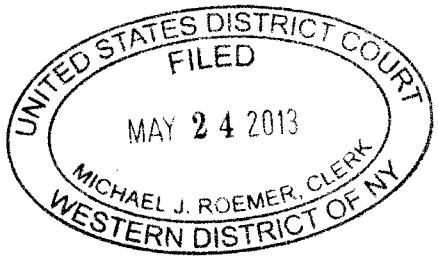

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

v.

ISTA PHARMACEUTICALS, INC.,

Defendant.

13-CR-99A

PLEA AGREEMENT

The United States Attorney's Office for the Western District of New York and the United States Department of Justice, by and through the Consumer Protection Branch (collectively referred to as "United States" or "government"), and the defendant, ISTA PHARMACEUTICALS, INC. ("ISTA"), acting through its counsel, pursuant to authority granted by ISTA's Board of Directors, confirmed in the Board of Directors' certification, attached hereto as **Exhibit A**, hereby enter into a Plea Agreement with the terms and conditions as set out below.

I. THE PLEA AND POSSIBLE SENTENCE

1. The defendant agrees to waive indictment and to plead guilty to a two count Information which charges:

a) in Count I, a violation of Title 18, United States Code, Section 371 and Title 21, United States Code, Sections 331(a), 352(f)(1), and 333(a)(2) (Conspiracy to Introduce a Misbranded Drug in Interstate Commerce with Intent to Defraud and Mislead), for

which the maximum possible sentence is a fine of $500,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greater, a mandatory $400 special assessment, and a term of probation of five years;

b) in Count II, a violation of Title 18, United States Code, Section 371 and Title 42, United States Code, Section 1320a-7b(b)(2)(B) (Conspiracy to Violate the Anti-Kickback Statute), for which the maximum possible sentence is a fine of $500,000, or twice the gross gain derived from the offense or twice the gross loss to a person other than the defendant, whichever is greater, a mandatory $400 special assessment, and a term of probation of five years.

c) The defendant understands that the penalties set forth in this paragraph are the maximum penalties that can be imposed by the Court at sentencing.

2. The defendant understands that, as to both Counts I and II, the Court may require restitution to be paid to any victims of the offenses as part of the sentence, pursuant to United States Sentencing Guidelines ("Sentencing Guidelines") Section 5E1.1 and Title 18, United States Code, Section 3663.

II. ELEMENTS AND FACTUAL BASIS

3. The defendant understands the nature of the offenses set forth in paragraph 1 of this Plea Agreement and understands that if this case proceeded to trial, the government would be required to prove beyond a reasonable doubt the following elements of the crimes:

COUNT I: (Title 18, United States Code, Section 371 and Title 21, United States Code, Sections 331(a), 352(f)(1), and 333(a)(2))

a) That on or about the dates set forth in the Information, the defendant knowingly and willfully combined, conspired and agreed to commit an offense against the United States;

b) That the defendant introduced or delivered for introduction into interstate commerce, or caused to be introduced or delivered for introduction into interstate commerce, a misbranded drug, Xibrom;

c) That the drug was misbranded within the meaning of the Food, Drug, and Cosmetic Act, in that the drug's labeling lacked adequate directions for use, that is, for uses that were not approved by the Food and Drug Administration; and

d) That the defendant acted with the intent to defraud or mislead.

COUNT II: (Title 18, United States Code, Section 371 and Title 42, United States Code, Section 1320a-7b(b)(2)(B))

a) That on or about the dates set forth in the Information, the defendant knowingly and willfully combined, conspired and agreed to commit an offense against the United States;

b) That the defendant offered or paid remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to physicians to induce them to refer individuals to pharmacies for the dispensing of the drug Xibrom, for which payments were made in whole or in part under a Federal health care program; and

c) That the defendant acted knowingly and willfully.

FACTUAL BASIS

4. The defendant and the government agree to the following facts, which form the basis for the entry of the pleas of guilty including relevant conduct:

COUNT I:

a) At all times relevant to this matter, defendant ISTA was a Delaware corporation with its principal place of business in Irvine, California.

b) ISTA was engaged in the licensing, development, promotion and sale of pharmaceutical drugs intended for human use, including the drug Xibrom.

c) ISTA promoted and sold Xibrom throughout the United States, including in the Western District of New York. Xibrom was prescribed by physicians and dispensed by pharmacies throughout the United States, including in the Western District of New York.

d) The uses of Xibrom approved by the Food and Drug Administration ("FDA") related only to treatment of the eye post cataract extraction surgery, a surgery that involved the front of the eye. In March 2005, the FDA approved Xibrom for the treatment of

inflammation post cataract surgery. In January 2006, the FDA approved Xibrom for the reduction of ocular pain post-cataract surgery.

e) At no time did the FDA approve Xibrom for any of the following uses: the treatment of ocular inflammation or pain associated with refractive surgeries; the treatment of ocular inflammation or pain associated with glaucoma surgery; or the prevention or treatment of cystoid macular edema ("CME").

f) ISTA and certain of its employees, acting in their official capacity as employees of ISTA, came to a mutual understanding to try to accomplish a common and unlawful plan to introduce a misbranded drug in interstate commerce with the intent to defraud using the means described in this section.

g) Beginning in or about September 2005 and continuing until in or about November 2010, some ISTA employees, with the knowledge and at the direction of some members of ISTA's management team, promoted Xibrom to physicians throughout the United States, including physicians in the Western District of New York, for uses other than its FDA approved uses. The new intended uses for which Xibrom was promoted by certain ISTA employees included: post Lasik surgery; post Photorefractive Keratectomy ("PRK") surgery; post glaucoma surgery; post Selective Laser Trabeculoplasty ("SLT") surgery; and following surgeries performed with YAG lasers. Xibrom was also promoted by certain ISTA employees for treatment and prevention of conditions associated with the retina (i.e., the back of the eye), such as CME. Some ISTA employees promoted Xibrom for these non-FDA approved uses based on directions and financial incentives from ISTA.

h) Certain ISTA employees, with the knowledge and at the direction of ISTA, paid for and provided post-operative instruction sheets to physicians for uses of Xibrom that were not approved by the FDA as safe and effective.

i) Certain ISTA employees, with the knowledge and at the direction of ISTA, sponsored and actively participated in providing continuing medical education programs to promote Xibrom for uses that were not approved by the FDA as safe and effective.

j) Some ISTA employees were told by management not to memorialize in writing certain interactions with physicians regarding unapproved new uses, and not to leave certain printed materials regarding unapproved new uses in physicians' offices. These instructions were given in order to avoid having their conduct relating to unapproved new uses being detected by others; in other words, with the intent to defraud.

k) The parties agree that, for purposes of relevant conduct, the pecuniary gain to ISTA for the period covered by Count I was $13,458,334.

COUNT II:

a) Xibrom prescriptions were paid for by federal health care programs on a nationwide basis.

b) ISTA and certain of its employees, acting in their official capacity as employees of ISTA, came to a mutual understanding to try to accomplish a common and unlawful plan to offer and pay remuneration, directly and indirectly, overtly and covertly, in cash and in kind, to physicians to induce such physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom, for which payments were made, in whole or in part, under a Federal health care program.

c) With the intent to induce certain unnamed physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom, certain ISTA employees, with the knowledge and at the direction of ISTA, offered and provided these physicians with free Vitrase, another ISTA product.

d) With the intent to induce certain unnamed physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom, certain ISTA employees, with the knowledge and at the direction of ISTA, made a substantial monetary payment to a non-profit entity associated with one of these physicians, which ISTA believed to be a personal benefit to that physician, and provided other remuneration to other physicians.

e) With the intent to induce certain unnamed physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom, certain ISTA employees, with the knowledge and at the direction of ISTA, offered such physicians paid consulting or speaker arrangements, pursuant to which such physicians were compensated in excess of fair market value of services received.

f) With the intent to induce certain unnamed physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom, certain ISTA employees, with the knowledge and at the direction of ISTA, invited such physicians to participate in certain advisory board meetings which were intended to be marketing opportunities and provided such physicians remuneration in excess of fair market value of services received.

5. The defendant also admits the facts set forth in the parties' "Agreed Statement of Facts", attached hereto as **Exhibit B**, and agrees that such Agreed Statement of Facts is incorporated herein by reference.

III. SENTENCING GUIDELINES

6. The defendant understands that the Court must consider but is not bound by the Sentencing Guidelines (Sentencing Reform Act of 1984).

7. The government and the defendant agree that the sentence will be calculated in accordance with Chapter 8 of the Sentencing Guidelines Manual, and Part 8C2 thereof, which pertains to the Sentencing of Organizations other than those that operate primarily for a criminal purpose.

COUNT I:

8. As to Count I, the government and the defendant agree that, pursuant to Sentencing Guidelines Sections 8A1.1, 8A1.2, 8C2.1, and 8C2.4(a)(2), the base fine amount is determined by the pecuniary gain to the organization from the offense.

BASE FINE AMOUNT

9. The government and the defendant agree that the pecuniary gain to the organization from the offense, and thus the Base Fine Amount, is $13,458,334.

CULPABILITY SCORE

10. The government and the defendant agree that, pursuant to Sentencing Guidelines Section 8C2.5, the defendant's Culpability

Score is 6, calculated as follows:

a. **Section 8C2.5(a):** Base Culpability Score of 5;

b. **Section 8C2.5(b)(3)(A)(i):** a 3-level increase is applied based on the fact that ISTA had 200 or more employees, and that an individual within high-level personnel participated in, condoned, or was willfully ignorant of the offenses;

c. **Section 8C2.5(g)(2):** a 2-level decrease is applied based on the fact that ISTA fully cooperated in the investigation and clearly demonstrated recognition and affirmative acceptance of responsibility for its criminal conduct.

MINIMUM AND MAXIMUM MULTIPLIERS

11. The government and the defendant agree that, pursuant to Sentencing Guidelines Section 8C2.6, the minimum and maximum multipliers corresponding to a Culpability Score of 6 are a minimum multiplier of 1.20, and a maximum multiplier of 2.40.

MINIMUM AND MAXIMUM FINE

12. The government and the defendant agree that, pursuant to Sentencing Guidelines Section 8C2.7(a), the minimum of the Guideline fine range is the product of the base fine ($13,458,334) and the minimum multiplier (1.20). The minimum of the Guideline fine range is therefore $16,150,000.

13. The government and the defendant agree that, pursuant to Sentencing Guidelines Section 8C2.7(b), the maximum of the

Guideline fine range is the product of the base fine ($13,458,334) and the maximum multiplier (2.40). The maximum of the Guideline fine range is therefore $32,300,000.

14. Accordingly, the Sentencing Guidelines fine range for Count I is $16,150,000 to $32,300,000.

Count II:

15. As to Count II, the government and the defendant agree that, pursuant to Sentencing Guidelines Sections 8A1.1, 8A1.2, 8C2.1, and 8C2.4(c), the base fine amount shall not be determined by the pecuniary gain or loss to the organization from the offense due to the fact that the calculation of either pecuniary gain or pecuniary loss would unduly complicate and prolong the sentencing process.

16. Notwithstanding the above calculations, it is the agreement of the parties, pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, that the Court at the time of sentence impose the minimum fine of $16,150,000 on Count I, and the statutory maximum fine of $500,000 on Count II. The government agrees that it will not seek a separate restitution

order as to ISTA as part of the resolution of this case. The parties also agree, pursuant to Rule 11(c)(1)(C), that, in consideration for the defendant's intention, through its current owner, Bausch + Lomb Incorporated ("B+L"), to execute, simultaneously with the execution of this document, a document entitled "Compliance and Ethics Program and Certifications," a copy of which is attached hereto as **Exhibit C**, the government will recommend that the Court not impose a term of probation as part of the sentence.

17. The government and the defendant agree that, if, at the time of sentencing, or if, after reviewing the Presentence Investigation Report ("PSR"), assuming one is prepared (see infra para. 25), the Court rejects this Plea Agreement, the parties will be relieved of their other obligations under this Plea Agreement, and the defendant shall then be afforded the opportunity to withdraw its guilty pleas.

18. The government and the defendant agree that the Compliance and Ethics Program and Certifications, **Exhibit C**, executed by defendant's current owner, B+L, is an integral part of this Plea Agreement.

19. The government and the defendant retain the right to withdraw from this Plea Agreement, and this Plea Agreement will be null and void if such right to withdraw is executed, if the civil settlement agreement (see infra Section IX) and the Compliance and Ethics Program and Certification (Exhibit C) are not executed prior to the filing of the Information.

20. With respect to the charges set forth in Paragraph 1 of the Plea Agreement, the defendant agrees that: (a) it is not a "prevailing party" within the meaning of the "Hyde Amendment" (Title 18, United States Code, Section 3006A note), and therefore will not file any claim under such law; and (b) it will not assert any claim under the Double Jeopardy Clause of the Fifth Amendment to the United States Constitution.

21. Defendant ISTA also waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States, any records pertaining to the investigation or prosecution of this case, including without limitation, any records that may be sought under the Freedom of Information Act, (Title 5, United States Code, Section 552, et. seq.), or the Privacy Act (Title 5, United States Code, Section 552a, et. seq.).

IV. STATUTE OF LIMITATIONS

22. The defendant acknowledges that it has previously entered into a tolling agreement relative to the applicable statute of limitations in this matter, and agrees that the criminal conduct set forth herein is timely charged. The defendant acknowledges that defendant's current owner, B+L, also entered into a tolling agreement relative to the applicable statute of limitations in this matter, and defendant agrees that the criminal conduct set forth herein is timely charged. The defendant knowingly waives its right to challenge the instant guilty pleas and/or convictions on the grounds of the statute of limitations.

23. However, in the event the defendant's guilty pleas are withdrawn, or convictions vacated, either pre- or post-sentence, by way of appeal, motion, post-conviction proceeding, collateral attack or otherwise, the defendant agrees that any charges dismissed pursuant to this Plea Agreement shall be automatically reinstated upon motion of the government and further agrees not to assert the statute of limitations as a defense to any other criminal offense involving or related to the introduction into interstate commerce of a misbranded drug or the offering of illegal kickbacks, which is not time barred as of the date of this Plea Agreement. The parties recognize that two tolling agreements

have been entered - one by the government and defendant, and one by the government and defendant's current owner, B+L, and specifically agree that those tolling agreements would continue to have force and effect. The waiver of the statute of limitations defense shall be effective for a period of six months following the date upon which the withdrawal of the guilty pleas or vacating of the convictions becomes final.

V. GOVERNMENT RIGHTS AND RESERVATIONS

24. The defendant understands that the government has reserved the right to:

a. provide to the Court and, if applicable, the Probation Office, all the information and evidence in its possession that the government deems relevant concerning the defendant's background, history, and involvement in the offenses charged, as well as the circumstances surrounding the offenses charged; and

b. respond at sentencing to any statements made by the defendant or on the defendant's behalf that are inconsistent with the information and evidence available to the government.

25. The government agrees not to oppose the defendant's request that the PSR be waived in this case. The parties understand and agree that if the Court accepts the terms and

conditions of the Plea Agreement pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure, the Court must either impose the agreed sentence, or allow the defendant to withdraw its guilty pleas and the government to withdraw from this Plea Agreement.

26. Except as provided herein, the government agrees that, other than the charges in the Information in this case, it will not bring any other criminal charges against defendant ISTA, its present and former parent companies, affiliates, divisions or subsidiaries, or their predecessors, successors and assigns, for conduct which: (a) falls within the scope of the criminal investigation in the Western District of New York relating to ISTA's drugs; or (b) was known to the United States Attorney's Office for the Western District of New York or the Consumer Protection Branch of the Department of Justice as of the date of the execution of this Plea Agreement, and which concerned the sale, promotion or marketing of ISTA's drugs in the United States.

27. The non-prosecution provisions of this Plea Agreement are binding on the Office of United States Attorney for the Western District of New York, the Consumer Protection Branch of the Department of Justice, and the United States Attorney's

Offices for each of the other 93 judicial districts of the United States. The non-prosecution provisions in this Plea Agreement are not binding on the United States with respect to any investigations of ISTA, its subsidiaries, affiliates, or parent that are or may be conducted in the future by the Fraud Section of the Criminal Division of the United States Department of Justice regarding possible violations of the Foreign Corrupt Practices Act and related offenses in connection with the sales and marketing of ISTA's products to foreign customers. A copy of the letter from the Assistant Attorney General, Criminal Division, Department of Justice to United States Attorney William J. Hochul, Jr. authorizing this Plea Agreement is attached hereto as **Exhibit D**.

28. The defendant understands that this Plea Agreement does not bind any other government agency or any component of the Department of Justice except as specified in paragraph 27, supra. Further, the defendant understands that the government takes no position relative to the proper tax treatment of any of the payments made by the defendant pursuant to this Plea Agreement, the civil settlement agreement, or the Compliance and Ethics Program and Certifications referenced in, and attached to, the Plea Agreement as **Exhibit C**.

29. The parties agree that this Plea Agreement relates solely to the conduct of defendant ISTA prior to its acquisition by B+L on June 6, 2012. The government agrees that it has no knowledge that B+L, any current director or officer of B+L, or any current director or officer of ISTA, (all of whom were appointed following B+L's acquisition of ISTA), have committed any violation of criminal law relating to the marketing, promotion, or sale of any of ISTA's drugs.

30. The government acknowledges that B+L has cooperated fully with the government's investigation of ISTA since B+L and ISTA entered into an Agreement and Plan of Merger on March 26, 2012.

31. In recognition of these facts, the Department of Justice agrees that it will not, in any context, assert or take the position that, by virtue of these guilty pleas, either B+L, any current director or officer of B+L, or any current director or officer of ISTA, has violated the Federal Food, Drug, and Cosmetic Act or the Anti-Kickback Statute, or that B+L has a "prior history" of a criminal offense for purposes of determining culpability and penalties under the Federal Sentencing Guidelines for Organizations.

VI. FINANCIAL PENALTY PROVISIONS

32. The defendant understands and agrees that the Court, at the time of sentencing, may order that all monetary penalties imposed at that time, (including any fine, restitution, or special assessment imposed in accordance with the terms and conditions of this Plea Agreement), are to be due and payable in full immediately and subject to immediate enforcement by the United States. The defendant understands and acknowledges that any schedule of payments imposed by the Court at the time of sentencing is merely a minimum schedule of payments and does not, in any way, limit those methods available to the United States to enforce the judgment.

VII. APPEAL RIGHTS

33. The defendant understands that Title 18, United States Code, Section 3742 affords a defendant a limited right to appeal the sentence imposed. The defendant, however, knowingly waives the right to appeal and collaterally attack any component of a sentence imposed by the Court which falls within or is less than the sentencing range for a fine set forth in Section III, above, notwithstanding the manner in which the Court determines the

sentence. In the event of an appeal of the defendant's sentence by the government, the defendant reserves the right to argue the correctness of the defendant's sentence.

34. The defendant understands that by agreeing not to collaterally attack the sentence, the defendant is waiving the right to challenge the sentence in the event that in the future the defendant becomes aware of previously unknown facts or a change in the law which the defendant believes would justify a decrease in the defendant's sentence.

35. The government waives its right to appeal any component of a sentence imposed by the Court which falls within or is greater than the sentencing range for a fine set forth in Section III above, notwithstanding the manner in which the Court determines the sentence. However, in the event of an appeal of the defendant's sentence by the defendant, the government reserves its right to argue the correctness of the defendant's sentence.

VIII. FORFEITURE PROVISIONS

36. As a condition of its plea of guilty to Count I of the Information, the defendant consents to the entry of a forfeiture

money judgment in the amount of one million eight hundred and fifty thousand dollars in United States currency ($1,850,000) (hereinafter, the "Forfeiture Money Judgment"), pursuant to Title 21, United States Code, Sections 334 and 853(p), and Title 28, United States Code, Section 2461(c). The Forfeiture Money Judgment shall be made payable to the "United States Marshals Service" pursuant to wire instructions provided by the United States. The Forfeiture Money Judgment shall be paid at any time prior to or on the date set for the taking of the guilty plea and/or Sentencing in this action.

37. If the Forfeiture Money Judgment is not paid prior to or on the date set for the imposition of sentence (The "Final Due Date"), interest shall accrue on any unpaid portion thereof at the judgment rate of interest from that date. Further, if the defendant fails to pay any portion of the Forfeiture Money Judgment on or before the Final Due Date, the defendant consents to the forfeiture of any other property up to the amount of the Forfeiture Money Judgment, pursuant to Title 21, United States Code, Section 853(p), the Federal Debt Collection Procedure Act, or any other applicable law.

38. The defendant agrees that the value of the quantities of Xibrom which were misbranded in violation of Title 21, United States Code, Section 331 totaled at least $1,850,000 in United States currency. The defendant acknowledges and agrees that the quantities of Xibrom which were misbranded in violation of Title 21, United States Code, Section 331 cannot be located upon exercise of due diligence, or have been transferred or sold to, or deposited with a third party, placed beyond the jurisdiction of the Court, substantially diminished in value, or commingled with other property which cannot be divided without difficulty. Accordingly, the defendant agrees that the government is entitled to forfeit as substitute assets any other assets of the defendant up to the value of the now missing directly forfeitable assets, pursuant to Title 21, United States Code, Section 853(p). The government and the defendant agree that payment in full of the Forfeiture Money Judgment shall satisfy any and all forfeiture obligations that the defendant may have as a result of this guilty plea.

39. After the acceptance of the defendant's guilty plea, and pursuant to Rule 32.2(b)(2) of the Federal Rules of Criminal Procedure, the Court will issue a Preliminary Order of Forfeiture. The defendant hereby waives any right to notice of such Preliminary Order of Forfeiture. The defendant further consents

and agrees that the Preliminary Order of Forfeiture and a Final Order of Forfeiture shall issue and become final as to the defendant at sentencing and agrees that it shall be made part of the defendant's sentence and included in the judgment pursuant to Rule 32.2(b)(4) of the Federal Rules of Criminal Procedure. The defendant acknowledges that the defendant understands that the forfeiture of property is part of the sentence that may be imposed in this case and waives any failure by the Court to advise the defendant of this, pursuant to Rule 11(b)(1)(J), at the time the guilty plea is accepted. Forfeiture of the defendant's property shall not be treated as satisfaction of any fine, restitution, cost of imprisonment, or any other penalty the Court may impose upon the defendant in addition to forfeiture.

40. The defendant agrees to fully assist the government in effectuating the payment of the Forfeiture Money Judgment. The defendant agrees not to file or interpose any claim or to assist others to file or interpose any claim to any property against which the government seeks to execute the Forfeiture Money Judgment in any administrative or judicial proceeding.

41. The defendant knowingly and voluntarily waives its right to any required notice concerning the forfeiture of the assets and monies forfeited hereunder, including notice set forth in an

indictment or information. In addition, the defendant knowingly and voluntarily waives its right, if any, to a jury trial on the forfeiture of the assets and monies forfeited hereunder, and waives all constitutional, legal and equitable defenses to the forfeiture of said assets, including, but not limited to, any defenses based on principles of double jeopardy, the Ex Post Facto clause of the Constitution, any applicable statute of limitations, venue, or any defense under the Eighth Amendment, including a claim of excessive fines.

42. The defendant agrees that the forfeiture of the above sum of money is not to be considered a fine or a payment on any income taxes that may be due.

43. The defendant also agrees that the properties listed above are properly forfeitable to the United States pursuant to Title 21, United States Code, Sections 334, 853(p) and Title 28, United States Code, Section 2461(c). The defendant further agrees to fully assist the government in the forfeiture of the aforementioned property and to take whatever steps are necessary to pass clear title to the United States, including, but not limited to surrender of title and execution of any documents necessary to transfer the defendant's interest in any of the above

property to the United States, as deemed necessary by the government.

IX. RESOLUTION OF CIVIL ACTIONS FILED PURSUANT TO THE QUI TAM PROVISIONS OF THE FALSE CLAIMS ACT 31 U.S.C. SECTIONS 3729-31

44. The defendant acknowledges that it has requested a global resolution in order to address civil liability issues relating to the acts involved in this criminal action, including resolution of two civil actions filed under seal in this District pursuant to the qui tam provisions of the False Claims Act, Title 31, United States Code, Sections 3729-31.

45. The parties acknowledge that, in conjunction with the instant criminal resolution, the defendant will enter into a settlement agreement with the United States resolving the sealed qui tam actions (07-CV-872A and 11-CV-367).

46. The defendant waives and agrees not to assert in any civil lawsuit arising from the conduct which gave rise to the criminal charges that are the subject of this Plea Agreement, any defense based on the double jeopardy or excessive fines clauses of the United States Constitution.

X. TOTAL AGREEMENT AND AFFIRMATIONS

47. This Plea Agreement represents the total agreement between the parties (other than the tolling agreements). There are no promises made by the parties other than those contained in this Plea Agreement. This Plea Agreement supersedes any other prior agreements, written or oral, entered into between the parties.

WILLIAM J. HOCHUL JR.
United States Attorney
Western District of New York

BY: _____
MARYELLEN KRESSE
Assistant U.S. Attorney

Dated: May 23, 2013

MICHAEL S. BLUME
Director
Consumer Protection Branch
U.S. Department of Justice

BY: _____
JEFFREY I. STEGER
Assistant Director
Consumer Protection Branch
U.S. Department of Justice

Dated: May 17, 2013

The corporate defendant, ISTA PHARMACEUTICALS, INC., by its attorneys, Paul E. Kalb, Esq. and Kristin Koehler, Esq. of Sidley Austin LLP, Alice Fisher, Esq. of Latham & Watkins, and General Counsel Robert Bailey, Esq., and by a vote of the Board of Directors, a copy of which resolution is attached hereto and marked **Exhibit A**, hereby agrees to all the terms of this Plea Agreement. Furthermore, the defendant, ISTA PHARMACEUTICALS,

INC., acknowledges that all the terms of this Plea Agreement, which consists of 26 pages, have been explained to the Board of Directors. The defendant has had a full opportunity to discuss this Plea Agreement with its attorneys. The defendant acknowledges that this Plea Agreement represents the total agreement reached between itself and the government (as that term is defined on page 1, supra). The defendant corporation agrees that no promises or representations have been made to the corporation or any representative of the corporation by the government(as that term is defined on page 1, supra), other than what is contained in this Plea Agreement. The defendant corporation understands all of the consequences of its pleas of guilty to Counts I and II of the Information. The defendant corporation fully agrees with the contents of this Plea Agreement. The defendant corporation is signing this Plea Agreement voluntarily.

ISTA PHARMACEUTICALS, INC.
BY: DENIS A. POLYN, ESQ.
President
ISTA Pharmaceuticals, Inc.
Defendant

Dated: May 10, 2013

PAUL E. KALB, ESQ.
Sidley Austin LLP
Counsel for Defendant ISTA

Dated: May 17, 2013

KRISTIN GRAHAM KOEHLER, ESQ.
Sidley Austin LLP
Counsel for Defendant ISTA

Dated: May 17, 2013

ALICE S. FISHER, ESQ.
Latham & Watkins
Counsel for Defendant ISTA

Dated: May 17, 2013

WRITTEN CONSENT OF THE SOLE DIRECTOR OF ISTA PHARMACEUTICALS, INC.

WHEREAS, ISTA Pharmaceuticals, Inc. ("ISTA") has been engaged in discussions with representatives of the United States government (including the Office of the United States Attorney for the Western District of New York, the U.S. Department of Justice Consumer Protection Branch, the U.S. Department of Justice Civil Division, and the Office of the Inspector General of the U.S. Department of Health and Human Services), and representatives of various States, concerning investigations of ISTA's conduct with regard to Xibrom, and a proposed resolution of those investigations;

WHEREAS, the sole Director of ISTA (the "Sole Director") has discussed with counsel the investigations and the proposed resolution thereof on the terms and conditions set forth in the following documents, and counsel has advised the Sole Director of the Company's legal rights, and the Sole Director has reviewed these documents: Plea Agreement (Exhibit A hereto), Agreed Statement of Facts (Exhibit B hereto), Civil Settlement Agreement (Exhibit C hereto), State Settlement Agreement (Exhibit D hereto), and Divestiture Agreement (Exhibit E hereto);

WHEREAS, the Sole Director has determined that resolution of the investigations on the terms and conditions discussed with counsel and contained in the documents attached as exhibits hereto would be in the best interest of ISTA;

NOW THEREFORE, BE IT:

RESOLVED, that the officers of ISTA (specifically including Denis A. Polyn, Esq.), and ISTA's outside counsel, are hereby directed and authorized to sign and enter into on behalf of ISTA the Plea Agreement substantially in the same form as reviewed by the Sole Director and attached hereto as Exhibit A, and to enter guilty pleas on behalf of ISTA as required by the Plea Agreement;

RESOLVED, that the officers of ISTA (specifically including Denis A. Polyn, Esq.), and ISTA's outside counsel, are hereby directed and authorized to sign and enter into on behalf of ISTA the Civil Settlement Agreement substantially in the same form as reviewed by the Sole Director and attached hereto as Exhibit C, settlement agreements with individual States as contemplated by the Civil Settlement Agreement (Exhibit C hereto) and the State Settlement Agreement (Exhibit D hereto), and the Divestiture Agreement substantially in the same form as reviewed by the Sole Director and attached hereto ad Exhibit E;

RESOLVED, that the officers of ISTA, and ISTA's outside counsel, are hereby authorized to take such other actions as may be required by ISTA pursuant to the documents attached to this Resolution or deemed necessary or appropriate to carry out the intent of the foregoing resolutions and that all steps heretofore taken to effect the purposes of the foregoing resolutions are hereby approved, ratified, and confirmed.

IN WITNESS WHEREOF, the undersigned has caused this consent to be executed and directs that it be filed with the minutes of the proceedings of the Board of Directors of the Company.

Dated: May 10 2013

Denis A. Polyn, Sole Director

EXHIBIT B

AGREED STATEMENT OF FACTS

General Facts

1. Defendant ISTA PHARMACEUTICALS, INC. ("ISTA") was a Delaware corporation with its principal place of business located in Irvine, California.

2. Defendant ISTA was engaged in the licensing, development, promotion, and sale of pharmaceutical drugs intended for human use, including the drug Xibrom.

3. Defendant ISTA promoted and sold Xibrom throughout the United States, including in the Western District of New York. Xibrom was prescribed by physicians and dispensed by pharmacies throughout the United States, including in the Western District of New York.

4. On May 24, 2004, defendant ISTA submitted a New Drug Application seeking approval of a drug called Xibrom (also known by the chemical name bromfenac) ophthalmic solution for the treatment of postoperative inflammation and for the reduction of eye pain and photophobia in patients who have undergone cataract extraction.

5. On March 24, 2005, the FDA approved Xibrom for the treatment of postoperative inflammation in patients who have undergone cataract extraction. The approved product label stated that dosage was one drop of Xibrom to the affected eye(s) two times daily beginning 24 hours after cataract surgery and continuing through the first 2 weeks of postoperative period. The approved product label included the following precautions: "All topical nonsteroidal anti-inflammatory drugs (NSAIDs) may slow or delay healing.... In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thinning, corneal erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should immediately discontinue use of topical NSAIDs and should be closely monitored for corneal health."

6. The initial retail trade package of Xibrom approved by FDA was 5.0mL of the Xibrom solution product.

7. The initial physician's sample size of Xibrom approved by FDA was 2.5mL of the Xibrom solution product.

8. On July 14, 2005, defendant ISTA submitted a supplemental New Drug Application for the use of Xibrom for the reduction of ocular pain in patients who have undergone cataract extraction.

9. On January 27, 2006, the FDA approved Xibrom for the reduction of ocular pain in patients who have undergone cataract extraction. The approved product label contained the same dosage and precautions as approved on March 24, 2005.

10. On or around February 14, 2006, defendant ISTA submitted a supplemental New Drug Application seeking approval of 1.0mL physician's sample size of the Xibrom solution product.

11. On or around March 1, 2006, defendant ISTA launched a retail trade package of 2.5mL of the Xibrom solution product.

12. On June 13, 2006, the FDA approved defendant ISTA's supplemental New Drug Application for a 1.0mL physician's sample size of the Xibrom solution product.

13. On December 4, 2008, defendant ISTA submitted a supplemental New Drug Application for the use of Xibrom for the treatment of ocular inflammation and pain associated with refractive surgeries.

14. On May 4, 2010, the FDA denied defendant ISTA's supplemental New Drug Application to extend the use of Xibrom for the treatment of ocular inflammation and pain associated with refractive surgeries. FDA informed ISTA that: "The submitted references do not support the extrapolation of clinical studies using a non-steroidal anti-inflammatory in cataract surgery to postoperative inflammation and pain in all ocular surgeries.... In summary, adequate and well controlled studies have not been conducted with bromfenac ophthalmic solution which demonstrate efficacy in the treatment of ocular inflammation and pain associated with refractive surgeries."

15. At no time did the FDA approve Xibrom for any of the following uses: the treatment of ocular inflammation or pain associated with refractive surgeries; the treatment of ocular inflammation or pain associated with glaucoma surgery; or the prevention or treatment of cystoid macular edema.

16. On or about November 16, 2005, defendant ISTA contacted FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") asserting that [Company A]'s promotion of [Drug A] was in violation of the law. ISTA stated that [Company A] "is engaging in a significant nationwide campaign to promote [Drug A] for a variety of indications for which the drug is not approved by the FDA." Specifically, ISTA asserted that [Company A] was promoting [Drug A] for use in treatment of CME, PRK and Lasik. ISTA noted that "depicting the retina ... for [Drug A] implies that the drug is approved for use in posterior segment eye diseases such as cystoid macular edema (CME).... However, no posterior chamber indications are approved for [Drug A]." ISTA also asserted that [Company A] used an "unrestricted educational grant" to promote [Drug A] for refractive patients, which was also an unapproved use. ISTA concluded: "[Company A] has engaged, and is continuing to engage, in a widespread and substantial marketing campaign to promote their product [Drug A] for various indications for non-cataract surgery related, posterior chamber conditions, none of which is approved by the FDA."

17. On or about February 14, 2006, defendant ISTA contacted FDA's DDMAC asserting that a sales aid by [Company A] was in violation of the law. ISTA stated that the headline and graphic used by [Company A] "show a clear intent by [Company A] to promote

[Drug A] for treatment of diseases of the posterior chamber and retina." ISTA concluded: "the mere fact the sales aide [sic] discusses [Drug A]'s effectiveness in the vitreous humor violates the new drug provisions since the product is not approved for any posterior chamber indication."

18. On or about July 10, 2006, defendant ISTA contacted FDA's DDMAC asserting that an advertisement on [Company A]'s website "continues [Company A]'s ongoing campaign ... to demonstrate that [Drug A] penetrates the vitreous and is efficacious for retinal and other posterior chamber indications." ISTA asserted that these uses were not within [Drug A]'s approved label, and urged the FDA "to take immediate action to compel [Company A] to cease its violative promotional activities."

19. On or about October 26, 2006, defendant ISTA contacted FDA's DDMAC and identified a new [Company A] advertisement "whose single purpose is to tout the use of [Drug A] for cystoid macular edema, a condition of the retina for which [Drug A] is not approved." ISTA considered the advertisement as "touting off label uses of [Drug A]" and urged the FDA to act.

20. On or about November 1, 2006, defendant ISTA contacted FDA's DDMAC asserting that a journal advertisement by [Company B] with respect to its NSAID medication, [Drug B], was misleading. ISTA wrote that [Company B] was promoting [Drug B] for "ocular surgery" when the drug was only approved for use following a specific type of surgery. ISTA asserted that the advertisement was "misleading" because it "broadens the scope of the indication for [Drug B]" and implied that the drug was effective for "any and all ocular surgeries" while its approved indication was "only a small subset." ISTA urged the FDA to investigate and take the appropriate action.

21. On or about December 14, 2006, defendant ISTA contacted FDA's DDMAC complaining about an "equally violative journal ad." ISTA asserted "[a]lthough [Company B] is using human data to support its claim, the human data studied was in patients undergoing [different treatments]. [Drug B] is not approved for this use. Therefore, the advertisement is false and misleading as it presents efficacy data and comparison data for an off-label use." ISTA also asserted that the advertisement was false and misleading because the advertisement presented "dosage and administration not contained in the FDA approved package insert." According to ISTA, the advertisement recommended use of [Drug B] pre-operatively, while the dosage and administration section of the approved product label only referenced postoperative use.

22. Federal health care programs paid for Xibrom prescriptions nationwide.

Count 1
Conspiracy to Introduce a Misbranded Drug in Interstate Commerce with Intent to Defraud or Mislead
(18 U.S.C. § 371; 21 U.S.C. §§ 331(a), 352(f)(1) and 333(a)(2))

23. Defendant ISTA and certain of its employees, acting in their official capacity as employees of ISTA, came to a mutual understanding to try to accomplish a common and unlawful plan to introduce a misbranded drug in interstate commerce with the intent to defraud or mislead using the means described in this section.

24. Beginning in or about September 2005 and continuing until in or about November 2010, some ISTA employees, with the knowledge and at the direction of some members of ISTA's management team, promoted Xibrom to physicians throughout the United States, including physicians in the Western District of New York, for uses other than its FDA approved uses. The new intended uses for which Xibrom was promoted by certain ISTA employees included: post Lasik surgery; post Photorefractive Keratectomy ("PRK") surgery; post glaucoma surgery; post Selective Laser Trabeculoplasty ("SLT") surgery; and following surgeries performed with YAG lasers. Xibrom was also promoted by certain ISTA employees for treatment and prevention of conditions associated with the retina (i.e., the back of the eye), such as cystoid macular edema. Some ISTA employees promoted Xibrom for these non-FDA approved uses based on directions and financial incentives from ISTA.

25. In or around November 2005, some of defendant ISTA's employees discussed the introduction into the market of a smaller size of Xibrom – 2.5mL – in order to broaden sales of Xibrom for short term use, such as after Lasik surgery. Use of Xibrom after Lasik surgery is a use not approved by FDA.

26. In or around December 2005, an ISTA employee prepared a presentation including a "Trade Plan" for Xibrom that stated that the "introduction of a 2.5mL provides opportunity to pursue 'short-term' treatments (i.e., LASIK) = 50% of the Xibrom market opportunity."

27. Beginning in or around February 2006, defendant ISTA distributed continuing medical educational materials to physicians throughout the United States, including physicians in the Western District of New York. In some cases, ISTA employees used some of these materials to promote Xibrom for uses not approved by FDA. Certain ISTA employees, with the knowledge and at the direction of ISTA, also sponsored and actively participated in providing continuing medical education programs to promote Xibrom for uses that were not approved by the FDA as safe and effective.

28. On or about April 28, 2006, one of defendant ISTA's employees informed a pharmaceutical industry analyst that Xibrom's smaller size "is short term use (post-Epi Lasik surgery)" and the original 5.0mL size package of Xibrom was used for "cataracts and CME [cystoid macular edema]." The use of Xibrom for post-Epi-Lasik surgery and for cystoid macular edema was not approved by FDA.

29. On or about August 7, 2006, a presentation for defendant ISTA's Sales and Marketing Leadership Team noted, referring to cystoid macular edema: "If you can treat it, you can prevent it!" The presentation concluded: "Tying it all together in a promotional message – The New Sales Aid.... Quickly knocking out prostaglandins in the anterior chamber helps resolve inflammation and prevent CME. If you can effectively treat CME, you can prevent CME." However, the presentation did not include an examination or results explicitly related to the effectiveness of Xibrom to prevent cystoid macular edema.

30. On or about October 8, 2006, one of defendant ISTA's employees e-mailed other employees asking them to invite physicians to listen to a lunch teleconference in which a speaker hired by ISTA "will cover many topics concerning Xibrom including surgical and off-label uses. Let's make sure we can get maximum impact with this program and target our physicians wisely for this excellent opportunity."

31. Beginning in or around December 2006, defendant ISTA paid for and distributed to physicians post-operative instruction sheets for uses of Xibrom not approved by FDA, including use after Lasik, PRK, and Pterygium surgeries.

32. On or about January 5, 2007, one of defendant ISTA's employees stated that he and another employee "closed a deal with [Physician Laser Practice] and 7 individual Centers that will have the centers converting to Xibrom for PRK and Lasik. This became effective January 1, 2007. Estimated 650+ new prescriptions per month for the various centers."

33. On or about February 16, 2007, one of defendant ISTA's employees e-mailed other employees an attachment "created to help the TM's [Sales Representatives] understand the 'real' opportunity for Xibrom on a daily basis." The attachment identified a significant number of uses for Xibrom not approved by FDA, including use after Lasik, PRK, glaucoma, SLT, and YAG surgeries, and use in connection with conditions associated with the retina, such as cystoid macular edema.

34. On or about February 27, 2007, some of defendant ISTA's employees attended a "Plan of Action" meeting and were instructed to promote Xibrom for a number of uses not approved by FDA, including use after refractive surgery such as Lasik, PRK, glaucoma, SLT, and YAG surgeries, and use in connection with conditions associated with the retina, such as cystoid macular edema.

35. On or about February 27, 2007, one of defendant ISTA's employees presented a slide deck titled "Pre-Call Planning & Product Positioning for Sales Impact" to other employees. The presentation identified a number of uses for Xibrom not approved by FDA, such as refractive, cystoid macular edema, allergy, and abrasions. These unapproved uses and others were termed "Pots of Gold." The presentation ended with a series of slides which asked "What's in it for me?" and answered "Financial Rewards, Recognition, Stock Growth, Job Satisfaction, Company Growth, [and] Promotion?"

36. On or about August 6, 2007, one of defendant ISTA's employees e-mailed other employees and stated that "I would like to see us sign a contract with [Physician Laser Practice]

for their Refractive Business." One employee responded "Good idea regarding [Physician Laser Practice]." Another employee responded "On the [Physician Laser Practice] contract[.] Go for it. What's in your way. You got ball."

37. On or about September 14, 2007, one of defendant ISTA's employees e-mailed other ISTA employees and stated: "The obvious challenge is that most of [Physician Laser Practice] is about Lasik. Some PRK. We are not indicated for Lasik and there is very little pain or inflammation."

38. In or around October 2007, defendant ISTA agreed to give $5,000 to sponsor a golf outing for physicians affiliated with [Physician Laser Practice], an organization that primarily focused on laser eye surgery. On or around October 25, 2007, defendant ISTA's general ledger included an entry of $5,000 for a "US EDUCATIONAL GRANT [Physician Laser Practice] LASER EYE." This money was used to fund the golf outing.

39. On or about November 12, 2007, one of defendant ISTA's employees e-mailed other employees and informed them that the cystoid macular edema "study was a physician initiated trial.... We do not plan to pursue the indication at this point...."

40. On or about January 11, 2008, one of defendant ISTA's employees e-mailed other employees and stated: "Beginning in February, [Physician Laser Practice] in Richmond will be adding Xibrom into all Lasik Procedures. This is a satellite office of [Physician A]. This will equate to 80 plus Rxes on a monthly basis for my territory, the district and the region. All of these Rxes will be written for the 5 ml bottle with a refill." A senior executive of ISTA responded "you amaze me (in a good way)!!! Congratulations."

41. On or about January 15, 2008, one of defendant ISTA's employees e-mailed other employees and informed them that three doctors "have all updated their Refractive Regimens [sic] to include Xibrom. Please see attached instruction sheet.... Who will be the next to take advantage of this unique selling opportunity?"

42. On or about January 15, 2008, some of defendant ISTA's employees attended a "Plan of Action" meeting and were instructed to "close for something on every call." Included as examples of uses to close on were post-Lasik, glaucoma, SLT, and PRK surgeries, none of which were FDA-approved uses.

43. On or about January 15, 2008, one of defendant ISTA's employees e-mailed another employee and described how, based upon training the employee received from a manager, the employee convinced two ophthalmologists to prescribe Xibrom for three days pre-operatively and up to six weeks post-operatively to prevent cystoid macular edema, a use not approved by FDA.

44. On or about January 15, 2008, one of defendant ISTA's employees e-mailed other employees and informed the employees with a laser eye center in their district that they "should have visited these accounts and provided a status report to your [district manager] by that day.

This report should include details and a profile of the OD's and MD's involved. What the Center is currently using and why and of course your goals going forward plus any needs from me...."

45. Some ISTA employees were told by management not to memorialize in writing certain interactions with physicians regarding unapproved new uses, and not to leave certain printed materials in physicians' offices relating to unapproved new uses. These instructions were given in order to avoid having their conduct relating to unapproved new uses being detected by others; in other words, with the intent to defraud.

Count 2
Conspiracy to Violate the Anti-Kickback Statute
(18 U.S.C. § 371; 42 U.S.C. § 1320A-7B(b)(2)(B))

46. Defendant ISTA and certain of its employees, acting in their official capacity as employees of ISTA, came to a mutual understanding to try to accomplish a common and unlawful plan to offer or pay remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to physicians to induce such physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom, for which payment was made in whole or in part under a Federal health care program, using the means described in this section.

47. With the intent to induce certain unnamed physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom, certain ISTA employees, with the knowledge and at the direction of defendant ISTA, offered and provided these physicians with free Vitrase, another ISTA product.

a. On or about September 21, 2006, one of defendant ISTA's employees e-mailed another employee and included an attachment noting that one way of "Growing the Business" was to use Vitrase as "Leverage for Xibrom."

b. On or about November 21, 2006, one of defendant ISTA's employees sent an e-mail with an attachment that included a "Proposal to leverage Vitrase for Xibrom" to other ISTA employees. The proposal "outlines the financial justification to leverage Vitrase in order to gain a significant amount of Xibrom business" from [Physician B]'s practice. In the first scenario, ISTA proposed giving free Vitrase to doctors in exchange for prescriptions of Xibrom. In the second scenario, ISTA proposed offering Vitrase at a discount if the doctor's practice "convert[ed] all NSAID Rxs to Xibrom." According to the proposal, "Scenario 2 is best and what [we] want to sell them. However, even worst case scenario 1 is a BIG WIN for ISTA!"

c. On or about February 6, 2007, defendant ISTA distributed free Vitrase to [Physician B]'s practice.

d. Between on or about March 5, 2007, and on or about September 10, 2007, defendant ISTA distributed 17 shipments of free Vitrase to [Physician B]'s practice.

e. On or about January 22, 2007, one of defendant ISTA's employees e-mailed other ISTA employees proposing to discount Vitrase for more prescriptions of Xibrom from [Physician's Practice]: "Net Net Discount Vitrase by about $5500.00 to make $35,000 on Xibrom. I'm okay with this. Your thoughts?" The recipient of this e-mail responded that same day: "Looks good to me, if it does to you!"

f. On or about January 31, 2007, defendant ISTA distributed six vials of free Vitrase to [Physician's Practice].

g. Between in or around January 2007 and in or around September 2007, defendant ISTA shipped more than 3,500 vials of free Vitrase to physician practices throughout the United States to induce such physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom.

48. With the intent to induce certain unnamed physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom, certain ISTA employees, with the knowledge and at the direction of defendant ISTA, made a substantial monetary payment to a non-profit entity associated with one of these physicians, which ISTA believed to be a personal benefit to that physician, and provided other remuneration to other physicians, as described herein.

a. On or about October 3, 2007, one of defendant ISTA's executives e-mailed other employees informing them of a monetary payment to sponsor an event of a non-profit group associated with [Physician C], and stating: "Lets make this work for us." One of ISTA's employees e-mailed another employee and stated the belief that "the cost of doing business with [the physician] to get all the nsaid business" included, among other things, "$50,000 for a sponsored meeting [the physician] is personally connected to[.]"

b. On or about January 9, 2008, defendant ISTA paid $50,000 to sponsor an event of a non-profit group associated with [Physician C] with the intent to induce such physician to refer individuals to pharmacies for the dispensing of the drug Xibrom.

c. Between in or around June 2007 and in or around November 2008, defendant ISTA provided remuneration in the form of a golf outing and a wine tasting reception to physicians in order to induce such physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom.

49. With the intent to induce certain unnamed physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom, certain ISTA employees, with the knowledge and at the direction of defendant ISTA, offered such physicians paid consulting or speaker arrangements, pursuant to which such physicians were compensated in excess of fair market value of services received.

a. Beginning in or around December 2005, defendant ISTA provided $20,000 in purported research grants, and additional remuneration to [Physician D] with the intent to induce [Physician D] to refer individuals to pharmacies for the dispensing of the drug Xibrom. For example, as a result of ISTA's efforts to create speaking opportunities for him, [Physician D], in the words of an ISTA employee, "committed ... to switching all of his cataract patients ... to Xibrom." In the aggregate, the compensation to [Physician D] was in excess of fair market value for services received.

b. With the intent to induce certain unnamed physicians to refer individuals to pharmacies for the dispensing of the drug Xibrom, certain ISTA employees, with the knowledge and at the direction of defendant ISTA, invited such physicians to participate in certain advisory board meetings which were intended to be marketing opportunities and provided such physicians remuneration in excess of fair market value of services received. For example:In or around September 2005, an ISTA employee emailed a manager, "urgently requesting" that his "#1 and #2 NSAID prescribers, [Physician E and Physician F]," be invited to participate in an ISTA advisory board panel. The ISTA employee explained that it was "a critical time in converting their nsaid business, and I think both doctors see participating with ISTA on a higher level as part of the deal." The ISTA manager responded "DONE!" In or around February 2007, one of defendant ISTA's employees wrote a "Strategic Plan for 2007" for his/her Region which identified the following strategy: "We continue to seek ways to Maximize our Opportunities by insuring the greatest ROI [return on investment]. History has proven that Advisors Meetings are an excellent program that supports our sales efforts. I expect that this most recent Advisors Meeting in NYC will exceed our expectations in market share growth throughout 2007."

c. In early 2008, defendant ISTA invited [Physician G], who practiced in the Western District of New York, to attend a market research meeting in Florida. [Physician G] attended the meeting, which ISTA intended to be a marketing opportunity and provided the physician remuneration in excess of fair market value of services received.

d. On or about April 25, 2007, one of defendant ISTA's employees e-mailed another ISTA employee and stated: "The NYC ad

board strikes again!" The sender proceeded to detail how a physician who attended an Advisory Board meeting agreed to switch his prescriptions to Xibrom and further stated: "Once again, a large Xibrom conversion on the heels of the NYC advisory board."

EXHIBIT C

EXHIBIT C

COMPLIANCE AND ETHICS PROGRAM AND CERTIFICATIONS

After the conduct at issue and prior to entering its plea of guilty, ISTA Pharmaceuticals, Inc. ("ISTA") was acquired by Bausch + Lomb Incorporated ("B+L"). As the owner of ISTA, B+L agrees to the provisions set forth in this Addendum to the Plea Agreement.

I. Compliance and Ethics Program

B+L has in place and will maintain a Compliance and Ethics Program, which governs B+L's United States Pharmaceutical Business. The Compliance and Ethics Program consists of a Chief Compliance Officer who reports to both the Chief Executive Officer of the Corporation and the Board of Directors, a Functional Compliance Committee comprised of senior executives, a comprehensive set of policies and procedures governing the conduct of its employees, a training program focused on the company's compliance policies and procedures, a hotline to allow employees to report potential violations of law or the company's compliance policies and procedures, an anti-retaliation policy, and a monitoring and auditing program designed to deter and detect compliance issues. The Compliance and Ethics Program does and will continue to contain policies and procedures designed to prevent violations of Federal health care program requirements and the Federal Food, Drug and Cosmetic Act ("FDCA") regarding sales, marketing, and promotion of prescription pharmaceutical products, including policies and procedures on the following subjects.

A. Independent Medical Education

B+L has in place and will maintain policies and procedures that prohibit the involvement of sales and marketing personnel and others on the businesses' commercial team in the final decision making process with respect to educational grants in the United States, while also ensuring that the educational programming is focused on objective scientific and educational activities and discourse. B+L will require that independent conference sponsors (e.g., continuing medical education providers) select attending Health Care Providers and are responsible for and control the selection of program content, faculty, educational activities and discourse. All applications will be reviewed by teams that do not report to either B+L's sales and marketing function or others on the businesses' commercial team. Any documentation or communication suggesting that an educational grant is tied in any way to past, present, or future prescribing, purchasing or recommending of any B+L product will cause the request to be denied.

B. Off-Label Promotion and Unsolicited Medical Information Requests

B+L has in place and will maintain its policy that requires sales agents to discuss only those product uses that are consistent with what is indicated on the products approved package labeling and to forward requests for information regarding off-label uses of B+L's products to a Medical Affairs Professional via a completed Medical Information Request Form signed by the individual making the request, including the individual's full contact information and the question posed, which confirms that the request was unsolicited.

C. No Offering or Paying Illegal Remuneration

B+L has in place and will maintain policies and procedures that prohibit the company and its employees and representatives from engaging in any conduct that violates the Federal anti-kickback statute, including, but not limited to, the offering or paying of any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to any person to induce such person to prescribe any prescription drug for which payment may be made in whole or in part under a Federal health care program.

II. Notice to Health Care Providers and Entities

Within 90 days after the date of sentencing, B+L shall send, by first class mail, postage prepaid, a notice containing the language set forth below to all Health Care Providers and Healthcare Institutions that B+L currently details. This notice shall be dated and shall be signed by B+L's President of Global Pharmaceuticals. The body of the letter shall state the following:

> "As you may be aware, B+L acquired ISTA Pharmaceuticals, Inc. ("ISTA") in June of 2012. Following the acquisition, B+L agreed that ISTA would enter into a global civil and criminal settlement with the United States in connection with the promotion and use of one of ISTA's products, Xibrom, based on conduct of ISTA before it was acquired by B+L. This letter provides you with additional information about the settlement, explains B+L's commitments going forward, and provides you with access to information about those commitments.
>
> In general terms, the Government alleged that ISTA unlawfully promoted Xibrom for uses not approved by the Food + Drug Administration ("FDA") and that ISTA unlawfully offered and provided kickbacks to healthcare providers in exchange for increased prescriptions of Xibrom. To resolve these matters, ISTA pled guilty to two felony criminal violations, including conspiracy to violate the Federal Food, Drug + Cosmetic Act ("FDCA"), and conspiracy to violate the anti-kickback statute. ISTA agreed to pay a criminal fine and forfeiture of $18.5 million. In addition, the Government alleged that ISTA violated the False Claims Act, and B+L entered into a civil settlement to resolve these allegations pursuant to which ISTA agreed to pay $15 million to the Federal Government and State Medicaid programs. More information about this settlement may be found at the following: **[B+L shall include a link to the USAO, Consumer Protection Branch, and B+L websites in the letter.]**
>
> As part of the federal settlement, B+L committed to maintaining its Compliance and Ethics Program. Under this agreement, which is available at **[B+L shall include a link to the Consumer Protection Branch website.],** B+L agreed to continue to undertake certain actions designed to promote compliance with Federal health care program and FDCA requirements and make periodic certifications to the Department of Justice. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by B+L's representatives to B+L's Compliance Department or the FDA.

Please call B+L at **XXXX** or **visit us at [insert name of web link]** if you have questions about the settlement referenced above or to report any instances in which you believe that a B+L representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by a B+L Representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about the products to **XXXXX."**

The Chief Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message.

III. Log, Certification and Board Resolution

B+L shall provide the Log required in Subsection II above and the following Certification and Board Resolution to the United States Department of Justice on an annual basis for a period of three years.

The Certification shall be sworn to under the pains and penalties of perjury and shall set forth that the representations contained therein may be provided to, relied upon and material to the government of the United States, and that a knowing false statement could result in criminal or civil liability for the signatory.

B+L shall provide the Log, Certification and Board Resolution to the United States Department of Justice within 60 calendar days following the end of each review period as follows:

Chief, Criminal Division
U.S. Attorney's Office
Western District of New York
138 Delaware Avenue
Buffalo, NY 14202

Director, Consumer Protection Branch
Civil Division
Department of Justice
450 5th Street, NW
Washington, DC 20530

A. Annual B+L's President of Global Pharmaceuticals Certification

B+L's President of Global Pharmaceuticals shall conduct a review of the effectiveness of B+L's Compliance and Ethics Program as it relates to the marketing, promotion, and sale of prescription pharmaceutical products during the preceding year. The first review period shall run from the date of sentencing through December 31, 2013. Thereafter, the reviews will be conducted on an annual basis. Based on his or her review, B+L's President of Global Pharmaceuticals shall submit to the United States a signed certification stating that, to the best of his or her knowledge, during the period [insert time period]: (1) B+L's Compliance and Ethics Program continued to include the policies and procedures set forth in the section of this Addendum entitled Compliance and Ethics Program, and (2) the Compliance and Ethics Program

was effective in preventing violations of Federal health care program requirements and the Federal Food, Drug and Cosmetic Act regarding sales, marketing, and promotion of prescription pharmaceutical products. The certification by B+L's President of Global Pharmaceuticals shall summarize the review described above that he or she conducted to provide the required certification. If B+L's President of Global Pharmaceuticals is unable to certify that the Compliance and Ethics Program was effective in preventing violations of Federal health care program requirements and the Federal Food, Drug and Cosmetic Act regarding sales, marketing, and promotion of prescription pharmaceutical products, he or she shall provide a detailed explanation of why the Compliance and Ethics Program was not effective, and the steps B+L is taking to ensure the effectiveness of the Compliance and Ethics Program. This detailed explanation will satisfy part 2 of the certification requirement above.

B. Annual Board of Directors Resolution

The Board of Directors of B+L, or a designated Committee thereof (the "Board"), shall conduct a review of the effectiveness of B+L's Compliance and Ethics Program as it relates to the marketing, promotion, and sale of prescription pharmaceutical products. This review shall be conducted on an annual basis and shall include, but not be limited to, updates and reports by B+L's Chief Compliance Officer and other compliance personnel. The Board shall evaluate the effectiveness of the Compliance and Ethics Program, including, among other means, by receiving updates about the activities of the Chief Compliance Officer and other company personnel and updates about adoption and implementation of policies, procedures, and practices designed to ensure compliance with applicable Federal health care program and FDCA requirements. The Board review shall not require the retention of third party experts. The first review will cover the time period from the date of sentencing through December 31, 2013. Thereafter the reviews will be conducted on an annual basis. Based on its review, the Board shall submit to the United States a resolution (the "Board Resolution") that summarizes its review and oversight of B+L's compliance with Federal health care program requirements and FDCA requirements and, at a minimum, includes the following language:

> The Board of Directors has made a reasonable inquiry as described in Section III.B of the Addendum to the Plea Agreement into the operations of B+L's Compliance and Ethics Program for the time period [insert time period], including the performance of the Chief Compliance Officer and other compliance personnel employed by B+L. The Board has concluded that, to the best of its knowledge, B+L has implemented an effective Compliance and Ethics Program, as defined by the U.S. Sentencing Guidelines Manual, Chapter 8: Sentencing of Organizations (2012), to meet Federal health care program requirements, FDCA requirements, and the requirements of the Addendum to the Plea Agreement.

If the Board is unable to provide any part of this statement, it shall include in the resolution an explanation of the reasons why it is unable to provide such a statement about the effectiveness of B+L's Compliance and Ethics Program.

IV. Breach of this Addendum

B+L recognizes that each of the terms in this Addendum constitutes a material term of this Addendum. As a contractual remedy, B+L and the United States agree that failure to comply with the obligations set forth in this Addendum may lead to the imposition of the following monetary penalties (hereafter referred to as "Stipulated Penalties") in accord with the following provisions.

A. A Stipulated Penalty of $3,000 per day for each day B+L (1) fails to maintain a Compliance and Ethics Program as set forth in Subsection I, above (if more than one specific compliance policy (i.e., Section I.A. through I.C., above) fails to be maintained, the Stipulated Penalty will apply separately to each compliance policy); or (2) fails to timely supply the Log, Certification, or Board Resolution required in Subsection III, above. With regard to the Log, Certification, and Board Resolution, the Stipulated Penalty will begin to accrue on the day after the date the obligation was due, subject to the provisions for extension of time for compliance and the opportunity to cure set forth below.

B. B+L may submit a timely written request for an extension of time to provide any Log, Certification, or Board Resolution required in Subsection III. A written request is timely if received by the U.S. Attorney's Office for the Western District of New York and the Civil Division's Consumer Protection Branch at least five business days prior to the date by which the Log, Certification, or Board Resolution is due. Timely requests for extension will not be unreasonably denied. If an extension of time is granted in writing, Stipulated Penalties shall not accrue until one day after B+L fails to meet the revised deadline. If not granted, Stipulated Penalties shall not begin to accrue until three business days after B+L receives the United States' written denial of such request or the original due date, whichever is later.

C. Upon the United States' sole reasonable determination that B+L has failed to comply with any of the obligations described herein, the United States shall notify B+L in writing of B+L's failure to comply and the United States' exercise of its contractual right to demand payment of the Stipulated Penalties (the "Demand Letter"). The Demand Letter shall set forth: (i) the provision breached; (ii) the date of the breach; (iii) a description of the breach sufficient to permit B+L to cure (as described below); and (iv) the amount of Stipulated Penalties claimed by the United States as of the date of the Demand Letter. Within fourteen (14) days after receipt of the Demand Letter, or such other period as the United States may agree in writing, B+L shall cure the breach to the United States' reasonable satisfaction ("Cure Period"). If B+L cures the breach within the Cure Period, no Stipulated Penalties shall be due. If B+L fails to cure the breach during the Cure Period, Stipulated Penalties calculated from the date of breach to the date of payment shall be immediately payable to the United States. The Stipulated Penalties shall be paid by electronic fund transfer according to wire instructions that will be provided by the United States. A joint reasonable determination by

the United States Attorney for the Western District of New York and the Assistant Attorney General for the Civil Division regarding B+L's failure to comply with any of the obligations described herein will be final and non-appealable. B+L agrees that the United States District Court for the Western District of New York shall have jurisdiction over any action to collect such a penalty.

FOR THE UNITED STATES

WILLIAM J. HOCHUL JR.
United States Attorney
Western District of New York

MARYELLEN KRESSE
Assistant U.S. Attorney
Dated: May 23, 2013

MICHAEL S. BLUME
Director
Consumer Protection Branch
U.S. Department of Justice

JEFFREY I. STEGER
Assistant Director
Consumer Protection Branch
U.S. Department of Justice
Dated: May 17, 2013

FOR BAUSCH + LOMB INCORPORATED

A. ROBERT D. BAILEY, ESQ.
General Counsel
Bausch + Lomb Incorporated
Dated: May 16, 2013

PAUL E. KALB, ESQ.
Sidley Austin LLP
Counsel for Bausch + Lomb Incorporated
Dated: May 16 2013

KRISTIN GRAHAM KOEHLER, ESQ.
Sidley Austin LLP
Counsel for Bausch + Lomb Incorporated
Dated: May 17, 2013

ALICE S. FISHER, ESQ.
Latham & Watkins
Counsel for Bausch + Lomb Incorporated
Dated: May 17, 2013

U.S. Department of Justice

Criminal Division

Office of the Assistant Attorney General

Washington, D.C. 20530

MAY - 7 2013

The Honorable William J. Hochul, Jr.
United States Attorney
Western District of New York
138 Delaware Avenue
Buffalo, NY 14202

Attention: MaryEllen Kresse
Assistant United States Attorney

Re: Global Plea Agreement for ISTA Pharmaceuticals, Inc.

Dear Mr. Hochul:

This is in response to your request for authorization to enter into a global plea agreement with defendant ISTA Pharmaceuticals, Inc.

I hereby approve the terms of the Plea Agreement, including Paragraphs 26-28, through which the United States agrees not to initiate further criminal proceedings against ISTA for the conduct at issue, with the exceptions and conditions noted within those paragraphs and elsewhere within the Plea Agreement.

You are authorized to make this approval a matter of record in this proceeding.

Sincerely,

Mythili Raman
Acting Assistant Attorney General

Denis J. McInerney

DENIS J McINERNEY
DEPUTY ASSISTANT ATTORNEY GENERAL
CRIMINAL DIVISION