U.S. Department of Justice

United States Attorney
District of Maryland
Southern Division

Civil Division
Consumer Protection Branch

Rod J. Rosenstein
United States Attorney

Stuart A. Berman
Chief, Greenbelt Branch

Linda I. Marks
Senior Litigation Counsel

Perham Gorji
Trial Attorney

400 United States Courthouse
6500 Cherrywood Lane
Greenbelt, MD 20770-1249

DIRECT: 301-344-4031
MAIN: 301-344-4433
FAX: 301-344-4516
TTY/TDD: 301-344-2426
Stuart.Berman@usdoj.gov

202-307-0060
Linda.Marks@usdoj.gov

202-353-3881
Perham.Gorji@usdoj.gov

January 2, 2013

Geoffrey R. Garinther, Esq.
W. Warren Hamel, Esq.
Winifred M. Weitsen, Esq.
Venable LLP
750 E. Pratt Street
Suite 900
Baltimore, Maryland 21202

Re: United States v. Ranbaxy USA, Inc.,
Crim. No. [to be determined] JFM-13-0238

Dear Mr. Garinther, Mr. Hamel and Ms. Weitsen:

This letter, together with the Sealed Supplement, confirms the plea agreement that has been offered to the Defendant by the United States Attorney's Office for the District of Maryland and the Consumer Protection Branch of the U.S. Department of Justice (collectively "this Office"). **The agreement will be presented to the Court pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C).** This agreement is contingent upon execution of a Civil Settlement Agreement between Ranbaxy USA, Inc. and the United States. If the Defendant accepts this offer, please have a responsible corporate officer execute it in the spaces provided below. The terms of the agreement are as follows:

Offenses of Conviction

1. The Defendant agrees to knowingly and voluntarily waive indictment and plead guilty to Counts One through Seven of a criminal information to be filed against it, which will charge it with introduction into interstate commerce of adulterated drugs, with intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(a), 333(a)(2), and 351(a)(2)(B); failure to timely file required reports with intent to defraud or mislead, in violation of 21 U.S.C. §§ 331(e) and 333(a)(2);

false statements, in violation of 18 U.S.C. § 1001; and aiding and abetting, in violation of 18 U.S.C. § 2. The Defendant admits that it is, in fact, guilty of these offenses and will so advise the Court.

Elements of the Offenses

2. The elements of the offenses to which the Defendant has agreed to plead guilty, and which this Office would prove if the case went to trial, are as follows:

Count One (Introduction into Interstate Commerce of Adulterated Drugs): (1) the Defendant introduced or caused the introduction of a drug; (2) the drug was adulterated; (3) the Defendant acted knowingly; (4) the drug was introduced into interstate commerce; and (5) the Defendant did so with the intent to defraud or mislead.

Counts Two and Three (Failure to Timely File Required Reports): (1) the Defendant was a manufacturer of a drug approved by the FDA pursuant to an Abbreviated New Drug Application; (2) the Defendant was aware of the failure of one or more distributed batches of a drug product to meet the specification established for it under the drug's ANDA; (3) the Defendant failed to submit a "field alert report" within three working days after receiving any information concerning such failure; and (4) the Defendant did so with the intent to defraud or mislead.

Counts Four through Seven (False Statements): (1) the Defendant made and/or aided and abetted the making of a statement or representation; (2) the statement or representation was within the jurisdiction of the Executive Branch of the United States government, specifically the Food and Drug Administration; (3) the statement or representation was false; (4) the false statement or representation was made knowingly and willfully; and (5) the statement or representation was material.

For each offense, the Defendant is guilty as an aider and abettor if the Defendant (1) willfully and knowingly associated itself in some way with the crime, and (2) willfully and knowingly sought by some act to help make the crime succeed.

Penalties

3. The maximum sentence provided by statute for each offense to which the Defendant is pleading guilty is as follows: a fine of $500,000, or an amount not more than the greater of twice the gross gain or twice the gross loss relating to the offense, pursuant to 18 U.S.C. § 3571(d), and a term of at least one year but not more than five years of probation, pursuant to18 U.S.C. § 3561(c)(1). On the basis of Defendant's gross gain of not less than $100,000,000 for the sale of drugs described in the criminal information and Attachment A, the maximum possible fine is $200,000,000. In addition, the Defendant must pay $2,800 ($400 per count) as a special assessment pursuant to 18 U.S.C. § 3013, which will be due and should be paid at or before the time of sentencing. This Court may also order it to make restitution pursuant to 18 U.S.C. §§ 3663,

3663A, and 3664.[1] If a fine or restitution is imposed, it shall be payable immediately, unless, pursuant to 18 U.S.C. § 3572(d), the Court orders otherwise.

Waiver of Rights

4. The Defendant understands that by entering into this agreement, it surrenders certain rights as outlined below:

a. If the Defendant had entered pleas of not guilty, it would have had the opportunity to assert the right to a speedy jury trial with the close assistance of competent counsel. That trial could be conducted by a judge, without a jury, if the Defendant, this Office, and the Court all agreed.

b. If the Defendant elected and were granted a jury trial, the jury would be composed of twelve individuals selected from the community. Counsel and the Defendant would have the opportunity to challenge prospective jurors who demonstrated bias or who were otherwise unqualified, and would have the opportunity to strike a certain number of jurors peremptorily. All twelve jurors would have to agree unanimously before the Defendant could be found guilty of any count. The jury would be instructed that the Defendant was presumed to be innocent, and that presumption could be overcome only by proof beyond a reasonable doubt.

c. If the Defendant went to trial, the government would have the burden of proving the Defendant guilty beyond a reasonable doubt. The Defendant would have the right to confront and cross-examine the government's witnesses. The Defendant would not have to present any defense witnesses or evidence whatsoever. If the Defendant wanted to call witnesses in its defense, however, it would have the subpoena power of the Court to compel the witnesses to attend.

d. The Defendant would have the right to call witnesses to testify in its own defense if it so chose, and it would have the right to refuse to call witnesses to testify. If it chose not to call witnesses to testify, the Court could instruct the jury that they could not draw any adverse inference from its decision not to call witnesses to testify.

e. If the Defendant were found guilty after a trial, it would have the right to appeal the verdict and the Court's pretrial and trial decisions on the admissibility of evidence to see if any errors were committed which would require a new trial or dismissal of the charges against it. By pleading guilty, the Defendant knowingly gives up the right to appeal the verdict and the Court's decisions.

---

[1] Pursuant to 18 U.S.C. § 3612, if the Court imposes a fine in excess of $2,500 that remains unpaid 30 days after it is imposed, the Defendant shall be charged interest on that fine, unless the Court modifies the interest payment in accordance with 18 U.S.C. § 3612(f)(3).

f. By pleading guilty, the Defendant will be giving up all of these rights, except the right, under the limited circumstances set forth in the "Waiver of Appeal" paragraph below, to appeal the sentence. By pleading guilty, the Defendant understands that its counsel and designated representative may have to answer the Court's questions both about the rights it is giving up and about the facts of the case. Any statements the Defendant's counsel and representative make during such a hearing would not be admissible against it during a trial except in a criminal proceeding for perjury or false statement.

g. If the Court accepts the Defendant's pleas of guilty, there will be no further trial or proceeding of any kind, and the Court will find it guilty.

Advisory Sentencing Guidelines Apply

5. The Defendant understands that the Court will determine a sentencing guidelines range for this case (henceforth the "advisory guidelines range") pursuant to the Sentencing Reform Act of 1984 at 18 U.S.C. §§ 3551 through 3742 (excepting 18 U.S.C. §§ 3553(b)(1) and 3742(e)) and 28 U.S.C. §§ 991 through 998. The Defendant further understands that the Court will impose a sentence pursuant to the Sentencing Reform Act, as excised, and must take into account the advisory guidelines range in establishing a reasonable sentence.

Factual and Advisory Guidelines Stipulation

6. This Office and the Defendant understand, agree, and stipulate to the Statement of Facts set forth in Attachment A hereto which this Office would prove beyond a reasonable doubt, and to the following sentencing guidelines factors:

a. The base fine is $100 million, which is the pecuniary gain to the organization from the offenses. *See* U.S.S.G. § 8C2.4(a)(2).

b. Pursuant to U.S.S.G. § 8C2.5, the culpability score is **6**, which is determined as follows:

i. Base culpability score is **5** pursuant to U.S.S.G. § 8C2.5(a);

ii. **1** point is added pursuant to U.S.S.G. § 8C2.5(b)(5), in that the organization had 10 or more employees and an individual within substantial authority personnel participated in, condoned, or was willfully ignorant of the offenses.

c. Pursuant to U.S.S.G. § 8C2.6, the appropriate multiplier range associated with a culpability score of **6** is 1.20 - 2.40.

d. Pursuant to U.S.S.G. § 8C2.7, the advisory Guideline Fine Range is $120,000,000 to $240,000,000.

7. This Office and the Defendant agree that with respect to the calculation of the advisory guidelines range, no other offense characteristics, sentencing guidelines factors, potential departures or adjustments set forth in the United States Sentencing Guidelines will be raised or are in dispute.

Agreed Disposition

8. The parties stipulate and agree pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C) that the following sentence is the appropriate disposition of this case:

a. a fine of $130,000,000, payable in full before the fifteenth day after the date of judgment.

b. a criminal forfeiture money judgment of $20,000,000, also payable in full before the fifteenth day after the date of judgment.

c. a special assessment of $2,800.

d. The above-referenced agreed-upon sentence is contingent upon the execution of a Civil Settlement Agreement between Ranbaxy USA, Inc. and the United States, which is being signed contemporaneously with this Plea Agreement and is appended as Attachment B, and which requires the payment of $350,000,000, plus interest.

e. In light of the Civil Settlement Agreement and the pending civil action, *United States of America ex rel. Dinesh S. Thakur v. Ranbaxy USA, Inc., et al.,* Civil Action No. JFM-07-962 (D. Md.), the parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a proper restitution order outweighs the need to provide restitution to any non-federal victims in this case given that numerous unknown individuals and insurance companies purchased or reimbursed for the drug products in question, and that tracing reimbursements to the various unknown insurance companies and patients and determining the apportionment of payment pertaining to the products at issue would be extraordinarily difficult, if not impossible. *See* 18 U.S.C. § 3663(a)(1)(B)(ii). Accordingly, this Office agrees that it will not seek a separate restitution order as to the Defendant as part of the resolution of the Information and the parties agree that the appropriate disposition of this case does not include a restitution order.

f. This agreement does not affect the Court's discretion to impose any lawful term of probation or to set any lawful conditions of probation. In the event that the Court rejects this plea agreement, *either* party may elect to declare the agreement null and void. Should the Defendant so elect, it will be afforded the opportunity to withdraw its plea pursuant to the provisions of Federal Rule of Criminal Procedure 11(c)(5).

g. This Office and the Defendant jointly submit that this Plea Agreement, together with the record that will be created by this Office and the Defendant at the plea and

sentencing hearings, will provide sufficient information concerning the Defendant, the crimes charged in this case, and the Defendant's role in the crimes to enable the meaningful exercise of sentencing authority by the Court under 18 U.S.C. § 3553. This Office and the Defendant agree to request jointly that the Court accept the Defendant's guilty pleas and impose sentence on an expedited schedule as early as the date of arraignment, based upon the record provided by the Defendant and this Office, under the provisions of Fed. R. Crim. P. 32(c)(1)(A)(ii) and U.S.S.G. § 6A1.1. The Court's denial of the request to impose sentence on an expedited schedule will not void this Plea Agreement.

Forfeiture

9. The Defendant understands that the court will, upon acceptance of its guilty plea, enter an order of forfeiture as part of its sentence, and that the order of forfeiture may include assets directly traceable to its offense, substitute assets and/or a money judgment equal to the value of the property derived from, or otherwise involved in, the offense. Specifically, the Court will order the forfeiture of a money judgment of $20 million, equivalent to quantities of drugs which were introduced into interstate commerce in violation of Title 21, United States Code, Section 331 and/or 351(a)(2)(b), namely the specified drugs introduced during the specified period identified in the Information. The Defendant agrees to consent to the entry of orders of forfeiture for such property and waives the requirements of Federal Rules of Criminal Procedure 11(b)(1)(J), 32.2 and 43(a) regarding notice of the forfeiture in the charging instrument, advice regarding the forfeiture at the change-of-plea hearing, announcement of the forfeiture at sentencing, and incorporation of the forfeiture in the judgment.

Assisting the Government with Regard to the Forfeiture

10. The Defendant agrees to assist fully in the forfeiture of the foregoing assets. The Defendant agrees to disclose all of its assets and sources of income to the United States, and to take all steps necessary to pass clear title to the forfeited assets to the United States, including but not limited to executing any and all documents necessary to transfer such title, assisting in bringing any assets located outside of the United States within the jurisdiction of the United States, and taking whatever steps are necessary to ensure that assets subject to forfeiture are not sold, disbursed, wasted, hidden or otherwise made unavailable for forfeiture. The Defendant further agrees that it will not assist any third party in asserting a claim to the forfeited assets in an ancillary proceeding and that its representatives will testify truthfully in any such proceeding.

Waiver of Further Review of Forfeiture

11. The Defendant further agrees to waive all constitutional, legal and equitable challenges (including direct appeal, habeas corpus, or any other means) to any forfeiture carried out in accordance with this Plea Agreement on any grounds, including that the forfeiture constitutes an excessive fine or punishment. The Defendant also agrees not to challenge or seek review of any civil or administrative forfeiture of any property subject to forfeiture under this agreement, and will not assist any third party with regard to such challenge or review or with regard to the filing of a petition

for remission of forfeiture.

Agreement Not to Further Prosecute Other Offenses the Defendant May Have Committed

12. a. Pursuant to Fed. R. Crim. P. 11(c)(1)(A), this Office agrees that, other than the charges in the Information described in Paragraph 1, it shall not further prosecute the Defendant and/or the related corporate entities collectively referred to as Ranbaxy in Attachment A for any additional federal criminal or forfeiture charges or charges under the Food Drug and Cosmetic Act with respect to the conduct that falls within the scope of the Information to which the Defendant is pleading guilty, was the subject of the grand jury investigation in the District of Maryland, or was known to this Office prior to the date of this Agreement relating to:

i. the production, manufacturing, processing, packing and/or holding of drugs at the manufacturing facilities at Paonta Sahib and Dewas ("Paonta Sahib and Dewas facilities") between the years 2003 and 2010; or

ii. conduct, actions, omissions, communications and reporting regarding the Food and Drug Administration's oversight, regulatory inspections and/or actions regarding the Paonta Sahib and Dewas facilities between the years 2003 and 2010.

b. This Office does not decline criminal prosecution of the Defendant for any other conduct beyond that set forth above.

c. This declination is expressly contingent upon:

i. the guilty plea of the Defendant to the Information being accepted by the Court and not withdrawn or otherwise challenged; and

ii. the Defendant's performance of all of its obligations as set forth in this Agreement and the Civil Settlement Agreement.

d. If the Defendant's guilty plea is not accepted by the Court or is withdrawn for any reason, or the Defendant should fail to perform any obligation under this Agreement or the Civil Settlement Agreement, this declination of prosecution shall be null and void. This Office expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of the Defendant, in connection with the conduct encompassed by this plea agreement, within the scope of the investigation, or known to this Office.

Waiver of Statute of Limitations

13. The Defendant understands and agrees that, pursuant to tolling agreements executed by the parties, the charges set forth in the Information are not time-barred by the statute of limitations. The Defendant explicitly waives all defenses based on the statute of limitations with

respect to any prosecution that is not time-barred on the date this plea agreement is signed. The Defendant understands and agrees that should the convictions following its pleas of guilty pursuant to this agreement be vacated for any reason, then any prosecution that is not time-barred as of the date of the signing of this agreement may be commenced or reinstated against the Defendant, notwithstanding the expiration of the statute of limitations between the signing of this agreement and the commencement or reinstatement of such prosecution.

Waiver of Appeal

14. In exchange for the concessions made by this Office and the Defendant in this plea agreement, if the Court accepts this agreement and imposes the agreed-upon sentence, this Office and the Defendant waive their rights to appeal as follows:

a. The Defendant knowingly waives all right, pursuant to 28 U.S.C. § 1291 or otherwise, to appeal the Defendant's conviction.

b. If the Court accepts the agreed-upon sentence, the Defendant and this Office knowingly waive all right, pursuant to18 U.S.C. § 3742 or otherwise, to appeal whatever sentence is imposed (including the right to appeal any issues that relate to the establishment of the advisory guidelines range, the weighing of the sentencing factors, and the decision whether to impose and the calculation of any fine, order of forfeiture, order of restitution, and term or condition of probation).

c. Nothing in this agreement shall be construed to prevent the Defendant or this Office from invoking the provisions of Federal Rule of Criminal Procedure 35(a), or from appealing from any decision thereunder, should a sentence be imposed that resulted from arithmetical, technical, or other clear error.

d. The Defendant waives any and all rights under the Freedom of Information Act relating to the investigation and prosecution of the above-captioned matter and agrees not to file any request for documents from this Office or any investigating agency.

Obstruction or Other Violations of Law

15. The Defendant agrees that it will not commit any offense in violation of federal, state or local law between the date of this agreement and its sentencing in this case. In the event that the Defendant (i) engages in conduct after the date of this agreement which would justify a finding of obstruction of justice under U.S.S.G. § 3C1.1, or (ii) fails to accept personal responsibility for its conduct by failing to acknowledge its guilt to the probation officer who prepares the Presentence Report, or (iii) commits any offense in violation of federal, state or local law, then this Office will be relieved of its obligations to the Defendant as reflected in this agreement. Specifically, this Office will be free to argue sentencing guidelines factors other than those stipulated in this agreement, and it will also be free to make sentencing recommendations other than those set out in this agreement. As with any alleged breach of this agreement, this Office will

bear the burden of convincing the Court of the Defendant's obstructive or unlawful behavior and/or failure to acknowledge personal responsibility by a preponderance of the evidence. The Defendant acknowledges that it may not withdraw its guilty plea because this Office is relieved of its obligations under the agreement pursuant to this paragraph.

Entire Agreement

16. This letter supersedes any prior understandings, promises, or conditions between this Office and the Defendant and, together with the Sealed Supplement, constitutes the complete plea agreement in this case. The Defendant acknowledges that there are no other agreements, promises, undertakings or understandings between the Defendant and this Office other than those referred to or set forth in this letter and the Sealed Supplement and none will be entered into unless in writing and signed by all parties.

If the Defendant fully accepts each and every term and condition of this agreement, please sign and have the Defendant sign the original and return it to me promptly.

Very truly yours,

Rod J. Rosenstein
United States Attorney

By: _____
Stuart A. Berman
Assistant United States Attorney

By: _____
Linda I. Marks
Senior Litigation Counsel

By: _____
Perham Gorji
Trial Attorney

U.S. Department of Justice
Consumer Protection Branch

By virtue of a Resolution Adopted by the Board of Directors of Ranbaxy USA, Inc. (appended to this agreement as Attachment C), I have been authorized, empowered and directed to represent Ranbaxy USA, Inc. before the Court in order to make statements and confirmations in accordance with this agreement, including entering a guilty plea on behalf of the Defendant. I have read this agreement, including the Sealed Supplement, and carefully reviewed every part of it with the attorneys for Ranbaxy USA, Inc. I understand it, and I voluntarily agree to it. Specifically, I have reviewed the Factual and Advisory Guidelines Stipulation with the attorneys, and I do not wish to change any part of it. Ranbaxy USA, Inc. is completely satisfied with the representation of its attorneys.

3/1/13
Date

Irving Kagan
Corporate Secretary
Ranbaxy USA, Inc.

We are the attorneys for Ranbaxy USA, Inc. We have carefully reviewed every part of this agreement, including the Sealed Supplement, with the Defendant and its designated representative. The Defendant has advised us that it understands and accepts its terms. To our knowledge, its decision to enter into this agreement is an informed and voluntary one.

March 1, 2013
Date

W. Warren Hamel, Esq.
Geoffrey R. Garinther, Esq.
Winifred M. Weitsen, Esq.

ATTACHMENT A: STATEMENT OF FACTS – RANBAXY USA, INC.

The undersigned parties hereby stipulate and agree that if this matter had gone to trial, the government would have proven the following facts beyond a reasonable doubt. The undersigned parties also stipulate and agree that the following facts do not encompass all of the evidence which would have been presented had this matter gone to trial.

A. Defendant RANBAXY USA, INC.

At times material to this case, defendant **RANBAXY USA, INC. ("RANBAXY USA")** was a Florida corporation that maintained its main office in Jacksonville, Florida. Defendant **RANBAXY USA** was one of several subsidiaries of Ranbaxy, Inc., a Delaware corporation with offices in Princeton, New Jersey. Ranbaxy, Inc. was also the parent company to Ranbaxy Pharmaceuticals, Inc. ("RPI"); Ohm Laboratories, Inc. ("Ohm"); and Ranbaxy Laboratories, Inc. ("RLI"). Ranbaxy, Inc., in turn, was owned by Ranbaxy Holdings (U.K.) Limited, a United Kingdom holding company, which was a wholly-owned subsidiary of Ranbaxy (Netherlands) B.V., a Netherlands intermediate holding company. Ranbaxy (Netherlands) B.V. was a wholly-owned subsidiary of Ranbaxy Laboratories Limited ("RLL"), an Indian corporation established in 1961 with corporate headquarters in Gurgaon, India. Defendant **RANBAXY USA**'s operations supported the efforts of RPI, Ohm and RLI, including but not limited to sales. RLL and its various subsidiaries are collectively referred to as Ranbaxy.

Defendant **RANBAXY USA** engaged in and aided and abetted, among other things, Ranbaxy's manufacture and interstate distribution of certain prescription drugs intended for human use throughout the United States, including the District of Maryland.

B. The FDA and FDCA

The United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA") and assuring, among other things, that drugs intended for use in humans were safe and effective for their intended uses and that the labeling of such drugs bore true and accurate information. Pursuant to such responsibility, FDA published and administered regulations relating to the approval, manufacture, and distribution of drugs. The FDCA defined drugs as, among other things, articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man, and articles intended to affect the structure or any function of the body of man. 21 U.S.C. §§ 321(g)(1)(B) and (C).

Prescription drugs under the FDCA were any drugs intended for use in humans which, because of their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, 21 U.S.C. § 353(b)(1)(A), or drugs limited by the terms of FDA approval to use under the professional supervision of a licensed practitioner, 21 U.S.C. § 353(b)(1)(B). The FDCA prohibited causing the introduction or delivery for introduction into interstate commerce, or introducing or delivering for introduction into interstate commerce, of any drug that was adulterated. 21 U.S.C. § 331(a).

Under the FDCA, a drug was deemed adulterated if the methods used in, or the facilities or controls used for, its manufacturing, processing, packing, or holding did not conform to or were not operated or administered in conformity with current good manufacturing practice ("cGMP") to assure that such drug met the requirements of the FDCA as to safety and had the identity and strength, and met the quality and purity characteristics, which it purported or was represented to possess. 21 U.S.C. § 351(a)(2)(B).

Implementing regulations under the FDCA further defined current good manufacturing practice required for finished pharmaceuticals, and included, among other specific requirements, the following:

a. *Quality Control Unit.* Drug manufacturers were required to maintain a quality control unit with the responsibility and authority to approve or reject all in-process materials and drug products and the authority to review production records to assure that no errors had occurred or, if errors had occurred, that they were fully investigated. 21 C.F.R. § 211.22(a). The quality control unit was to have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product. 21 C.F.R. § 211.22(c).

b. *Contamination and Product Mix-ups.* Separate or defined areas or such other control systems were required for the firm's operations as necessary to prevent contamination or mix-ups during the course of packaging and labeling operations, and aseptic processing. 21 C.F.R. §§ 211.42(c)(6) and (10). Packaging and labeling facilities were required to be inspected immediately before use to assure that all drug products were removed from previous operations, and results of such inspections were required to be documented in the batch records. 21 C.F.R. § 211.130(e)(2003).

c. *Equipment.* Equipment used in the manufacture, processing, packing or holding of a drug product was required to be of appropriate design to facilitate operations for its intended use. 21 C.F.R. § 211.63. Equipment was required to be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. 21 C.F.R. § 211.68(a).

d. *In-Process Testing.* In-process materials were required to be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit during the production process. 21 C.F.R. § 211.110(c).

e. *Drug Product Testing.* Drug products failing to meet established standards or specifications and any other relevant quality control criteria were required to be rejected, unless satisfactorily reprocessed. 21 C.F.R. § 211.165(f).

f. *Production and control records.* Drug manufacturers were required to prepare batch production and control records, and to have those records reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures, before a batch was released or distributed. 21 C.F.R. §§ 211.188 and 192. Any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications were required to be thoroughly investigated whether or not the batch was already distributed, and the investigation was required to extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. 21 C.F.R. § 211.192.

As part of its mission to enforce the FDCA and protect the public health, the FDA had the authority to enter and inspect at reasonable times all establishments where drugs were manufactured, processed, packed, or held for introduction into interstate commerce or after shipment in interstate commerce. 21 U.S.C. § 374(a)(1). Upon conclusion of such inspection, if violations were observed, the FDA issued a "Form 483," otherwise known as a "Notice of Inspectional Observations," to set forth the cGMP deficiencies observed by the FDA inspectors during the inspection. If the violations were significant, the FDA could issue a "Warning Letter" to notify a firm of the agency's observation that certain of its manufactured products appeared to be adulterated, and that, unless sufficient corrective actions were implemented, further regulatory action could be taken without notice.

Drug manufacturers had certain duties and responsibilities to notify the FDA of information that might affect the safety or efficacy of the drugs it manufactured. Pursuant to 21 C.F.R. § 314.81, manufacturers of drugs subject to a New Drug Application were required to make certain post-marketing reports. Manufacturers of drugs subject to an Abbreviated New Drug Application ("ANDA") also were required to file certain post-marketing reports. 21 C.F.R. § 314.98(c). These regulations were promulgated pursuant to 21 U.S.C. § 355(k). The failure of a manufacturer to file any such required report was prohibited under 21 U.S.C. § 331(e). These required reports included:

a. *Field Alert Reports.* The manufacturer of a drug subject to an ANDA was required to submit a "field alert report" within three working days after receiving any information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in a distributed drug product, or any failure of one or more distributed batches of a drug product to meet the specification established for it under the drug's ANDA. 21 C.F.R. § 314.81(b)(1)(ii).

b. *Annual Reports.* The manufacturer of a drug subject to an ANDA was required to submit to FDA an annual report with the following information: (1) a brief summary of significant new information from the previous year that might affect safety, effectiveness, or labeling of the drug product, 21 C.F.R. § 314.81(b)(2)(i); (2) reports of experiences, investigations, studies, or tests involving chemical or physical properties, or any other properties of the drug that may affect the FDA's previous conclusions about the safety or effectiveness of the drug product, 21 C.F.R. § 314.81(b)(2)(iv)(a); and (3) a full description of the manufacturing and controls changes not requiring a supplemental application, listed by date in the order in which they were implemented,

21 C.F.R. § 314.81(b)(2)(iv)(b). The annual report was required to include a status report on each postmarketing study of the drug product that the applicant committed to conduct at the time of approval, including ongoing stability studies. 21 C.F.R. § 314.81(b)(2)(viii). The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors, such as temperature, humidity, and light, and to establish a retest period for the drug substance or a shelf life for the drug product and recommended storage conditions. The cGMP regulations require a drug manufacturer to develop, implement, and follow a written testing program to assess the stability characteristics of each drug that it manufactures. The results of this stability testing were used in determining appropriate storage conditions and expiration dates for the drug. 21 U.S.C. § 211.166(a).

C. Ranbaxy Drugs Marketed in the United States

Defendant **RANBAXY USA** facilitated the marketing and sale of Ranbaxy generic drugs in the United States, including but not limited to: Acyclovir, Amoxicillin, Amoxicillin and Clavulanate Potassium, Cefaclor, Cefadroxil, Cefpodoxime Proxetil, Cefprozil, Cefuroxime Axetil, Cephalexin, Ciprofloxacin HCl, Clarithromycin, Fenofibrate, Fluconazole, Fosinopril Sodium, Fosinopril Sodium and Hydrochlorothiazide, Gabapentin, Ganciclovir, Glimepiride, Loratadine, Metformin HCl, Nefazodone HCl, Nitrofurantoin and Macrocrystalline, Ofloxacin, Ranitidine, Sotret (Ranbaxy brand for Isotretinoin)("Sotret"), and Zidovudine.

D. FDA Inspections of Ranbaxy's Manufacturing Facilities

Ranbaxy owned and operated numerous drug manufacturing facilities in India, including ones located at Sirmour District, Himanchal Pradesh, India ("Paonta Sahib") and Industrial Area-3, Dewas, India ("Dewas") that manufactured or have manufactured drugs that were the subject of ANDAs on file with FDA. The Paonta Sahib and Dewas facilities also manufactured active pharmaceutical ingredients ("APIs") used by Ranbaxy to manufacture finished drug products.

Paonta Sahib Inspections

FDA inspected the Paonta Sahib facility from February 20, 2006 to February 25, 2006. During that inspection, FDA investigators documented eight deviations from cGMP in the manufacture of certain drug products, which included, but were not limited to:

a. Failure to include in certain laboratory records a complete record of all data secured in the course of each test, including all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific drug product and lot tested, as required by 21 C.F.R. § 211.194(a)(4);

b. Failure to establish and follow an adequate written testing program designed to assess the stability characteristics of certain drug products and, with respect to certain drugs, to determine appropriate drug storage conditions and expiration dates, as required by 21 C.F.R. § 211.166; and

c. Failure of the quality control unit to have adequate laboratory resources, including personnel and equipment, for conducting stability testing of certain drugs, as required by 21 C.F.R. § 211.22(b).

Dewas Inspections

FDA inspected Ranbaxy's Dewas facility from February 27, 2006 to March 2, 2006. During that inspection, FDA investigators documented deviations from cGMP including, but not limited to:

a. Failure to maintain complete data derived from all tests necessary to assure compliance with established specifications and standards, as required by 21 C.F.R. § 211.194;

b. Failure to have batch production and control records for each batch of drug product produced that includes complete information relating to the production and control of each batch, as required by 21 C.F.R. § 211.188; and

c. Failure to extend investigations into any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy, whether or not the batch has already been distributed, as required by 21 C.F.R. § 211.192.

FDA inspected Ranbaxy's Dewas facility from January 28 - February 12, 2008. During that inspection, FDA investigators documented significant deviations from cGMP in the manufacture of certain sterile and non-sterile finished products and in the manufacture and control of certain APIs. These observations included, but were not limited to:

a. Failure to adequately establish separate or defined areas for the manufacture and processing of certain non-penicillin beta-lactam products to prevent contamination and mix-ups, and failure to separate adequately the operations related to the manufacturing, processing, and packaging of certain penicillin from non-penicillin products, as required by 21 C.F.R. § 211.42(c)(5) and (d);

b. Failure to include required information relating to the production and control of each batch produced in batch production and control records, as required by 21 C.F.R. § 211.188(b);

c. Failure to have procedures that provide for a thorough review of unexplained discrepancies or failure of a batch or any of its components to meet its specifications, whether or not the batch has already been distributed, as required by 21 C.F.R. § 211.192;

d. Failure of the quality control unit to ensure that its organizational structure, procedures, processes, resources, and activities were adequate to ensure that APIs and drug products, sterile and non-sterile, meet their intended specifications for quality and purity, as required by 21 C.F.R. § 211.22;

e. Failure to have and follow adequate written procedures designed to prevent microbiological contamination of certain drug products and APIs purported to be sterile, as required by 21 C.F.R. § 211.113(b); and

f. Failure to have adequate controls established to prevent contamination or mix-ups in aseptic processing operations, as required by 21 C.F.R. § 211.42(c)(10).

E. Stability Testing

At the Paonta Sahib and Dewas facilities, Ranbaxy, among other things, conducted stability testing of certain drugs several weeks or months later than the dates that were reported to FDA in annual reports. Additionally, in many instances, the stability test results for certain drugs for different time intervals (e.g., three, six, and nine months) actually were conducted on the same day or within a few days of each other.

One specific aspect of Ranbaxy's problems with the late stability testing was that employees stored stability samples pending testing in a four-degree Celsius refrigerator (the "Four-Degree Refrigerator"). This procedure was neither provided for in the protocols Ranbaxy submitted to FDA nor disclosed in subsequent filings. That is, stability testing protocols called for testing of each drug to be conducted at certain specified frequencies. For example, for a drug with a 24-month shelf-life (*i.e.*, the expiration date was 24 months after the date of manufacture), stability testing was to be conducted at the following intervals: three months, six months, nine months, 12 months, 18 months, and 24 months. Stability testing protocols also called for samples of the drugs to be tested (the "stability samples") to be stored in a designated "stability chamber" under certain specified conditions (including specified temperature and humidity ranges), from the time they were manufactured until the time they were tested, in order to approximate the storage conditions under which the drug could be expected to be held once marketed. Internal procedures allowed for a maximum period between (1) the time a stability sample was due to be tested and the sample was removed from the stability chamber, and (2) the time the test actually was conducted.

As Ranbaxy fell behind in its stability testing of certain drugs and did not timely test samples of those drugs according to the protocols that had been submitted to FDA, employees began to store in the Four-Degree Refrigerator samples that had been removed from the stability chamber but had not been tested within the specified time. The use of the Four-Degree Refrigerator was not disclosed to FDA in Annual Reports. Instead, Ranbaxy entities continued to represent that its stability testing program was being conducted according to the protocols that had been submitted to FDA. Additionally, no historical documentation was maintained of what stability samples had been stored in the Four-Degree Refrigerator, or for how long any particular sample had been stored in the Four-Degree Refrigerator.

F. Outside Consultants' Reports About cGMP Violations

Ranbaxy was repeatedly informed of cGMP problems by consultants that it hired to review its operations. For example, one audit report conducted in or about October 2003 by Consulting Firm A was sent to Ranbaxy's Director of Regulatory Affairs and concluded, among other things,

that "formalized training, as required by the cGMPs . . . was essentially non-existent," that investigations into product complaints were "incomplete and poorly documented," and that "[n]umerous discrepancies were found in the 'source data.'"

In or about February and March 2005, Consulting Firm A audited Ranbaxy's manufacturing facilities, including those located at Dewas and Paonta Sahib, "to evaluate the firm's level of GMP compliance relative to FDA current expectations." Consulting Firm A observed that "common compliance themes were noted from all sites that warrant the firm to consider further enhancement and improvement to its systems, controls and procedures to achieve [a] state of sustainable compliance," and warned that certain findings, "if not addressed, could potentially result in regulatory action and/or a significant FDA 483 observation." These findings included process validation; equipment qualification (manufacturing and laboratory); master production records (including batch records); procedures (manufacturing and laboratory); site-wide good documentation practices; and stability program.

a. Consulting Firm A recommended "that Ranbaxy personnel acquire a better understanding of the principles of validation to meet current U.S. regulatory requirements and expectations and to be in alignment with the accepted U.S. industry practices."

b. Consulting Firm A also observed that "[b]atch records from all sites were found to be deficient," identified "a need for the company to overhaul the batch records . . . to ensure consistency in the manufacture of batches," and stated that "[a] procedure on good documentation practices was found to be lacking at all the sites."

c. Consulting Firm A also stated that Ranbaxy's "Stability Program needs enhancement to be in alignment with accepted U.S. industry practices," and noted specifically that staffing was inadequate in the Stability Department at Ranbaxy's Paonta Sahib facility.

In or about April 2005, Consulting Firm A proposed to conduct a series of training programs at Ranbaxy, including a program titled "Creating a Culture of Trust, Ethical Behavior and a 'Quality First' Mindset." Ranbaxy never presented any of the training programs recommended for it by Consulting Firm A.

The above-described violations of cGMP resulted in the introduction into interstate commerce, including into the District of Maryland, of some adulterated drugs, because the manufacturing processes and laboratory testing procedures were insufficient to ensure that the drugs manufactured at the Paonta Sahib facility, including the drugs Ciprofloxacin, Gabapentin and Sotret, were of the strength, purity, and quality that the drugs were represented to possess.

Introduction of Adulterated Drugs

Between on or about January 1, 2005, and on or about December 31, 2006, in the District of Maryland and elsewhere, **RANBAXY USA, INC.**, did, with intent to defraud and mislead, cause to be introduced and delivered for introduction into interstate commerce certain batches of drugs manufactured at Ranbaxy's Paonta Sahib facilities, including certain batches of Ciprofloxacin,

Gabapentin and Sotret, that were adulterated in that the methods used in, and the controls used for drug manufacturing, processing, packing, and holding did not conform to and were not operated and administered in conformity with current good manufacturing practice, as required by 21 C.F.R. § 211.

Failure to Timely File Required Reports

Ranbaxy produced Sotret, a drug used to treat severe recalcitrant nodular acne, at its Paonta Sahib facility. It produced Sotret in 10 mg, 20 mg, 30 mg and 40 mg capsules. Ranbaxy was aware that Batch #1266265, a 20 mg batch manufactured in January 2003, had failed 45-day accelerated dissolution stability tests, but nonetheless distributed drug product from that batch in the United States until at least February 2004. Ranbaxy did not timely report the failure of this distributed batch's 45-day accelerated dissolution stability tests to FDA, as required by 21 C.F.R. § 314.81(b)(1). As a result, the defendant delivered the following shipments of Sotret 20 mg Batch #1266265 into the District of Maryland:

DATE	ITEM
October 24, 2003	Sotret 20 mg capsule, shipment to Baltimore, Maryland
October 31, 2003	Sotret 20 mg capsule, shipment to Baltimore, Maryland
November 4, 2003	Sotret 20 mg capsule, shipment to Baltimore, Maryland
December 2, 2003	Sotret 20 mg capsule, shipment to Baltimore, Maryland
December 5, 2003	Sotret 20 mg capsule, shipment to Baltimore, Maryland
December 11, 2003	Sotret 20 mg capsule, shipment to Baltimore, Maryland
February 19, 2004	Sotret 20 mg capsule, shipment to Baltimore, Maryland

On or about April 21, 2003, in the District of Maryland and elsewhere, **RANBAXY USA, INC.**, with the intent to defraud and mislead, did fail to submit to FDA a field alert report within three days after it determined that Sotret 20 mg Batch #1266265 had failed 45-day accelerated dissolution stability testing.

Ranbaxy also produced Gabapentin, a drug used to treat epilepsy and nerve pain, at its Paonta Sahib facility. It produced Gabapentin in 600 mg and 800 mg tablets and 100 mg, 300 mg, and 400 mg capsules. On or about June 21, 2007, on or about July 9, 2007, and again on or about August 30, 2007, Ranbaxy became aware that certain batches of Gabapentin were testing out-of-specification, had demonstrated the presence of unknown impurities, and would, therefore, not maintain their expected shelf life. Ranbaxy was obligated to timely report these problems to FDA, as required by 21 C.F.R. § 314.81(b)(1), but failed to do so.

On or about October 17, 2007, Ranbaxy notified FDA that certain batches of Gabapentin had tested out of specification for "related substances," and thereafter initiated a voluntary recall of over

73,286,200 tablets of 600 mg and 800 mg Gabapentin. These batches had been distributed in the United States as early as September 26, 2005, including the following shipments into the District of Maryland:

DATE	ITEM
September 12, 2007	Gabapentin 600 mg tablet, shipment to Landover, MD
September 14, 2007	Gabapentin 800 mg tablet, shipment to Landover, MD
October 18, 2007	Gabapentin 600 mg tablet, shipment to Landover, MD

Between on or about June 26, 2007, and on or about September 4, 2007, in the District of Maryland and elsewhere, **RANBAXY USA, INC.,** with the intent to defraud and mislead, did fail to submit to FDA a field alert report within three days after it determined that certain batches of Gabapentin, had exceeded impurity specifications for "related substances" during expected shelf life.

False Statements

Ranbaxy produced Cefaclor, Cefadroxil, Amoxicillin, and Amoxicillin and Clavulanate Potassium, antibiotics for oral administration, in capsule and oral suspension form at its Dewas facility. Various forms of these drugs were approved by the FDA pursuant to ANDA numbers 64-155, 64-165, 65-015, 65-113, and 65-132. As described above, Ranbaxy conducted stability testing of certain batches of these drugs several weeks or months later than the dates that were reported to FDA in Annual Reports, and in many instances, the stability test results that were reported as having occurred at three, six, nine, twelve and eighteen months time intervals actually were conducted on the same day or within a few days of each other.

On or about January 2, 2007, in the District of Maryland, **RANBAXY USA, INC.** knowingly and willfully made and aided and abetted the making of materially false, fictitious, and fraudulent statements and representations in a matter within the jurisdiction of the Executive Branch of the United States government, to wit, the FDA, in that it stated and represented in the Annual Report for ANDA 64-155 (Cefaclor Oral Suspension, 375 mg/5 ml) that stability testing for the batches listed below was conducted on the dates listed in the second column of the tables below, when in fact, it then and there well knew that stability testing for the batches listed below had not been tested as stated and represented in the aforementioned Annual Report:

Batch No. 1367794

TEST TYPE	REPORTED TEST DATE
6 Month Station: Assay – 0 day	September 30, 2004
6 Month Station: Related Substances – 0 day	September 30, 2004
18 Month Station: Related Substances – 0 day	September 15, 2005

Batch No. 1367797

TEST TYPE	REPORTED TEST DATE
6 Month Station: Assay – 0 day	September 30, 3004
6 Month Station: Related Substances – 0 day	September 30, 2004
18 Month Station: Related Substances – 0 day	September 15, 2005

On or about January 2, 2007, in the District of Maryland, **RANBAXY USA, INC.** knowingly and willfully made and aided and abetted the making of materially false, fictitious, and fraudulent statements and representations in a matter within the jurisdiction of the Executive Branch of the United States government, to wit, the FDA, in that it stated and represented in the Annual Report for ANDA 64-165 (Cefaclor Oral Suspension, 187 mg/5 ml) that stability testing for Batch No. 1293626 had been conducted on the dates listed in the second column of the table below, when in fact, it then and there well knew that stability testing for Batch No.
1293626 was not tested as stated and represented in the aforementioned Annual Report:

TEST TYPE	REPORTED TEST DATE
12 Month Station: Assay – 0 day	July 5, 2005
18 Month Station: Related Substances – 0 day	December 25, 2004

On or about March 20, 2006, in the District of Maryland, **RANBAXY USA, INC.** knowingly and willfully made and aided and abetted the making of materially false, fictitious, and fraudulent statements and representations in a matter within the jurisdiction of the Executive Branch of the United States government, to wit, the FDA, in that it stated and represented in the Annual Report for ANDA 65-113 (Amoxicillin Oral Suspension) that stability testing for Batch No. 1258258 was conducted on the dates listed in the second column of the table below, when in fact, it then and there well knew that stability testing for Batch No. 1258258 was not tested as stated and represented in the aforementioned Annual Report:

TEST TYPE	REPORTED TEST DATE
24 Month Station: Assay – 0 day	December 10, 2004
24 Month Station: Related Substances – 0 day	December 10, 2004

On or about June 29, 2006, in the District of Maryland, **RANBAXY USA, INC.** knowingly and willfully made and aided and abetted the making of materially false, fictitious, and fraudulent statements and representations in a matter within the jurisdiction of the Executive Branch of the United States government, to wit, the FDA, in that it stated and represented in the Annual Report for ANDA 65-132 (Amoxicillin and Clavulanate Potassium Oral Suspension) that stability testing for Batch No. 1289117 was conducted on the dates listed in the second column of the table below, when in fact, it then and there well knew that stability testing for Batch No. 1289117 was not tested as stated and represented in the aforementioned Annual Report:

TEST TYPE	REPORTED TEST DATE
18 Month Station: Assay – 0 day	November 14, 2004
18 Month Station: Related Substances – 0 day	November 14, 2004

For purposes of determining the alternative maximum fine pursuant to Title 18, United States Code, Section 3571(d), **RANBAXY USA, INC.** derived gross gains of not less than $100 million.

I have read this statement of facts and carefully reviewed it with the attorneys for Ranbaxy USA, Inc. I acknowledge that it is true and correct.

3/1/13
Date

Irving Kagan
Corporate Secretary
Ranbaxy USA, Inc.

March 1, 2013
Date

W. Warren Hamel, Esq.
Geoffrey R. Garinther, Esq.
Winifred M. Weitsen, Esq.

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"); TRICARE Management Activity ("TMA"), through its General Counsel; the Office of Personnel Management ("OPM"), which administers the Federal Employees Health Benefits Program ("FEHBP"); the United States Department of Veterans Affairs ("VA"); and the United States Agency for International Development ("USAID"), which administers the United States President's Emergency Plan for AIDS Relief ("PEPFAR"), (collectively the "United States"); Ranbaxy Laboratories Limited, Ranbaxy, Inc., Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories, Inc., Ohm Laboratories, Inc., and Ranbaxy USA, Inc. (collectively, "Ranbaxy"); and Dinesh S. Thakur ("Thakur" or "Relator") (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Ranbaxy Laboratories Limited is a public company incorporated under Indian law with headquarters in Gurgaon, India. Ranbaxy, Inc., incorporated in Delaware, is the United States subsidiary of Ranbaxy Laboratories Limited. Ohm Laboratories, Inc., incorporated in New Jersey; Ranbaxy Pharmaceuticals, Inc., incorporated in Florida; Ranbaxy Laboratories, Inc., incorporated in Delaware; and Ranbaxy USA, Inc., incorporated in Florida, are all subsidiaries of Ranbaxy, Inc. At all relevant times, Ranbaxy distributed and sold in the United States pharmaceutical products that were manufactured at its facilities in Paonta Sahib, India, and

Dewas, India (the "Covered Drugs").

B. On or about April 13, 2007, Dinesh S. Thakur filed a *qui tam* action in the United States District Court for the District of Maryland ("Court") captioned *United States ex rel. Dinesh S. Thakur v. Ranbaxy USA, Inc., et al.*, Civil Action No. 1:07-00962-JFM (D. Md.) pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the "Civil Action"). On or about February 26, 2010, Relator filed a First Amended Complaint in the District of Maryland under the same caption and case number, and this First Amended Complaint sets forth the current allegations in the *qui tam* action.

C. On such date as may be determined by the Court, Ranbaxy USA, Inc. will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) (the "Plea Agreement") to an Information to be filed in *United States of America v. Ranbaxy USA, Inc.*, Criminal Action No. [to be assigned] (D. Md.) (the "Criminal Action") that will allege a violation of Title 21, United States Code, Sections 331(a), 331(e), 333(a)(2) and 351(a)(2)(B), and Title 18, USC, Sections 2 and 1001.

D. On January 25, 2012, Ranbaxy Laboratories Limited, et al. consented to the entry of a Consent Decree of Permanent Injunction (the "Consent Decree") to a Complaint filed in *United States of America v. Ranbaxy Laboratories, Ltd., et al.*, Civil Action No. 12-0250 (D. Md.) that alleges a violation of Title 21, United States Code, Sections 331(a), 331(d), 331(e), and 331(k), namely, the introduction of adulterated drugs into interstate commerce, the delivery of unapproved new drugs into interstate commerce, failing to make required reports to the Food and Drug Administration, and causing drugs to be adulterated while the drugs were held for sale after

shipment in interstate commerce, in violation of the Food, Drug and Cosmetic Act.

E. Ranbaxy has entered into or will be entering into separate settlement agreements, described in Paragraph 1(b) below (hereinafter referred to as the "Medicaid State Settlement Agreements") with certain states and the District of Columbia in settlement of the Covered Conduct described in Recitals Paragraph G, below. States with which Ranbaxy executes a Medicaid State Settlement Agreement in the form to which Ranbaxy and the National Association of Medicaid Fraud Control Units ("NAMFCU") Negotiating Team have agreed, or in a form otherwise agreed to Ranbaxy and an individual State, shall be defined as "Medicaid Participating States."

F. The United States contends that Ranbaxy submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 ("Medicare"); the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid"); the TRICARE Program, 10 U.S.C. §§ 1071-1110b; the FEHBP, 5 U.S.C. §§ 8901-8914; and caused purchases by the Veterans Affairs Program, 38 U.S.C. §§ 1701-1743; and PEPFAR, 22 U.S.C. §§ 7601-7682 (collectively "the Federal Health Care Programs").

G. The United States contends that it and the Medicaid Participating States have certain civil claims against Ranbaxy, as specified in Paragraph 2 below, for allegedly engaging in the following conduct concerning the manufacture, distribution, and sale of the Covered Drugs at various points during the period from April 1, 2003, through September 16, 2010 ("Covered Conduct"):

> Ranbaxy knowingly manufactured, distributed, and sold in interstate commerce, and made false statements (including in annual reports to the Food and Drug Administration) about, certain batches, lots, or portions of lots of the Covered Drugs during the period referenced above in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331, 351, 352, and 355, including batches, lots, or portions of lots of the Covered Drugs (1) the strength of which materially differed from, or the purity or quality of which materially fell below, the strength, purity, or quality which they purported or were represented to possess, or (2) that were not manufactured according to the approved formulation and were, therefore, unapproved new drugs, in violation of the FDCA, 21 U.S.C. §§ 331(d) and 355(a), and were not "covered outpatient drugs" under 42 U.S.C. § 1396r-8(k)(2).

As a result of the foregoing alleged conduct, the United States contends that Ranbaxy knowingly caused false and/or fraudulent claims to be submitted to, or caused purchases by, the Federal Health Care Programs.

H. This Agreement is neither an admission of liability by Ranbaxy, except to the extent admitted by Ranbaxy USA, Inc. under the terms of the Plea Agreement, nor a concession by the United States that its claims are not well founded. Ranbaxy expressly denies the contentions and allegations of the United States and Relator as described in the Covered Conduct and set forth herein and in the Civil Action, and denies that it engaged in any wrongful conduct, except as to such admissions that Ranbaxy USA, Inc. is required to make under the terms of the Plea Agreement.

I. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Agreement and to Relator's reasonable expenses, attorneys' fees, and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Agreement, the

Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Ranbaxy shall pay to the United States and the Medicaid Participating States, collectively, the sum of Three Hundred and Fifty Million Dollars ($350,000,000.00), plus interest at the rate of 1.75% per annum from February 1, 2012, and continuing until and including the day before payment is made under this Agreement (the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of this Agreement. This debt shall be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) Ranbaxy shall pay the United States the sum of $231,844,066.00 plus accrued interest as set forth above ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States no later than thirty (30) days after (i) this Agreement is fully executed by the Parties and delivered to Ranbaxy's attorneys; or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea as described in Recitals Paragraph C in connection with the Criminal Action and imposes the agreed upon sentence, whichever occurs later.

(b) Ranbaxy shall pay to the Medicaid Participating States the sum of $118,155,933.00, plus accrued interest as set forth above ("Medicaid State Settlement Amount"). The Medicaid State Settlement Amount shall be paid by electronic funds

transfer pursuant to written instructions from the NAMFCU Negotiating Team and under the terms and conditions of the Medicaid State Settlement Agreements that Ranbaxy will enter into with the Medicaid Participating States no later than thirty (30) days after (i) this Agreement is fully executed by the Parties and delivered to Ranbaxy's attorneys; or (ii) the Court accepts a Fed. R. Crim. P. 11(c)(1)(C) guilty plea as described in Recitals Paragraph C in connection with the Criminal Action and imposes the agreed upon sentence, whichever occurs later.

(c) Conditioned upon the United States receiving the Federal Settlement Amount from Ranbaxy and as soon as feasible after receipt, the United States agrees to pay $48,687,254.01, plus a proportionate share of the actual accrued interest paid to the United States by Ranbaxy, as set forth in Paragraph 1.a., above, ("Relator's Share") to Dinesh S. Thakur as Relator's share of the proceeds pursuant to 31 U.S.C. § 3730(d).

(d) Ranbaxy agrees to pay Relator's fees and costs, pursuant to 31 U.S.C. § 3730(d) incurred in connection with the Civil Action, to Relator's counsel by electronic funds transfer pursuant to a separate written agreement between Ranbaxy and Relator and Relator's attorneys.

(e) If Ranbaxy's agreed-upon guilty plea pursuant to Fed. R. Crim. P. 11(c)(1)(C) in the Criminal Action described in Preamble Paragraph C is not accepted by the Court or the Court does not impose the agreed-upon sentence for whatever reason, this Agreement shall be null and void at the option of either the United States or Ranbaxy. If either the United States or Ranbaxy exercises this option, which option shall

be exercised by notifying all Parties, through counsel, in writing within five (5) business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, Ranbaxy will not 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, actions or proceedings arising from the Covered Conduct that are brought by the United States within ninety (90) calendar days of rescission, except to the extent such defenses were available on the day on which the *qui tam* complaint listed in Preamble Paragraph B, above, was filed.

2. Subject to the exceptions in Paragraph 7 (concerning excluded claims) below, and conditioned upon Ranbaxy's full payment of the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Ranbaxy, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers, and employees, individually and collectively, 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; any statutory provision creating a cause of action for civil damages or civil penalties for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R., Part 0, Subpart I, 0.45(d); and common law claims of payment by mistake, fraud, disgorgement, unjust enrichment, and, if applicable, breach of contract.

3. Subject to the exceptions in Paragraph 9 below, and conditioned upon Ranbaxy's full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns and any other person or entity acting on his behalf or asserting his rights, releases Ranbaxy from any civil monetary claim Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

4. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Ranbaxy Laboratories Limited, Ranbaxy, Inc., Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories, Inc., Ohm Laboratories, Inc., and Ranbaxy USA, Inc. and/or officers, directors, and employees of all of these entities from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) under 42 U.S.C. § 1320a-7(a) (mandatory exclusion), or 42 U.S.C. § 1320a-7(b) or 42 U.S.C. § 1320a-7a (permissive exclusion).

5. TMA expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Ranbaxy Laboratories Limited, Ranbaxy, Inc., Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories, Inc., Ohm Laboratories, Inc., and Ranbaxy USA, Inc. and/or officers, directors, and employees of all of these entities from TRICARE under 32 C.F.R. 199.9.

6. OPM expressly reserves all rights to institute, direct, or to maintain any administrative action seeking debarment against Ranbaxy Laboratories Limited, Ranbaxy, Inc., Ranbaxy Pharmaceuticals, Inc., Ranbaxy Laboratories, Inc., Ohm Laboratories, Inc., and Ranbaxy USA, Inc. and/or officers, directors, and employees of all of these entities from the

FEHBP under 5 U.S.C. § 8902a(b) (mandatory debarment), or (c) and (d) (permissive debarment).

7. Notwithstanding the releases given in Paragraphs 2 and 3 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any 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 the suspension and debarment rights of any Federal agency and mandatory and permissive 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 obligations created by this Agreement;

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

g. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or

h. Any liability of individuals (including current or former directors, officers, employees, agents, or shareholders of Ranbaxy) who receive written notification that they are the target of a criminal investigation (as defined in the United States Attorneys' Manual), are indicted or charged, or who enter into a plea agreement related to the Covered Conduct.

8. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but 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). Conditioned upon Relator's receipt of the payment described in Paragraph 1, Relator and his heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action. This Agreement does not resolve or in any manner affect any claims the United States has or may have against Relator arising under Title 26 U.S. Code (Internal Revenue Code), or any claims arising under this Agreement.

9. In consideration of the obligations of Ranbaxy set forth in this Agreement, and conditioned upon receipt of the payments described in Paragraph 1 above, the Relator, for himself, and his heirs, successors, attorneys, agents, assigns, and any other person or entity acting on his behalf or asserting his rights, hereby fully and finally releases, waives and forever discharges Ranbaxy, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees, heirs, and assigns, and their current and former directors, officers and employees, individually and collectively from any and all liability, claims, allegations, demands, actions or causes of action whatsoever, known or unknown, fixed or contingent, in law or in equity, in contract or tort, under any Federal or State statute or regulation, or under common law or that the Relator otherwise would have standing to bring, arising from or relating to the Covered Conduct, and that the Relator asserted or could

have asserted in, or arising from or relating to, the Civil Action, or under 31 U.S. C. § 3730(d) for expenses or attorney's fees and costs.

10. Ranbaxy waives and shall not assert any defenses Ranbaxy 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.

11. Ranbaxy fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Ranbaxy has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution of the Civil Action. Nothing in this Agreement shall constitute a waiver of Ranbaxy's right to assert against the United States, or any agency of the United States, claims or challenges that are permitted under the Complaint or Consent Decree filed in *United States of America v. Ranbaxy Laboratories, Ltd., et al.*, Civil Action No. 12-250 (D. Md.).

12. Should this Agreement be challenged by any person as not fair, adequate, or reasonable pursuant to 31 U.S.C. § 3730(c)(2)(B), Ranbaxy agrees that it will take all reasonable

and necessary steps to defend this Agreement.

13. In consideration of the obligations of the Relators set forth in this Agreement, Ranbaxy, on behalf of itself, its predecessors, and its current and former divisions, parents subsidiaries, agents, successors, assigns, and their current and former directors, officers, and employees, fully and finally release, waive, and forever discharge the Relator and his respective heirs, successors, assigns, agents, and attorneys from any claims or allegations that Ranbaxy has or could have asserted, arising from the Covered Conduct.

14. 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 or any other state or Federal payer, related to the Covered Conduct; and Ranbaxy agrees not to resubmit to any Medicare carrier or intermediary or any other state or Federal payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

15. Ranbaxy agrees to the following:

(a) Unallowable Costs Defined: 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. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Ranbaxy, its present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "Unallowable Costs" on government contracts and under the Federal Health Care Programs:

(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) Ranbaxy's 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 attorneys' fees);

(4) the negotiation and performance of this Agreement, the Plea Agreement, and the Medicaid State Settlement Agreements;

(5) the payment Ranbaxy makes to the United States pursuant to this Agreement, the Plea Agreement, or the Medicaid State Settlement Agreements, and any payments that Ranbaxy may make to Relator, including costs and attorneys' fees; and

(b) Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Ranbaxy, and Ranbaxy 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 Ranbaxy or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: Ranbaxy further agrees that within ninety (90) days of the Effective Date of this

Agreement it 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 Ranbaxy or any of its 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. Ranbaxy agrees that the United States, at a minimum, shall be entitled to recoup from Ranbaxy 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 Ranbaxy or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Ranbaxy's or any of its 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 Ranbaxy's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this

Paragraph.

16. Ranbaxy agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Ranbaxy shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Ranbaxy further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

17. 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, except to the extent provided for in Paragraph 18 (waiver for beneficiaries paragraph), below.

18. Ranbaxy agrees that it waives 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.

19. Ranbaxy warrants that it has reviewed its financial situation and that it currently is 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 herein constitute a contemporaneous exchange for new value given to Ranbaxy, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded 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 which Ranbaxy was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

20. Within five (5) business days following receipt of the payment of the Settlement Amount described in Paragraph 1, above, the United States and Relator shall file a stipulation of dismissal in the Civil Action as follows:

(a) the Stipulation of Dismissal shall be with prejudice to the United States' and Relator's claims as to Ranbaxy as to the Covered Conduct, pursuant to and consistent with the terms and conditions of this Agreement; and

(b) the Stipulation of Dismissal shall be without prejudice to the United States and with prejudice as to the Relator as to all other claims.

21. 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.

22. Each Party and signatory to this Agreement represents that it freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

23. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Maryland

24. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

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

26. The individuals signing this Agreement on behalf of Ranbaxy represent and warrant that they are authorized by Ranbaxy to execute this Agreement. The individuals signing this Agreement on behalf of Relator represent and warrant that they are 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.

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

28. This Agreement is binding on Ranbaxy's successors, transferees, heirs, and assigns.

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

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

31. This Agreement is effective on the date of signature of the last signatory to the

Agreement ("Effective Date of this Agreement"). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

ROD J. ROSENSTEIN
United States Attorney

DATED: 5/9/13 BY: _____
ROANN NICHOLS
Assistant United States Attorney
United States Attorney's Office
District of Maryland

DATED: 5/9/13 BY: _____
MICHAEL D. GRANSTON
JAMIE ANN YAVELBERG
NATALIE A. PRIDDY
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 5/9/13 BY: Robert K. DeConti

ROBERT K. DeCONTI
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:_____ BY: _____

PAUL J. HUTTER
General Counsel
TRICARE Management Activity
United States Department of Defense

DATED:_____ BY: _____

SHIRLEY R. PATTERSON
Assistant Director for Federal Employee Insurance
Operations
United States Office of Personnel Management

DATED:_____ BY: _____

ROBERT K. DeCONTI
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: 5/6/13 BY: _____

PAUL J. HUTTER
General Counsel
TRICARE Management Activity
United States Department of Defense

DATED:_____ BY: _____

SHIRLEY R. PATTERSON
Assistant Director for Federal Employee Insurance
Operations
United States Office of Personnel Management

DATED:_____ BY:_____

ROBERT K. DeCONTI
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:_____ BY:_____

PAUL J. HUTTER
General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: 5/3/2013 BY: Shirley R Patterson

SHIRLEY R. PATTERSON
Assistant Director for Federal Employee Insurance
Operations
United States Office of Personnel Management

RANBAXY LABORATORIES LIMITED

DATED: 3/4/13 BY: _____
SUSHIL K. PATAWARI
Company Secretary

DATED: March 4, 2013 BY: _____
W. WARREN HAMEL
GEOFFREY R. GARINTHER
WINIFRED M. WEITSEN
Venable LLP

RANBAXY, INC.

DATED: 3/4/13 BY: _____
AHMAD ABOELEZZ
Corporate Secretary

DATED: March 4, 2013 BY: _____
W. WARREN HAMEL
GEOFFREY R. GARINTHER
WINIFRED M. WEITSEN
Venable LLP

RANBAXY PHARMACEUTICALS, INC.

DATED: 3/4/13 BY: _____
AHMAD ABOELEZZ
Corporate Secretary

DATED: March 4, 2013 BY: _____
W. WARREN HAMEL
GEOFFREY R. GARINTHER
WINIFRED M. WEITSEN
Venable LLP

RANBAXY LABORATORIES, INC.

DATED: 3/4/13 BY: _____
AHMAD ABOELEZZ
Corporate Secretary

DATED: March 4, 2013 BY: _____
W. WARREN HAMEL
GEOFFREY R. GARINTHER
WINIFRED M. WEITSEN
Venable LLP

OHM LABORATORIES, INC.

DATED: 3/4/13 BY: _____
AHMAD ABOELEZZ
Corporate Secretary

DATED: March 4, 2013 BY: _____
W. WARREN HAMEL
GEOFFREY R. GARINTHER
WINIFRED M. WEITSEN
Venable LLP

RANBAXY USA, INC.

DATED: 3/1/13 BY: _____
IRVING KAGAN
Corporate Secretary

DATED: March 1, 2013 BY: _____
W. WARREN HAMEL
GEOFFREY R. GARINTHER
WINIFRED M. WEITSEN
Venable LLP

RELATOR DINESH S. THAKUR

DATED: May 2, 2013 BY: _____
DINESH S. THAKUR

DATED: May 8, 2013 BY: _____
ANDREW M. BEATO
Stein, Mitchell, Muse & Cipollone, LLP

CERTIFIED COPY OF RESOLUTIONS OF THE BOARD OF DIRECTORS OF RANBAXY USA, INC. (the "Corporation") Adopted March 1, 2013

I, the undersigned Secretary of the Corporation and custodian of the minute book and other records of the Board of Directors of the Corporation, do hereby certify that in a meeting of the Board of Directors of the Corporation, duly called and held on March 1, 2013, the following resolutions were duly adopted by the Directors of the Corporation and that the same are in full force and effect:

WHEREAS, the U.S. Attorney's Office of Maryland and the Department of Justice's Office of Consumer Protection has investigated the Corporation's methods used in, and the controls used for drug manufacturing, processing, packing, and holding and the Corporation's reporting practices thereto ("Investigation");

WHEREAS, a Relator has filed a complaint alleging civil False Claims Act violations by the Corporation ("Civil Case"), which allegations the Corporation denies except as admitted in the resolution of the Investigation;

WHEREAS, the Board has consulted with legal counsel in connection with the Investigation and the Civil Case;

WHEREAS, the Corporation's legal counsel has been negotiating a resolution of the Investigation and the Civil Case;

WHEREAS, the Corporation's legal counsel has reported to the Board the terms and conditions of proposed resolutions of the Investigation and Civil Case, and the Board has had sufficient opportunity to consult with the Corporation's legal counsel regarding same;

WHEREAS, the Board has reviewed the Criminal Information, Plea Agreement and attached Statement of Facts concerning the Corporation related to the Investigation (attached), and has deliberated and discussed the matters therein;

WHEREAS, the Board has reviewed and been advised of the contents of the proposed Federal Settlement Agreement and State Settlement Agreements (collectively, the "Settlement Agreements") related to the Civil Case (attached), and has deliberated and discussed the matters therein; and

WHEREAS, the Board acknowledges that the Plea Agreement and Settlement Agreements fully set forth the Corporation's agreements with the United States and the States and that no additional promises or representations have been made to the Corporation by any officials of the United States or the States in connection with the disposition of the Investigation and the Civil Case, other than those set forth in these documents.

NOW, THEREFORE, in consideration of the promises and such other facts and circumstances as determined relevant or otherwise appropriate to consider in acting on the matter, be it:

RESOLVED, that the Corporation does hereby authorize, approve, adopt and ratify the Settlement Agreements, and hereby directs the Corporate Secretary to execute the Settlement Agreements, with such additional modifications as counsel may recommend;

IT IS FURTHER RESOLVED, that the Corporation authorize, approve, adopt and ratify the Plea Agreement and Statement of Facts, and hereby authorizes the Corporation to plead guilty to the charges specified in the Criminal Information;

IT IS FURTHER RESOLVED, that the Corporation authorizes Corporate Secretary or a member of the Board of Directors of Ranbaxy USA, Inc., or other appropriate officer or personnel, to appear in U. S. District Court for the District of Maryland to enter the plea set forth in the Plea Agreement on behalf of the Corporation;

IT IS FURTHER RESOLVED, that Officers of the Corporation or their duly authorized representatives or attorneys, are hereby authorized and directed to take all actions and deliver any agreements, certificates and documents and instruments with respect to or contemplated by the matters set forth above, including, without limitation, the signature of relevant documents, the payment of all amounts, fees, costs and other expenses, necessary or appropriate to effectuate the purpose and intent of the foregoing resolutions and to effectuate and implement the resolutions contemplated hereby; and

IT IS FURTHER RESOLVED, that any actions taken by the Officers of the Corporation, or their duly authorized representatives or attorneys, prior to the adoption of this resolution, that are within the authority conferred hereby, are fully ratified, confirmed and approved as the acts and deeds of the Corporation.

MOVED, SECONDED AND APPROVED BY UNANIMOUS VOTE OF THE BOARD OF DIRECTORS of Ranbaxy USA, Inc., this 1st day of March, 2013.

* * * * * * * * * * * * * *

Given under my hand and the seal of the Corporation this 1st day of March, 2013.

Irving Kagan
Corporate Secretary
Ranbaxy USA, Inc.
(SEAL)