the Medicaid Participating States receiving the Settlement Amount payments set forth in Schedule A. It is expressly understood and agreed that the United States and the Medicaid Participating States in no way promise, guarantee, nor are liable to Relator for the collection or payment of any funds pursuant to this Agreement or the payment of Relator's share except as provided herein for funds actually collected and received by the United States.

d. If, for any calendar year, JPI's audited financial statements show net income, Defendants agree, within thirty days after the issuance of such financial statements, to apply fifty percent of such net income to pay the portion of the Settlement Amount that is owed pursuant to this Agreement (see Schedule A), and those payments shall be applied to the payment schedule in reverse chronological order (i.e., toward the amount owed in 2012 first, and then to the amount owed in 2011, etc.). These payments shall be apportioned between the federal and state settlement amounts on a pro rata basis.

e. In the event that JPI is acquired, in whole or in part, by another entity, the portion of the Settlement Amount that is owed pursuant to this Agreement (see Schedule A) shall be due on or before the closing date of the acquisition.

f. Default:

i. Defendants shall be in default of this Agreement if they fail to pay any amount set forth in Paragraph 1 and Schedule A of this Agreement within five (5) days after such payment is due.

ii. On the date of any such event of default, the United States agrees that it will provide written notice of the default and an opportunity for Defendants to cure

said default within five (5) business days after receipt of the notice. Upon default, the full remaining unpaid balance (including all unpaid interest and principal) will become immediately due and payable. Interest will accrue at the rate of 18% (eighteen percent) per annum compounded daily from the date of default on the remaining unpaid principal balance.

iii. Upon declaration of default, the United States may exercise, at its sole option, one or more of the following rights, as applicable: (1) declare this Agreement breached, and proceed against Defendants for any claims under the Civil Action, including those to be released by this Agreement; (2) file an action for specific performance of the Agreement, excluding the Corporate Integrity Agreement (the "CIA") which will be separately enforced by HHS-OIG pursuant to its own terms; (3) offset the remaining unpaid balance, inclusive of interest, from any amounts due and owing to Defendants by any department, agency, or agent of the United States at the time of default; (4) exercise any other right granted by law, or under the terms of this Agreement or the CIA, or recognizable at common law or in equity. Defendants agree not to contest any offset imposed pursuant to this provision, either administratively or in any State or Federal court. In addition, Defendants shall pay the United States all reasonable costs of collection and enforcement of this Agreement, including attorney's fees and expenses. The United States reserves the option of referring such matters for private collection.

iv. in the event of default, as defined in Paragraph 1 above, HHS-OIG may exclude Defendants from participating in all Federal health care programs until Defendants pay the Settlement Amount and reasonable costs as set forth above. HHS-OIG will provide written notice of any such exclusion to Defendants. Defendants waive any further notice of the exclusion under 42 U.S.C. § 1320a-7(b)(7), and agree not to contest such exclusion either

administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion Defendants wish to apply for reinstatement, Defendants must submit a written requests for reinstatement to HHS-OIG in accordance with the provisions of 42 C.F.R. §§ 1001.3001-.3005. Defendants will not be reinstated unless and until HHS-OIG approves such requests for reinstatement.

v. in the event of default, as defined in Paragraph 1 above, OPM may debar Defendants from participating in the FEHB until Defendants pay the Settlement Amount and reasonable costs as set forth above. OPM will provide written notice of any such debarment to Defendants. Defendants waive any further notice of the debarment under 5 U.S.C. § 8902a(c)(5), and agree not to contest such exclusion either administratively or in any state or federal court. Reinstatement to program participation is not automatic. If at the end of the period of exclusion Defendants wish to apply for reinstatement, Defendants must submit a written requests for reinstatement to OPM in accordance with the provisions of 42 C.F.R. §8902a(g)(4). Defendants will not be reinstated unless and until OPM approves such requests for reinstatement

2. Subject to the exceptions in Paragraph 7 below, and in consideration of the obligations of Defendants in this Agreement, and conditioned upon Defendants' full payment of the Settlement Amount, and subject to Paragraph 22 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Defendants from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud. No individuals are released by this Agreement.

3. Subjects to the exceptions in Paragraph 7 below, and in consideration of the obligations of Defendants in this Agreement and conditioned upon Defendants' full payment of the Settlement Amount, Relator, for herself and for her heirs, successors, attorneys, agents, and assigns, agrees to release Defendants from any civil monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

4. In consideration of the obligations of JPI in this Agreement and the CIA entered into between HHS-OIG and JPI, conditioned upon Defendants' full payment of the Settlement Amount, and subject to Paragraph 22 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the HHS-OIG agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against JPI under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 7 below, and as reserved in this Paragraph. The HHS-OIG expressly reserves all rights to comply with any statutory obligations to exclude JPI from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the HHS-OIG from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7 below.

5. In consideration of the obligations of Defendants set forth in this Agreement, conditioned upon Defendants' full payment of the Settlement Amount and subject to Paragraph 22, below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), TMA agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the TRICARE Program against JPI under 32 C.F.R. § 199.9 for the Covered Conduct, except as reserved in Paragraph 7 below and as reserved in this Paragraph. TMA expressly reserves authority to exclude JPI from the TRICARE Program under 32 C.F.R. §§ 199.9 (f)(1)(i)(A), (f)(1)(i)(B), and (f)(1)(iii), based upon the Covered Conduct. Nothing in this Paragraph precludes TMA or the TRICARE Program from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7 below.

6. In consideration of the obligations of Defendants in this Agreement, conditioned upon Defendants' full payment of the Settlement Amount and subject to Paragraph 22 below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), OPM agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the FEHBP against JPI under 5 U.S.C. § 8902a or 5 C.F.R. Part 970 for the Covered Conduct, except as reserved in Paragraph 7 below and except if excluded by HHS-OIG pursuant to 42 U.S.C. § 1320a-7(a). Nothing in this Paragraph precludes OPM from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 7 below. OPM further reserves the right to take administrative action against Orphan pursuant to 5 U.S.C. § 8902a and 5 C.F.R. Part 970 for the Covered Conduct.

7. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Defendants and Relator) are the following claims of the United States:

a. Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon such obligations as are created by this Agreement;

f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

g. Any liability for failure to deliver goods or services due;

h. Any liability of individuals, including officers and employees.

8. Relator and her heirs, successors, attorneys, agents, and assigns agree not to object to this Agreement and agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

9. Relator, for herself individually, and for her heirs, successors, agents, and assigns, fully and finally releases, waives, and forever discharges the United States, its officers, agents, and employees, from any claims arising from or relating to 31 U.S.C. § 3730; from any claims arising from the filing of the Civil Action; and from any other claims for a share of the

Settlement Amount; and in full settlement of any claims Relator may have under this Agreement, with the exception of any claims by Relator pursuant to 31 U.S.C. § 3730(d)(1) for Relator's share of the proceeds (discussed above in Paragraph 1(c)). This Agreement does not resolve or in any manner affect any claims the United States has or may have against the Relator arising under Title 26, U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

10. Conditioned upon receipt of the payments described in Paragraph 1, Relator, for herself, and for her heirs, successors, attorneys, agents, and assigns, hereby fully and finally releases and forever discharges Orphan, JPI, their parents, subsidiaries, related entities, officers, directors, trustees, agents, servants, employees, representatives, attorneys, consultants, successors, heirs, executors, administrators and assigns, individually and collectively, current or former, from any and all claims, claims for relief, actions, rights, causes of actions, suits, debts, obligations, liabilities, demands, losses, damages (including treble damages and any civil penalties), punitive damages, costs and expenses of any kind, character or nature whatsoever, known or unknown, fixed or contingent, in law or in equity, in contract or tort, or under any state or federal statute or regulation or otherwise that the Relator has standing to bring, which Relator may now have or claim to have against Orphan or JPI, arising in any way out of or connected in any way with the facts, claims and circumstances alleged in, arising under, or arising from the filing of, the Civil Action, or from any other past activities and actions of Orphan or JPI, with the exception that Relator does not release Orphan or JPI for any claims that Relator has (1) for expenses, attorney's fees and costs pursuant to 31 U.S.C. §§ 3730(d) and (h), and (2) pursuant to 31 U.S.C. § 3730(h). Relator does not release the Medicaid Participating States from any claims that Relator has for a share of any settlement or judgment obtained by the Medicaid Participating States concerning the Covered Conduct.

11. Defendants fully and finally release Relator and her attorneys, and their respective successors, assigns, and agents, from any claims that they have asserted, could have asserted, or may assert in the future against Relator or her attorneys related to the Covered Conduct or related to the investigation and prosecution of the Covered Conduct by Relator or her attorneys.

12. Defendants fully and finally release the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Defendants has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

13. JPI has provided audited financial statements for the calendar year ended December 31, 2006 (which include Orphan as a consolidated subsidiary from June 24, 2005) (the "Financial Statements") to the United States, and the United States has relied on the accuracy and completeness of the Financial Statements in reaching this Agreement. JPI warrants that the Financial Statements are complete, accurate, and current as of the dates thereof. JPI has additionally provided unaudited financial information to the United States, which JPI warrants as accurate and consistent with information provided to JPI's Board of Directors and underwriters for JPI's initial public offering. JPI has informed the United States that the unaudited financial information contains estimates and projections as to future products, sales and operations, all of which are based on assumptions and contingencies that cannot be guaranteed. If the United States learns of asset(s) in which Defendants had an interest at the date of either the Financial Statements or the unaudited financial information that were not disclosed therein, or if the United States learns of any misrepresentation by Defendants on, or in connection with, the Financial

Statements or unaudited financial information, and if such non-disclosure or misrepresentation changes the estimated net worth set forth in the Financial Statements by seven hundred and fifty thousand dollars or more, the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct, or (b) let the Agreement stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth of Defendants previously undisclosed. Defendants agree not to contest any collection action undertaken by the United States pursuant to this provision.

14. In the event that the United States, pursuant to Paragraph 13 above, opts to rescind this Agreement, Defendants agree not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 90 calendar days of written notification to JPI that this Agreement has been rescinded, and (b) relate to the Covered Conduct, except to the extent these defenses were available on March 15, 2007.

15. Defendants waive and shall not assert any defenses that they may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this Paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

16. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary,

any other federal payer, or any state payer, related to the Covered Conduct; and Defendants shall not resubmit to any Medicare carrier or intermediary, any other federal payer, or any state payer any previously denied claims related to the Covered Conduct, and shall not appeal any such denials of claims.

17. Defendants agree to the following:

a. Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Defendants, their present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "unallowable costs" on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program:

(1) the matters covered by this Agreement and any related plea agreement;

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;

(3) Defendants' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement and any plea agreement;

(5) the payment Defendants make to the United States pursuant to this Agreement and any payments that Defendants may make to Relator, including costs and attorneys fees; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to:

(i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and

(ii) prepare and submit reports to HHS-OIG. However, nothing in this Paragraph that may apply to the obligations undertaken pursuant to the CIA affect the status of costs not allowable under any other authority applicable to Defendants (all costs described or set forth in this Paragraph are hereafter "unallowable costs.").

b. Future Treatment of Unallowable Costs: These unallowable costs shall be separately determined and accounted for by Defendants, and Defendants shall not charge such unallowable costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by Defendants or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, the VA or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Defendants further agree that within 90 days of the Effective Date of this Agreement that they shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost

statements, information reports, or payment requests already submitted by Defendants or any of their subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Defendants agree that the United States, at a minimum, shall be entitled to recoup any overpayment plus applicable interest and penalties as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Defendants or any of its subsidiaries or affiliates on the effect of inclusion of unallowable costs (as defined in this Paragraph) on Defendants or any of their subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Defendants' books and records to determine that no unallowable costs have been claimed in accordance with the provisions of this Paragraph.

18. Defendants agree to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement, for the Covered Conduct. Upon reasonable notice, Defendants shall make reasonable efforts to facilitate access to, and encourage the cooperation of their directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals, and shall furnish to the United States, upon reasonable request, all non-privileged documents and records in its possession, custody, or control relating to the Covered Conduct.

19. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity.

20. Defendants waive and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

21. Defendants warrant that they have reviewed their financial situation and that they currently are solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they: (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Defendants, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to that Defendants were or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

22. If within 91 days of the Effective Date of this Agreement or of any payment made under this Agreement**,** Defendants commence, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of Defendants' debts, or seeking to adjudicate Defendants as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Defendants or for all or any substantial part of Defendants' assets, Defendants agree as follows:

a. Defendants' obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and Defendants shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) Defendants' obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) Defendants were insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Defendants.

b. If Defendants' obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action, or proceeding against Defendants for the claims that would otherwise be covered by the releases provided in Paragraphs 2 and 4 through 6 above. Defendants agree that (i) any such claims, actions, or proceedings brought by the United States (including any proceedings to exclude Defendants from participation in Medicare, Medicaid, or other Federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and Defendants shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) Defendants shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding that are brought by the United States within 120

calendar days of written notification to Defendants that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on March 15, 2007; and (iii) the United States has a valid claim against Defendants in the amount of $3.75 million dollars plus interest and applicable penalties under the False Claims Act, and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

c. Defendants acknowledge that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

23. Except as expressly provided to the contrary in this Agreement, each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

24. Defendants represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

25. Relator represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

26. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement is the United States District Court for the Eastern District of New York, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions in the CIA. The Parties agree that, in the event the following three claims are not resolved, the United States District Court for the Eastern District of New York shall retain jurisdiction over them: (a) claims made by Relator for a share of the Settlement Amount pursuant to 31 U.S.C. § 3730(d)(1); (b) claims by Relator for reasonable attorneys' fees and costs pursuant to 31 U.S.C. § 3730(d)(1); and (c) claims by Relator against Defendants brought pursuant to 31 U.S.C. § 3730(h).

27. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

28. Upon receipt of the initial payments described in Paragraph 1 above, and after the three claims raised in Paragraph 26 are resolved, the United States and Relator shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal with prejudice of the Civil Action pursuant to the terms of the Agreement.

29. The individuals signing this Agreement on behalf of Defendants represent and warrant that they are authorized by Defendants to execute this Agreement. The individual signing this Agreement on behalf of Relator represents and warrants that she is authorized by Relator to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

30. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

31. This Agreement is binding on Defendants' successors, transferees, heirs, and assigns.

32. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

33. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

34. This Agreement is effective on the date of signature of the last signatory to the Agreement (the "Effective Date of this Agreement"). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

ROSLYNN R. MAUSKOPF
United States Attorney
Eastern District of New York

DATED: 7/13/07

BY: /s/ Paul Kaufman
PAUL KAUFMAN
Assistant United States Attorney
Chief, Civil Health Care Fraud
United States Attorney's Office
Eastern District of New York

DATED: 7/13/07

BY: /s/ Brian McCabe
BRIAN McCABE
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 7/13/07

BY: /s/ Gregory E. Demske
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: 7/11/07

BY: /s/ Laurel C. Gillespie
LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: 7/12/07

BY: /s/ Kathleen McGettigan
KATHLEEN McGETTIGAN
Deputy Associate Director
Center for Retirement and
Insurance Services
United States Office of
Personnel Management

DATED: 7/12/07

BY: /s/ J. David Cope
J. DAVID COPE
Assistant Inspector General
For Legal Affairs
United States Office of
Personnel Management

JPI AND ORPHAN — Defendants

DATED: 7/13/07

BY: /s/ Samuel R. Saks, M.D.
SAMUEL R. SAKS, M.D.
Chief Executive Officer
JPI Pharmaceuticals, Inc.

DATED: 7/13/07

BY: /s/ Robert Myers
ROBERT MYERS
President
Orphan Medical Inc.

DATED: 7/13/07

BY: /s/ J. Sedwick Sollers III, Esq.
J. SEDWICK SOLLERS III, Esq.
MARK A. JENSEN, Esq.
King & Spalding LLP.
Counsel for JPI Pharmaceuticals, Inc. and
Orphan Medical Inc.

RELATOR

DATED: 7/11/07

BY: /s/ Shelly Lauterbach
SHELLY LAUTERBACH
Relator

DATED: 7/12/07

BY: /s/ Erika A. Kelton
ERIKA A. KELTON, Esq.
Phillips and Cohen LLP
Counsel for Relator

SCHEDULE A

Federal Settlement Amount

	Total	PortionPaid In Accordance With Restitution Agreement (Federal Criminal Action)[1]	Portion Paid In Accordance With The Civil Settlement Agreement
7/20/07	$ 169,004	$ 61,344	$ 107,659
1/15/08	$ 338,007	$ 122,689	$ 215,318
1/15/09	$ 422,509	$ 153,361	$ 269,148
1/15/10	$ 507,011	$ 184,033	$ 322,978
1/15/11	$ 507,011	$ 184,033	$ 322,978
1/15/12	1,436,530	$ 521,427	$ 915,103

State Settlement Amount

	Total	Portion Paid In Accordance With Restitution Agreement (Federal Criminal Action	Portion Paid In Accordance With The Civil Settlement Agreement
7/20/07	$ 45,896	$ 16,659	$ 29,237
1/15/08	$ 91,792	$ 33,318	$ 58,474
1/15/09	$ 114,740	$ 41,648	$ 73,092
1/15/10	$ 137,689	$ 49,978	$ 87,711
1/15/11	$ 137,689	$ 49,978	$ 87,711
1/15/12	$ 390,118	$ 141,604	$ 248,514

[1] Defendants are obligated to make the payments in this column pursuant to the Plea Agreement and Non-prosecution agreement in the Federal Criminal Action. While these payments are therefore accounted for in both the Federal Criminal Action and this Agreement, Defendants are obligated to make them once.

Exhibit 10.57B

NON-PROSECUTION AGREEMENT BETWEEN JAZZ PHARMACEUTICALS, INC. AND THE U.S. ATTORNEY'S OFFICE FOR THE EASTERN DISTRICT OF NEW YORK

JAZZ PHARMACEUTICALS, INC. ("JPI"), by its undersigned attorneys, pursuant to authority granted by its Board of Directors, and the UNITED STATES ATTORNEY'S OFFICE FOR THE EASTERN DISTRICT OF NEW YORK (the "Office"), hereby enter into this Agreement (the "Agreement").

1. Since April 2005, the Office has been conducting a criminal investigation into allegations that Orphan Medical, Inc. ("Orphan"), a specialty pharmaceutical manufacturer acquired by JPI through a merger transaction completed in June 2005, engaged in illegal marketing activities designed to expand the market for its prescription drug Xyrem by promoting Xyrem to physicians for "off-label" medical indications that were not approved by the U.S. Food and Drug Administration ("FDA"). The investigation has also focused on allegations that Orphan paid medical professionals to assist in these illegal marketing activities and to provide advice on how to disguise "off-label" indications from public and private insurers in order to ensure that Xyrem prescriptions would be reimbursed. Further details of Orphan's criminal conduct are set forth in a criminal information (the "Information"), a copy of which is incorporated by reference herein and attached hereto as Exhibit A. Orphan has agreed to plead guilty to the Information pursuant to a plea agreement (the "Plea Agreement"), a copy of which is incorporated by reference herein and attached hereto as Exhibit B.

2. Based on the evidence gathered during this investigation, the government maintains that it would be able to prove that JPI, as a consequence of the criminal conduct committed by its subsidiary Orphan ("the Unlawful Conduct"), is likewise guilty of introducing and causing the introduction of a misbranded drug into interstate commerce, in violation of 21 U.S.C. §§ 331(a) and 333(a)(2).

3. JPI accepts responsibility to remediate Orphan's misconduct by entering into this Agreement and by, among other things, the proactive and remedial actions that it has taken to date, its continuing commitment to full cooperation with the Office, the Federal Bureau of Investigation ("FBI"), the Department of Health and Human Services ("HHS"), the Department of Veteran's Affairs ("VA") and the FDA (collectively, the "Investigative Entities"), and the other undertakings it has made as set forth in this Agreement.

4. In 2006, JPI conducted a review of Orphan's alleged illegal marketing conduct. JPI brought relevant facts to the attention of the Investigative Entities and provided the Investigative Entities with voluminous discovery materials responsive to their requests. JPI acknowledges that its prior, ongoing and future cooperation are important factors in the Office's decision to enter into this Agreement, and therefore, JPI agrees to continue to cooperate fully with the Investigative Entities regarding any matter about which JPI has knowledge that is related to the Office's investigation.

5. JPI agrees that its cooperation shall include, but is not limited to, the following insofar as such cooperation is consistent with any existing applicable privileges held by JPI:

(a) Completely and truthfully disclosing information in its possession to the Investigative Entities about which the Investigative Entities may inquire;

(b) Assembling, organizing and providing all documents, records, or other tangible materials in JPI's possession, custody, or control as reasonably may be requested by any of the Investigative Entities;

(c) Providing any documents, records, information, or testimony requested by the Office;

(d) Using its best efforts to make available its present and former employees to provide information and/or testimony as requested by any of the Investigative Entities, including, without limitation, sworn testimony in court proceedings, as well as interviews with law enforcement authorities. Cooperation under this paragraph shall include identification of witnesses who, to JPI's knowledge, may have material information regarding the Unlawful Conduct;

(e) Providing testimony and other information deemed necessary by any of the Investigative Entities or a court to establish the evidentiary foundation necessary to admit into evidence documents in any criminal or other proceeding; and

(f) With respect to any information, testimony, document, record or other tangible material provided by JPI to the Office or a grand jury, JPI consents to any and all disclosures of such materials to any other governmental agency designated by the Office as the Office, in its sole discretion, deems appropriate. With respect to any such materials that constitute "matters occurring before the grand jury" within the meaning of Rule 6(e) of the Federal Rules of Criminal Procedure, JPI further consents to (a) any order sought by the Office permitting such disclosures; and (b) the Office's ex parte or in camera application for such orders.

6. JPI agrees to guarantee Orphan's obligation under the Plea Agreement to pay restitution of $ 12,262,078 and a criminal fine of $ 5 million pursuant to the payment schedule set forth in paragraph 3 of the Plea Agreement. Any violation of this paragraph will constitute a material breach of this Agreement and subject JPI to criminal prosecution pursuant to paragraphs 10-12 below.

7. JPI represents that its Board of Directors and current Senior Management have taken numerous proactive and remedial actions in response to the Unlawful Conduct at Orphan, which were confirmed through its review of marketing practices and the investigations conducted by the Investigative Entities, including proactive measures adopted prior to JPI's becoming aware of the Office's investigation. These remedial actions and proactive measures have included:

(a) A November 14, 2005 memorandum from the Chief Executive Officer of JPI to all sales personnel emphasizing that "off-label" promotion is strictly prohibited and that personnel violating this prohibition will face "severe consequences."

(b) Requiring training for promotional speakers and sales representatives;

(c) Creating a Medical Affairs group independent of sales and marketing;

(d) Requiring company-wide compliance training;

(e) Adoption and implementation of a Code of Conduct prohibiting "off-label" promotion that was signed by all JPI employees;

(f) Delaying three months in presenting positive clinical data for "off-label" indication of fibromyalgia to ensure that data was released in an appropriate medical forum;

(g) Appointment of a Chief Compliance Officer; and

(h) Replacing former Orphan regional sales managers responsible for overseeing conduct of sales representatives in their respective territories.

8. JPI has agreed to enter into a Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("Inspector General") for HHS, a copy of which is incorporated by reference herein and attached hereto as Exhibit C. Any violation of the remedial provisions mandated by the CIA will constitute a material breach of this Agreement and subject JPI to criminal prosecution pursuant to paragraphs 10-12 below.

9. In consideration of JPI's: (a) acceptance of responsibility as acknowledged herein; (b) cooperation-to-date and agreement to continue to cooperate with the Investigative Entities; (c) agreement to guarantee the payments set forth in paragraph 6 above; (d) implementation of remedial measures as set forth in paragraph 7 above; (e) agreement to enter into the CIA and comply with its provisions; and (f) agreement otherwise to comply with all of the terms of this Agreement, the Office agrees that, except as provided in paragraphs 10-12 below, JPI will not be prosecuted for the Unlawful Conduct.

10. JPI understands and agrees that should the Office, in its sole discretion, determine that JPI deliberately has given false, incomplete, or misleading information under this Agreement, has otherwise deliberately violated any provisions of the Agreement or has committed, or attempted to commit, any crimes other than crimes relating to the Unlawful Conduct, JPI shall thereafter be subject to prosecution for any federal criminal violation of which the Office has knowledge, including a prosecution relating to the Unlawful Conduct. Moreover, JPI agrees that any prosecution relating to the Unlawful Conduct that is not time-barred by the applicable statute of limitations on the date of this Agreement may be commenced against JPI in accordance with this Agreement, notwithstanding the expiration of any statute of limitations. By this Agreement, JPI expressly intends to and does waive any rights in this respect. Such waiver is knowing, voluntary and in express reliance on the advice of JPI's counsel.

11. JPI further understands and agrees that in the event that the Office, in its sole discretion, determines that JPI has knowingly violated any provision of this Agreement or has committed or attempted to commit any crimes other than crimes relating to the Unlawful Conduct, (a) all statements made by or on behalf of JPI to any of the Investigative Entities, including the acknowledgment and acceptance of responsibility set forth in this Agreement, and any testimony given by JPI before a grand jury or elsewhere, whether before or after the date of this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any criminal proceeding brought by the Office against JPI; and (b) JPI shall not assert in any criminal proceeding brought by the Office against JPI any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule or provision, that statements made by or on behalf of JPI before or after the date of this Agreement, or any leads derived therefrom, should be suppressed.

12. JPI agrees that the decision whether conduct and/or statements of any individual will be imputed to JPI for purposes of determining whether JPI has violated any provision of this Agreement shall be in the sole discretion of the Office, provided, however, that the statements of any former officer, director or employee of JPI or Orphan shall not be attributed to JPI for the purposes of paragraphs 10-12. Should the Office determine that JPI has committed a knowing breach of any provision of this Agreement, the Office will provide written notice to JPI addressed to its General Counsel, Carol A. Gamble, Esq., 3180 Porter Drive, Palo Alto,

California 94304, and to JPI's counsel, J. Sedwick Sollers III, Esq. and Mark Jensen, Esq., King & Spalding, 1700 Pennsylvania Avenue, N.W., Washington, D.C. 20006-4706, or to any successor that JPI may designate, and will provide JPI with a two-week period from the date of receipt of such notice in which to make a presentation to the Office to demonstrate that no breach has occurred or, to the extent relevant, that the breach was not knowing or had been cured. JPI understands and agrees that the exercise of discretion by the Office is not subject to review in any court or tribunal outside the Department of Justice.

13. JPI agrees that it shall not, through its attorneys, Board of Directors, agents, officers or employees, make any public statement, in litigation or otherwise, contradicting its acceptance of responsibility to remediate Orphan's misconduct or the Information. Any such contradictory statement by JPI, its present or future attorneys, Board of Directors, agents, officers or employees shall constitute a breach of this Agreement and JPI thereafter shall be subject to prosecution as set forth in paragraphs 10-12. The decision as to whether any such contradictory statement will be imputed to JPI for the purpose of determining whether JPI has breached this Agreement shall be at the sole discretion of the Office. Upon the Office's notifying JPI of any such contradictory statement, JPI may avoid a breach of this Agreement by publicly repudiating such statement within 72 hours after notification by the Office. This paragraph is not intended to apply to any statement made by any JPI or Orphan officer, director or employee or former officer, director or employee who has been charged with a crime or other wrongdoing by the government or an agency thereof.

14. JPI agrees that, if it sells or merges all or substantially all of its business operations as they exist as of the date of this Agreement to or into a single purchaser or group of affiliated purchasers during the term of this Agreement, it shall include in any contract for sale or merger a provision binding the purchaser/successor to the obligations described in this Agreement.

15. JPI agrees that it will continue to cooperate with the Investigative Entities in connection with any proceeding relating to the Unlawful Conduct. JPI's obligation to cooperate is not intended to apply where JPI is a defendant in any such proceeding.

16. JPI agrees that this Agreement, including Exhibits A, B and C may be released to the public.

17. It is understood that this Agreement is binding upon the Attorney General of the United States, the United States Department of Justice, including all United States Attorneys, except that this agreement does not bind the Tax Division of the United States Department of Justice or the Internal Revenue Service of the United States Department of the Treasury. It is further understood that this agreement does not bind any state or local law enforcement agencies, any licensing authorities, or any regulatory authorities. However, the Office will bring the Agreement and JPI's cooperation, remedial actions and proactive measures to the attention of other federal agencies, state or local law enforcement agencies, and any licensing or regulatory authorities if JPI so requests. It is the intent of the parties to this Agreement that the Agreement does not confer or provide any benefits, privileges or rights to any individual or any entity other

than the parties hereto, and that nothing in the Agreement shall be construed as acknowledging that the Agreement, including the Information and the evidence underlying the Agreement and the Information, shall be admissible in any proceeding other than a proceeding brought by the Office. No promises, agreements or conditions have been entered into other than those set forth in this Agreement, and none will be entered into unless memorialized in writing and signed by all parties. This agreement supersedes any prior promises, agreements or conditions between the parties. To become effective, this agreement must be signed by all signatories listed below.

Dated: July 13, 2007
Brooklyn, New York

ROSLYNN R. MAUSKOPF
United States Attorney
Eastern District of New York

/s/ Samuel R. Saks, M.D.
Samuel R. Saks, M.D.
Chief Executive Officer
Jazz Pharmaceuticals, Inc.

By: /s/ Geoffrey R. Kaiser
Geoffrey R. Kaiser
Chief, Health Care Fraud Prosecutions

/s/ J. Sedwick Sollers III, Esq.
J. Sedwick Sollers III, Esq.
Mark Jensen, Esq.
Counsel to Jazz Pharmaceuticals, Inc.

/s/ Greg Andres
Greg Andres
Chief, Criminal Division

Form Date 5/06
GRK:grk
F.#2005RO697

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----------X

UNITED STATES OF AMERICA — PLEA AGREEMENT

—against— — 07 CR 531 (ENV)

ORPHAN MEDICAL, INC.,

Defendant.

----------X

Pursuant to Rule 11 of the Federal Rules of Criminal Procedure, the United States Attorney's Office for the Eastern District of New York (the "Office") and ORPHAN MEDICAL, INC. (the "defendant") agree to the following:

1. The defendant will waive indictment and plead guilty to an information to be filed in this district charging a violation 21 U.S.C. §§ 331(a) and 333(a)(2). The count carries the following statutory penalties:

a. Maximum fine: $500,000 or twice the pecuniary gain or loss, whichever is greater. (18 U.S.C. § 3571(c)(3) and (d)).

b. Restitution: $12,262,078. (18 U.S.C. §§ 3663 and 3663A).

c. $400 special assessment. (18 U.S.C. § 3013).

d. Other penalties: mandatory exclusion from participation in federal health care programs.

2. The defendant understands that although imposition of a sentence in accordance with the United States Sentencing Guidelines (the "Guidelines") is not mandatory, the Guidelines are advisory and the Court is required to consider any applicable Guidelines provisions as well as other factors enumerated in 18 U.S.C. § 3553(a) to arrive at an appropriate sentence in this case. The Office will advise the Court and the Probation Department of information relevant to sentencing, including criminal activity engaged in by the defendant, and such information may be used by the Court in determining the defendant's sentence. The Office estimates the recommended fine range is $28,500,000 to $57,000,000, which is predicated on the following calculation pursuant to the Guidelines effective November 1, 2006:

Base Fine

Base offense level: (U.S.S.G. §§ 2B1.1(a)(2) and 8C2.4(a)(1))	6
Loss of more than $7,000,000: (U.S.S.G. §§ 2B1.1(b)(1)(K) and 8C2.4(a)(1))	+ 20
Offense involved more than 50 victims: (U.S.S.G. §§ 2B1.1(b)(2)(B) and 8C2.4(a)(1))	+ 4
Offense involved conscious or reckless risk of death or serious bodily injury: (U.S.S.G. §§ 2B1.1(b)(12)(A) and 8C2.4(a)(1))	+ 2
Defendant derived more than $1 million in gross receipts from one or more financial institutions: (U.S.S.G. §§ 2B1.1(b)(12)(A) and 8C2.4(a)(1))	+ 2

Adjusted offense level:	34

Base fine: $28,500,000
(U.S.S.G. § 8C2.4(d))

Culpability Score

Base culpability score: (U.S.S.G. § 8C2.5(a))	5
Organization had 50 or more employees and substantial authority personnel condoned or were willfully ignorant of offense: (U.S.S.G. § 8C2.5(b)(4))	+ 2
Organization fully cooperated in investigation and demonstrated acceptance of responsibility: (U.S.S.G. § 8C2.5(g)(2))	- 2
Total culpability score:	5

Minimum and Maximum Fine Range

Minimum fine $28,500,000 base fine x 1.00 multiplier: (U.S.S.G. §§ 8C2.6 and 8C2.7(a))	$ 28,500,000
Maximum fine $28,500,000 base fine x 2.00 multiplier: (U.S.S.G. §§ 8C2.6 and 8C2.7(b))	$ 57,000,000

The defendant does not stipulate to this estimate of the recommended fine range. The government represents and for purposes of this agreement the defendant does not object that, pursuant to U.S.S.G. §8C2.4(a) and 18 U.S.C. § 3571(d), the loss from this offense for criminal sentencing purposes is $12,262,078. The defendant and the government both acknowledge that the loss figure cannot be determined with precision and that the loss figure of $12,262,078 for criminal sentencing purposes is an estimate.

3. The government and the defendant agree that, pursuant to U.S.S.G. § 8C3.3(b), the defendant is not able and, even with the use of a reasonable installment schedule, is not likely to become able to pay the minimum fine required by U.S.S.G. § 8C2.7. Therefore, the government and the defendant agree, pursuant to Fed. R. Crim. P. 11(c)(1)(C), that the following sentence is the appropriate disposition of the Information:

a. Restitution in the amount of $12,262,078, to be paid after sentencing in installments pursuant to the following schedule:

July 20, 2007	$ 613,104
January 15, 2008	$1,226,208
January 15, 2009	$1,532,760
January 15, 2010	$1,839,312
January 15, 2011	$1,839,312
January 15, 2012	$5,211,382

b. A criminal fine in the amount of $5 million, to be paid after sentencing in installments pursuant to the following schedule:

July 20, 2007	$ 250,000
January 15, 2008	$ 500,000
January 15, 2009	$ 625,000
January 15, 2010	$ 750,000
January 15, 2011	$ 750,000
January 15, 2012	$2,125,000

c. a mandatory special assessment of $400 pursuant to 18 U.S.C. § 3013.

4. The Guidelines estimate set forth in paragraph 2 is not binding on the Office, the Probation Department or the Court.

If the Guidelines offense level advocated by the Office, or determined by the Probation Department or the Court, is different from the estimate, the defendant will not be entitled to withdraw the plea. The defendant's plea will be tendered pursuant to Fed. R. Crim P. 11(c)(1)(C). The defendant cannot withdraw its plea of guilty unless the sentencing judge rejects this agreement or fails to impose the stipulated sentence referenced above. If the sentencing judge rejects this agreement, this agreement shall be null and void at the option of either the government or the defendant. The defendant intends to seek a sentencing by the Court immediately following the Rule 11 plea hearing and in the absence of a Presentence Report in this case. The defendant understands that the decision whether to proceed immediately following the plea hearing with the sentencing proceeding, and to do so without a Presentence Report, is exclusively that of the Court.

5. The defendant will not file an appeal or otherwise challenge by petition pursuant to 28 U.S.C. § 2255 or any other provision the conviction or sentence in the event that the Court imposes a total fine of $57 million or less. This waiver is binding without regard to the sentencing analysis used by the Court. The defendant waives all defenses based on the statute of limitations and venue with respect to any prosecution that is not time-barred on the date that this agreement is signed in the event that (a) the defendant's conviction is later vacated for

any reason, (b) the defendant violates this agreement, or (c) the defendant's plea is later withdrawn. The defendant waives any right to additional disclosure from the government in connection with the guilty plea. The defendant agrees that with respect to all charges referred to in paragraphs 1 and 5(a) it is not a "prevailing party" within the meaning of the "Hyde Amendment," 18 U.S.C. § 3006A note, and will not file any claim under that law. The defendant agrees to pay the special assessment by check payable to the Clerk of the Court at or before sentencing.

6. The Office agrees that:

a. no further criminal charges will be brought against the defendant for its participation in criminal activity involving a scheme to market the drug Xyrem for medical indications that were not approved by the U.S. Food and Drug Administration and to secure insurance reimbursement for such unapproved medical indications, all from the period of in or about 2003 through in or about 2006, it being understood that this agreement does not bar the use of such conduct as a predicate act or as the basis for a sentencing enhancement in a subsequent prosecution including, but not limited to, a prosecution pursuant to 18 U.S.C. §§ 1961 et seq.

and, based upon information now known to the Office, it will

b. advocate the agreed sentence set forth in paragraph 3 before the Court.

If information relevant to sentencing, as determined by the Office, becomes known to the Office after the date of this agreement, the Office will not be bound by paragraph 5(b). Should it be judged by the Office that the defendant has violated

any provision of this agreement, the defendant will not be released from its plea of guilty but this Office will be released from its obligations under this agreement, including but not limited to the provisions of paragraph 5 (a) and (b).

7. This agreement is binding upon the Attorney General of the United States, the Department of Justice, and all United States Attorneys on the matters as set forth in paragraph 6 but cannot and does not bind the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury. The defendant also understands that this agreement does not bind any state or local prosecuting authority.

8. No promises, agreements or conditions have been entered into by the parties other than those set forth in this agreement and none will be entered into unless memorialized in writing and signed by all parties. This agreement supersedes all

prior promises, agreements or conditions between the parties. To become effective, this agreement must be signed by all signatories listed below.

Dated: Brooklyn, New York
July 13, 2007

ROSLYNN R. MAUSKOPF
United States Attorney
Eastern District of New York

By: /s/ Geoffrey R. Kaiser
Geoffrey R. Kaiser
Assistant United States Attorney

Approved by:

/s/ Richard T. Faughnan
Richard T. Faughnan
Supervising Assistant U.S. Attorney

I have read the entire agreement and discussed it with my attorney. I understand all of its terms and am entering into it knowingly and voluntarily.

/s/ Robert M. Myers
Robert M. Myers
President, ORPHAN MEDICAL, INC.

Approved by:

/s/ J. Sedwick Sollers III
J. Sedwick Sollers III
Mark Jensen
Counsel to Defendant

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

I. PREAMBLE

Jazz Pharmaceuticals, Inc. (Jazz) 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) (FDA requirements). Contemporaneously with this CIA, Jazz is entering into a Settlement Agreement with the United States. Jazz will also enter into settlement agreements with various states and Jazz's agreement to this CIA is a condition precedent to those settlement agreements.

Prior to the Effective Date, Jazz established a comprehensive 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 Jazz, to promote compliance with applicable laws and the promotion of high ethical standards.

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

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Jazz 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 July 1, 2007 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) Jazz's final Annual Report; or (2) any additional materials submitted by Jazz 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 Jazz; and

b. all contractors, subcontractors, agents, and other persons who perform Product Services Related Functions (as defined below in Section II.C.2) on behalf of Jazz.

Notwithstanding the above, the term "Covered Persons" does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to 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 Jazz whose job responsibilities relate to: i) the sales, marketing, or promotion of Jazz's products; ii) research and development (except preclinical researchers and clinical investigators); iii) the distribution of Jazz's products (except those Covered Persons with no sales, marketing, or promotional related responsibilities); or iv) the provision of information about or services relating to Jazz products (collectively "Product Services Related Functions.").

3. 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.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee.

1. *Compliance Officer*. Within 120 days after the Effective Date, Jazz shall appoint an individual to serve as its compliance officer (Compliance Officer), and Jazz shall maintain a Compliance Officer for 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 and FDA requirements. The Compliance Officer is and shall continue to be a member of the management of Jazz, shall report to the Chief Executive Officer, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Jazz, and shall be authorized to report on such matters to the Board of Directors (or a designated committee or subcommittee of the Board) 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 Jazz as well as for any reporting obligations created under this CIA.

Jazz 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, Jazz established a Compliance Committee, and Jazz shall maintain the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, consist of the General Counsel; the Compliance Officer; the Senior Vice President, Development; the

Chief Financial Officer; the Vice President, Sales; and the Vice President, Marketing and New Product Planning. As represented by Jazz, the aforementioned individuals are the members of management necessary to meet the requirements of this CIA. 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 Jazz's risk areas and shall oversee monitoring of internal and external audits and investigations).

Jazz 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*. To the extent not already accomplished, within 90 days after the Effective Date, Jazz shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Jazz shall 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. Jazz's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to comply with all requirements relating to Product Services Related Functions;

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

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

d. the possible consequences to both Jazz and Covered Persons of failure to comply with Federal health care program or FDA requirements and with Jazz'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 Jazz's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

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 Jazz'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.

Jazz 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.

2. *Policies and Procedures*. To the extent not already accomplished, within 90 days after the Effective Date, Jazz shall implement written Policies and Procedures regarding the operation of Jazz'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 of Jazz 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) and the False Claims Act codified at 31 U.S.C. § 3729-3733;

c. selling, marketing, promoting, advertising, and disseminating

information about Jazz'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 Jazz's products;

e. disciplinary policies and procedures for violations of Jazz's Policies and Procedures, including those policies relating to Federal health care program and FDA requirements;

f. the manner in which Jazz receives and response to requests for information about off-label uses of Jazz's products; the form and content of information disseminated by Jazz in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Jazz develop one or more databases to track requests for information about Jazz' products that are made to Jazz' Medical Information department. Collectively these databases shall be referred to as the "Inquiries Database." The Inquiries Database shall includes the following items of information for each unique inquiry (Inquiry) received for information about Jazz'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 Jazz (including a record of the materials provided to the HCP in response to the request); 7) the name of the Jazz representative who called on or interacted with the HCP; and 8) the status and findings of any follow-up review conducted by Jazz 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.3 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 Jazz'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 Jazz'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 Jazz'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 Jazz in a manner that is designed to ensure that Jazz'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.

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), Jazz 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.

C. Training and Education.

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

a. CIA requirements;

b. Jazz'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 Jazz'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. Jazz may satisfy its remaining General Training obligation for those Covered Persons who received training as described above by notifying the Covered Persons in writing of the fact that Jazz entered a CIA and notifying them of Jazz'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 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.

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. Each Relevant Covered Person shall also receive at least one additional hour of Specific Training during the first Reporting Period. This Specific Training shall include a discussion of:

a. all Federal health care program requirements relevant to Product Services Related Functions, 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 Product Services Related Functions, 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.

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.

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. A Jazz 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.

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.

In addition to the Specific Training obligations set forth in this Section III.2.C, as part of its Compliance Program, Jazz provides additional regular periodic training to Relevant Covered Persons on the topics outlined above in this Section III.C.2. This training shall be known as the "Periodic Compliance Training". Jazz shall continue to provide Periodic Compliance Training to Relevant Covered Persons during the term of the CIA. Jazz shall include a description of the Periodic Compliance Training as part of its Annual Reports, but Jazz shall not be required to formally track the Periodic Compliance Training for each individual Relevant Covered Person.

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, including the applicable Federal health care program and FDA requirements.

5. *Update of Training.* Jazz shall review the training annually, and, where appropriate, update the training to reflect changes in applicable 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.* Jazz may provide the training required under this CIA through appropriate computer-based training approaches. If Jazz 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, Jazz 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 Jazz shall have expertise in the requirements of the requirements of the Federal health care program and FDA requirements applicable to the Promotional and Product Services Engagement. Each IRO shall assess, along with Jazz, whether it can perform the IRO review in a professionally independent and 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.

The IRO shall perform the Promotional and Product Services Systems Review for the first Reporting Period as outlined in Appendix B.

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

2. *Review Reports*. The IRO shall prepare a report (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 the 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). Jazz 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 Jazz's final Annual Report shall be initiated no later than one year after Jazz's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Jazz 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, Jazz 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. Jazz 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 Jazz 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 Jazz 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.

Prior to the Effective Date, Jazz established a Disclosure Program that includes mechanisms (a toll-free compliance telephone line and an e-mail mechanism) 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 Jazz's policies, conduct, practices, or procedures with respect to any Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Jazz shall continue the Disclosure Program during the term of this CIA. Jazz shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. 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, Jazz 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 (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 Jazz.

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

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

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

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

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Jazz shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Jazz conducted or brought by a governmental entity or its agents involving an allegation that Jazz 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. Jazz 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 prescription drugs for which penalties or exclusion may be authorized; or

iii. the filing of a bankruptcy petition by Jazz.

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

b. Reporting *of Reportable Events*. If Jazz determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Jazz 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;

iii. a description of Jazz's actions taken to correct the Reportable Event; and

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

v. 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 and/or FDA authorities implicated.

I. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication from Jazz to the FDA that materially discusses Jazz's or a Covered Person's unlawful or improper promotion of Jazz's products (including any improper dissemination of information about off-label indications), Jazz shall provide a copy of the report, correspondence, or communication to the OIG. Jazz 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.

Each Reporting Period beginning with the second Reporting Period, Jazz shall obtain non-Jazz 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 Jazz products (Covered Products) to be selected by OIG as described below. In order to satisfy its obligations under this Section III.J, Jazz 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 Jazz's proposal, and, after considering Jazz's proposal, shall, in its discretion, identify the type of survey records to be obtained. Prior to the beginning of the second Reporting Period, the OIG will determine (after input from Jazz) whether the Field Sales Force Monitoring Program outlined below in Section III.L and the accompanying documentation required under that Section are sufficient to justify waiving the requirement to obtain and review records reflecting the content of detailing sessions as set forth in this Section III.J.

For each Covered Product, Jazz shall contract with the Survey Entity to conduct inquiries into the content and subject matter of the detailing interactions. The OIG shall select and notify the Survey Entity of a one-week period within every other quarter of the Reporting Period for which the surveys shall be conducted, beginning in the second full quarter after the Effective Date. For each Covered Product, Jazz shall obtain records reflecting the purported content and subject matter of detailing sessions during the identified week in all regions across the United States.

Jazz 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. Jazz 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, Jazz shall endeavor to gather

additional factual information about the circumstances relating to any Off-Label Findings. As part of each Annual Report, Jazz shall provide the OIG with copies of the underlying records of the detailing interactions, a copy of Jazz's Off-Label Findings, and a description of the action(s), if any, Jazz took in response to the Off-Label Findings.

Prior to the start of the second Reporting Period and every Reporting Period thereafter, based on the information provided by Jazz and other information known to it, and after consultation with Jazz, the OIG shall select up to three Jazz products to be reviewed under this Section III.J. These products shall be known as the "Covered Products", and the OIG shall notify Jazz of the Covered Products for each applicable Reporting Period. The parties have already identified the Covered Products for the first Reporting Period.

K. Monitoring and Review of Medical Information Requests.

Jazz's Policies and Procedures address the selling, marketing, promoting, and dissemination of information about Jazz's products in compliance with all applicable Federal health care program and FDA requirements and the procedures governing the manner in which sales personnel are to respond to requests for information about non-FDA approved uses (*e.g.*, off-label uses). Among other things, Jazz's Policies and Procedures provide that its sales personnel may not directly or indirectly solicit, encourage, or promote any Jazz product for off-label uses. In addition, the Policies and Procedures provide that inquiries about off-label uses are to be directed to Jazz's Medical Information department. Jazz's Medical Information department responds to requests for medical and scientific information from physicians, patients, and others (Inquiries).

Jazz records and documents all Inquiries in the Inquiries Database. The Inquiries Database contains the information identified in Section III.B.2.f above for each Inquiry. On at least a monthly basis, Jazz generates and shall continue to generate reports of the Inquiries received and the responses to the Inquiries. These reports shall continue to be forwarded to the Compliance Officer or other compliance personnel. The Compliance Officer (or designee) shall continue to review these reports to assess whether the information contained in the report suggests that improper promotion may have occurred in connection with any Inquiry(ies).

If the Compliance Officer, in consultation with other appropriate Jazz personnel, suspects that improper promotion may have occurred in connection with one or more Inquiries, the Compliance Officer shall undertake a follow-up review of the Inquiry (Off-Label Review). The Compliance Officer shall make specific findings based

on the Off-Label Review, and take any responsive action (including disciplinary action and reporting of the conduct (including disclosing Reportable Events pursuant to Section III.H above, if applicable) deemed necessary and appropriate. On at least a semi-annual basis, the Compliance Officer shall review the Medical Information department's policies and procedures relating to the handling of Inquiries concerning off-label uses of Jazz's products and shall provide a report on the results of such review to the Compliance Committee.

Jazz shall maintain a record of the steps undertaken during each Off-Label Review, including a general description of the process by which the Compliance Officer conducted the Off-Label Review, the types of records reviewed and the identities of individuals interviewed. Any findings made during the Off-Label Review and any corrective action taken shall be recorded in the files of the Compliance Department and summarized in the Annual Reports. Jazz shall make its records relating to its reviews of Inquiries and any Off-Label Reviews available to the OIG upon request

L. Jazz's Field Sales Force Monitoring Program.

Jazz compliance and legal personnel conduct at least two types of reviews of the activities of Jazz's field sales force. First, Jazz conducts periodic and regular reviews of the call notes recorded by its field sales force (Call Note Reviews). Second, Jazz conducts compliance-focused ride-alongs with its field sales force personnel (Ride-Along Reviews). These activities shall collectively be referred to as the "Field Sales Force Monitoring Program", and Jazz shall continue the Field Sales Force Monitoring Program as set forth below during the term of the CIA.

In connection with the Call Note Review, in the first quarter of each Reporting Period, Jazz shall conduct an audit of a sample of call notes prepared by field sales representatives. The sample will consist of all call notes prepared by at least 20 percent of Jazz's field sales representatives during two different months of the preceding Reporting Period. If the number of field sales representatives for the applicable Reporting Period exceeds 100 employees, Jazz shall notify the OIG of this fact and the OIG will determine, after input from Jazz, whether to reduce the percentage of field sales representatives whose call notes are included as part of the sample. The field sales representatives and the months to be sampled will be selected randomly by Jazz's compliance department. After the sample of call notes has been selected, the Compliance Officer (or designee) shall review the call notes to assess whether the information contained in the call notes suggests that any improper promotion may have occurred.

In connection with the Ride Along Reviews, the Compliance Officer or other trained personnel from the Compliance, legal, or regulatory affairs departments shall directly observe all meetings between Jazz field sales representatives and HCPs during a full work day for at least 10 of Jazz's field sales representatives during each Reporting Period. The field sales representatives observed shall be located throughout the country and shall be supervised by different sales managers. If the number of field sales representatives for the applicable Reporting Period exceeds 100 employees, Jazz shall notify the OIG of this fact and the OIG will determine, after input from Jazz, whether to increase the number of field sales representatives who are observed during Ride Along Reviews and, if so, the number of field sales representatives to be observed. Jazz shall continue these Ride Along Reviews during the term of this CIA as outlined below.

After the completion of each observation day conducted as part of the Ride Along Reviews, compliance personnel shall complete an Observation Report which, for each interaction observed between a sales representatives and an HCP or his/her office staff, shall include the following information: 1) the identity of the sales representative and the compliance or other personnel conducting the observation; 2) the date and duration of the observation; 3) the Jazz product(s) promoted during the observation; 4) assessments about the interaction between the sales representative and each HCP visited; and 5) an identification and description of any potential improper promotion of any Jazz product(s). The Observation Reports shall be forwarded to the Compliance Officer for review.

If the Compliance Officer, in consultation with other appropriate Jazz personnel, suspects that improper promotion may have occurred in connection with either the Call Note Review or any Ride Along Review, the Compliance Officer shall undertake a follow-up review (Compliance Review). The Compliance Officer shall make specific findings based on the Compliance Review, and take any responsive action (including disciplinary action and reporting of the conduct (including disclosing Reportable Events pursuant to Section III.H above, if applicable) deemed necessary and appropriate. Jazz shall retain records relating to the Call Note Reviews, the Ride Along Reviews, and any Compliance Reviews, and shall make such records available to the OIG upon request. A description of the Call Note Reviews, the Ride Along Reviews, any Compliance Reviews, and any findings made during the Compliance Reviews shall be summarized in the Annual Reports.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Jazz changes locations or sells, closes, purchases, or establishes a new business unit or location related to Product Services Related Functions, Jazz 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.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Jazz 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 Jazz's Code of Conduct required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2;

5. the number of individuals required to complete the Code of Conduct 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 Jazz and the IRO; and the proposed start and completion dates of each Review;

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

10. a description of the process by which Jazz 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; and the actions taken in response to the screening and removal obligations set forth in Section III.F;

12. a list of all of Jazz'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 and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Jazz currently submits claims (if applicable);

13. a description of Jazz'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. Jazz shall submit to OIG annually a report with respect to the status of, and findings regarding, Jazz'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 contractor policy);

3. the number of individuals required to complete the Code of Conduct 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. Jazz'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 Jazz 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 Jazz;

9. a summary of all internal reviews, audits, or analyses related to Speaker Programs/Teleconferences or any other Product Services Related Functions (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;

10. 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;

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

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

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

14. 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;

15. a summary describing any ongoing communication with the FDA required to have been reported pursuant to Section III.I. The summary shall include a description of the matter, and the status of such matter;

16. a copy of all information required by Section III.J;

17. a list and description of all actively promoted Jazz products; and information about the estimated relative usage (*e.g.*, the percentage) of those products for off-label purposes;

18. a summary describing the findings resulting from any Off-Label Reviews, as required by Section III.K;

19. a copy of all information required by Section III.L;

20. a description of all changes to the most recently provided list of Jazz'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 Jazz currently submits claims (if applicable); and

21. 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, Jazz 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. if applicable, Jazz 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; and

4. Jazz': 1) Policies and Procedures as referenced in Section III.B.2 above; 2) templates for the standardized contracts and other similar documents; 3) training materials used for purposes of Section III.C, above; and 4) promotional or educational materials containing claims or information about Jazz's products have been reviewed by competent legal counsel and have been found to be in compliance with the requirements of the Federal anti-kickback statute, the Prescription Drug Marketing Act, and other

applicable laws. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request.

D. Designation of Information. Jazz 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. Jazz 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

Jazz: Compliance Officer
Jazz Pharmaceuticals, Inc.
3180 Porter Drive
Palo Alto, CA 94304
Telephone: 650.496.2777
Facsimile: 650.396.3781

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.

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 Jazz's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Jazz's locations for the purpose of verifying and evaluating: (a) Jazz's compliance with the terms of this CIA; and (b) Jazz's compliance with the requirements of the Federal health care programs in which it participates and with applicable FDA requirements. The documentation described above shall be made available by Jazz 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 Jazz'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. Jazz shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Jazz's employees may elect to be interviewed with or without a representative of Jazz present.

VIII. Document and Record Retention

Jazz 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 Jazz prior to any release by OIG of information submitted by Jazz pursuant to its obligations under this CIA and identified upon submission by Jazz as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Jazz shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Jazz 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, Jazz 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 Jazz 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 regarding off-label related matters;
j. a review of records reflecting the content of detailing sessions;
k. monitoring and review of Medical Information Requests; and
l. the Field Sales Force Monitoring Program as described in Section III.L.

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 Jazz fails to engage an IRO, as required in Section III.D and Appendices A and 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 Jazz fails to submit the Implementation Report or any 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 Jazz fails to submit the annual Report associated with any of the Reviews in accordance with the requirements of Section III.D and Appendix B.

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

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of Jazz 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 Jazz fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Jazz stating the specific grounds for its determination that Jazz has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Jazz shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Jazz 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. Jazz 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 Jazz 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 Jazz 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 Jazz 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 Jazz of: (a) Jazz'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, Jazz 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 Jazz elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Jazz 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 Jazz 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 Jazz to report a Reportable Event, take corrective action, and make the appropriate refunds, 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 and Appendices A-B.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by Jazz constitutes an independent basis for Jazz's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Jazz has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Jazz of: (a) Jazz'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*. Jazz 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. Jazz 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) Jazz has begun to take action to cure the material breach; (ii) Jazz is pursuing such action with due diligence; and (iii) Jazz has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30-day period, Jazz fails to

satisfy the requirements of Section X.D.3, OIG may exclude Jazz from participation in the Federal health care programs. OIG shall notify Jazz in writing of its determination to exclude Jazz (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 Jazz'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, Jazz 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 Jazz 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, Jazz 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 Jazz was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Jazz 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 Jazz to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Jazz 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 Jazz 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) Jazz had begun to take action to cure the material breach within that period; (ii) Jazz has pursued and is pursuing such action with due diligence; and (iii) Jazz provided to OIG within that period a reasonable timetable for curing the material breach and Jazz 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 Jazz, only after a DAB decision in favor of OIG. Jazz's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Jazz 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 Jazz 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. Jazz 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 Jazz, Jazz 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

Jazz and OIG agree as follows:

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

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 Jazz 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.

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.

/s/ Samuel R. Saks, M.D. — 7/13/07

Samuel R. Saks, M.D. — DATE
Chief Executive Officer
Jazz Pharmaceuticals, Inc.

/s/ John T. Bentivoglio — 7/13/07

John T. Bentivoglio — DATE
Mark A. Jensen
Counsel for Jazz Pharmaceuticals, Inc.

Corporate Integrity Agreement
Jazz Pharmaceuticals, Inc.

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

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

7/13/07
DATE

Corporate Integrity Agreement
Jazz Pharmaceuticals, Inc.

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.

Jazz 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 Jazz if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Jazz may continue to engage the IRO.

If Jazz 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, Jazz shall submit the information identified in Section V.A.8 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 Jazz if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Jazz may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

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

2. assign individuals to design and select the Promotional and Product Services Engagement samples 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 Engagement in accordance with the specific requirements of the CIA, including Appendix B to the CIA;

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

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

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

D. IRO Independence and Objectivity.

The IRO must perform the Promotional and Product Services Engagement 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 Jazz.

E. IRO Removal/Termination.

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

Prior to requiring Jazz to engage a new IRO, OIG shall notify Jazz 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, Jazz 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. Jazz 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 Jazz prior to requiring Jazz to terminate the IRO. However, the final determination as to whether or not to require Jazz to engage a new IRO shall be made at the sole discretion of OIG.

Appendix B
Promotional and Product Services Engagement

I. IRO Engagement, General Description

As specified more fully below, Jazz shall retain an Independent Review Organization (IRO) to perform engagements to assist Jazz in assessing and evaluating its systems, processes, policies, and procedures related to Product Services Related Functions (Promotional and Product Services Engagement). 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 below. Jazz may engage, at its discretion, a single IRO to perform both components of the Promotional and Product Services Engagement, provided that the entity has the necessary expertise and capabilities to perform both. As set forth below and in the CIA, Jazz shall engage an IRO to conduct the Promotional and Product Services Transactions Review for each year of the CIA. The IRO shall perform the Promotional and Product Services Systems Review for the first Reporting Period.

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 Jazz's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Product Services Related Functions. Where practical, Jazz 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 Jazz pursuant to the preceding sentence.

For the first Reporting Period, the IRO shall review Jazz' systems, processes, policies, and procedures associated with the following (hereinafter, "Reviewed Policies and Practices"):

1. Jazz's systems, policies, processes, and procedures applicable to the manner in which the Jazz field sales force and Jazz headquarters personnel handle requests or inquiries relating to information about off-label uses of Jazz products, and the manner in which Jazz disseminates materials relating to off-label uses of products. This review includes:

    (i) the instructions to field sales personnel and/or headquarters personnel who receive and respond to requests for information about off-label uses and the manner in which such personnel implement the instructions;

(ii) the procedures for reviewing the form and content of information disseminated by headquarters personnel (*e.g.* the Medical Information department);

(iii) Jazz's internal review process for the information disseminated by headquarters personnel;

(iv) Jazz's systems, processes, and procedures (including its Inquiries Database described in Section III.B.2.f of the CIA) to track requests for information about off-label uses of products and responses to those requests;

(v) the manner in which Jazz collects and supports information reported in its Inquiries Database;

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

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

2. Jazz's policies and procedures applicable to the manner and circumstances under which Medical Information personnel participate in meetings or events with physicians, pharmacists, or other health care professionals (HCPs) (either alone or with members of the sales force) and the role of the Medical Information personnel at such meeting or events;

3. Jazz's systems, policies, processes, and procedures relating to the retention of HCPs as consultants (*e.g.,* including as members of advisory boards, focus groups, or clinical research project teams) or speakers. This shall include a review of:

(i) the criteria used to determine whether, how many, and under what circumstances (including venue for the performance of any services) Jazz will enter contracts for such consulting or speaking arrangements;

(ii) the processes and criteria used to identify and select HCPs with whom Jazz enters consultant, speaker, or other contractual arrangements, including the role played by field sales personnel in the process. This includes a review of Jazz's internal review and approval process for such contracts, and the circumstances under which there may be exception to the process;

(iii) Jazz's tracking or monitoring of services provided or the work performed by the consultants or speakers (including the receipt of the consultant's work product, if any);

(iv) Jazz's policies and procedures related to circumstances, if any, under which the recipient or the recipient's agent is required to disclose the existence of the consulting or speaking arrangement in place between Jazz and the HCP;

(v) the uses made of work product received from consultants or speakers, if any;

(vi) Jazz's processes for establishing the amounts paid to HCPs and the reasons or justifications for any differentials in the amounts paid to different HCPs;

(vii) the criteria used to determine under what circumstances entertainment, recreation, travel, lodging, meals and/or other items or reimbursements are provided to consultants or speakers, and Jazz's processes for establishing the amounts reimbursed or the type of entertainment or recreation provided;

(viii) whether and in what manner Jazz tracks or monitors the prescribing habits or product use of individuals or entities with whom it enters consulting, speakers, or other contractual arrangements, if any; and

(ix) the budget funding source within Jazz (*e.g.,* department or division) for the consulting or contractual arrangement;

4. Jazz's systems, policies, processes, and procedures relating to funding or sponsorship of any Educational or Informational Activity. This review shall include a review of the following items:

(i) the processes and procedures used to approve the funding or sponsorship of an Educational or Informational Activity;

(ii) the criteria used to determine whether and under what circumstances the funding or sponsorship will be provided;

(iii) the processes and criteria used to select recipients of the funding or sponsorships, including the role played by field sales personnel in the processes (if any), and the circumstances under which there may be exceptions to the processes;

(iv) Jazz's policies and procedures related to circumstances, if any, under which the recipient or the recipient's agent is required to disclose Jazz's funding or sponsorship and any financial relationship Jazz may have with the recipients;

(v) Jazz's policies or procedures for determining and memorializing the amounts paid to recipients of the funding or sponsorship and the purpose or justifications for the amounts paid;

(vi) Jazz's policies and procedures relating to the independence of any programs funded through the funding or the sponsorship;

(vii) Jazz's policies and procedures relating to the content and promotional nature of any programs sponsored through the funding or sponsorship;

(viii) whether and in what manner Jazz tracks or monitors the prescribing habits or product use of individuals or entities receiving the funding or sponsorship, if any; and

(ix) the budget funding source within Jazz (*e.g.,* department or division) from which the funding or sponsorships are provided;

5. Jazz's systems, policies, processes, and procedures for compensating (including with salaries and bonuses) non-Overtime Eligible employees, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do no inappropriately motivate sales and marketing personnel to engage in the improper promotion, sales, and marketing of Jazz'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. Jazz's systems, policies, processes, and procedures relating to the development of call plans for Jazz's sales staff. This shall include a review of the basis upon which physician specialties are included or excluded from the call plan based upon their potential on-label and off-label utilization of Jazz products.

B. Promotional and Product Services Systems Review Report

The IRO shall prepare a report which, for each of the Reviewed Policies and Practices identified in Section II.A above, shall include the following items:

1) a description of the documentation (including policies) reviewed and any personnel interviewed, and a list and description of the activities and efforts undertaken by Jazz to assist the IRO in connection with the Systems Review;

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

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 Jazz;

4) a detailed description of any system used to track and respond to requests for information about Jazz's products (*e.g.*, through the Inquiries Database);

5) a detailed description of Jazz's compensation system (including salaries and bonuses) for non-Overtime Eligible employees, included 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

Jazz may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangements;

6) findings and supporting rationale regarding any weaknesses in Jazz's systems, policies, processes, and practices relating to Reviewed Policies and Practices, if any; and

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

Prior to the IRO's submission of the report to the OIG, Jazz shall be provided with a copy of the report and an opportunity to respond to each comment made by the IRO. Provided it does not delay the timely filing of the Annual Reports, any responses by Jazz may be included in the IRO report submitted to the OIG. Otherwise, any responses by Jazz to the IRO's findings may be submitted separately to the OIG following the Annual Report submission.

III. Promotional and Product Services Transactions Review

The IRO shall conduct a Promotional and Product Services Transactions Review for each Reporting Period. As described below, each Transactions Review shall include a review of a sample of Inquiries reflected in the Inquiries Database.

A. Promotional and Product Services Transactions Review

As described in Section III.K of the CIA, Jazz has implemented a policy addressing the appropriate handling of requests for information about non-FDA approved uses of products (off-label information). Jazz documents and records all Inquires (as defined in Section III.B.2.f) and the responses thereto in an Inquiries Database. The Inquiries Database shall include the items set forth in Section III.B.2.f for each Inquiry. On a monthly basis, reports of the Inquiries are provided to the Compliance Officer and reviewed to determine whether improper promotion may have occurred in connection with one or more Inquires. If the Compliance Officer suspects that improper promotion may have occurred, the Compliance Officer undertakes an Off-Label Review as described in Section III.K.

As part of the Promotional and Product Services Transactions Review, the IRO shall evaluate Jazz's processes relating to its Inquiries Database. Specifically, the IRO shall select a random sample of 25 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period.

For each Inquiry reviewed, the IRO shall determine:

i) whether each item of information listed in Section III.B.2.f of the CIA is reflected in the Inquiries Database for each reviewed Inquiry; 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 Jazz based on the Compliance Officer's findings.

B. Promotional and Product Services Transactions Review Report

The IRO shall prepare a report which shall include the following:

1. Elements to be Included:

a. Promotional and Product Services Transactions Review Objectives: A clear statement of the objectives intended to be achieved by the Review;

b. Engagement Protocol: A detailed narrative description of the procedures performed and a description of the universe of Inquiries from which the samples were selected; and

c. Sources of Data: A full description of the documentation (and/or other information) relied upon by the IRO when performing the Promotional and Product Services Transactions Review.

2. Results to Be Included:

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

a. a description of each type of sample unit reviewed, including the number of each type of sample reviewed (*i.e.,* 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 contained in the Inquiries Database about the Inquiry;

c. for each Inquiry sample unit, the IRO shall state its findings and supporting rational as to whether: (i) each element listed in Section III.B.2.f of the CIA is reflected in the Inquiries Database for each

reviewed Inquiry; (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 Jazz as a result of the Compliance Officer's findings;

d. the findings and supporting rationale regarding any weaknesses in Jazz's systems, processes, policies, and practices relating to the Inquiries, if any; and

e. recommendations for improvement in Jazz's systems, processes, policies, and practices relating to the Inquires, if any.

Prior to the IRO's submission of the report to the OIG, Jazz shall be provided with a copy of the report and an opportunity to respond to each comment made by the IRO. Provided it does not delay the timely filing of the Annual Reports, any responses by Jazz may be included in the IRO report submitted to the OIG. Otherwise, any responses by Jazz to the IRO's findings may be submitted separately to the OIG following the Annual Report submission.