SAB/LM/PG: USAO 2006R00132

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	*	
	*	
v.	*	**CRIMINAL NO.**
	*	
RANBAXY USA, INC.,	*	**(Introduction into Interstate**
	*	**Commerce of Adulterated Drugs,**
Defendant	*	**21 U.S.C. §§ 331(a), 333(a)(2), and**
	*	**351(a)(2)(B); Failure to Timely File**
	*	**Required Reports, 21 U.S.C. §§ 331(e)**
	*	**and 333(a)(2); False Statements,**
	*	**18 U.S.C. § 1001; Aiding and Abetting,**
	*	**18 U.S.C. § 2; Forfeiture, 21 U.S.C.**
	*	**§ 334, 28 U.S.C. § 2461(c))**
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INFORMATION

COUNT ONE
(Introduction into Interstate Commerce of Adulterated Drugs)

The United States Attorney for the District of Maryland charges that:

Introduction

A. Defendant RANBAXY USA, INC.

1. At times material to this Information, 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 commercial efforts of RPI, Ohm and RLI, including but not limited to sales. RLL and its various subsidiaries are collectively referred to as Ranbaxy.

2. 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

3. 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.

4. 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).

5. 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).

6. 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).

7. 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).

8. 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.

9. 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.

10. 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**

11. 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**

12. 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

13. 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

14. 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.

15. 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

16. 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.

17. 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.

18. 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

19. 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.'"

20. 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.

21. 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.

22. 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.

The Charge

23. Between on or about January 1, 2005 and on or about December 31, 2006, in the District of Maryland and elsewhere, the defendant,

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.

21 U.S.C. §§ 331(a), 333(a)(2) and 351(a)(2)(B)
18 U.S.C. § 2

COUNT TWO
(Failure to Timely File Required Reports)

The United States Attorney for the District of Maryland further charges that:

1. Paragraphs 1 through 22 of Count One are incorporated here.

2. At times relevant to this Information, 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.

3. 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

4. On or about April 21, 2003, in the District of Maryland and elsewhere, the defendant,

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.

21 U.S.C. §§ 331(e), 333(a)(2), 355(k)
18 U.S.C. § 2

COUNT THREE
(Failure to Timely File Required Reports)

The United States Attorney for the District of Maryland further charges that:

1. Paragraphs 1 through 22 of Count One are incorporated here.

2. At times relevant to this Information, Ranbaxy 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.

3. 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.

4. 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

5. Between on or about June 26, 2007 and on or about September 4, 2007, in the District of Maryland and elsewhere, the defendant,

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 their expected shelf life.

21 U.S.C. §§ 331(e), 333(a)(2), 355(k)
18 U.S.C. § 2

COUNT FOUR
(False Statements)

The United States Attorney for the District of Maryland further charges that:

1. Paragraphs 1 through 22 of Count One are incorporated here.

2. At times relevant to this Information, 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.

3. On or about January 2, 2007, in the District of Maryland, the defendant,

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, 2004
6 Month Station: Related Substances – 0 day	September 30, 2004
18 Month Station: Related Substances – 0 day	September 15, 2005

18 U.S.C. § 1001
18 U.S.C. § 2

COUNT FIVE
(False Statements)

The United States Attorney for the District of Maryland further charges that:

1. Paragraphs 1 through 22 of Count One and paragraph 2 of Count Four are incorporated here.

2. On or about January 2, 2007, in the District of Maryland, the defendant,

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

18 U.S.C. § 1001
18 U.S.C. § 2

COUNT SIX
(False Statements)

The United States Attorney for the District of Maryland further charges that:

1. Paragraphs 1 through 22 of Count One and paragraph 2 of Count Four are incorporated here.

2. On or about March 20, 2006, in the District of Maryland, the defendant,

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

18 U.S.C. § 1001
18 U.S.C. § 2

COUNT SEVEN
(False Statements)

1. Paragraphs 1 through 22 of Count One and paragraph 2 of Count Four are incorporated here.

2. On or about June 29, 2006, in the District of Maryland, the defendant,

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

18 U.S.C. § 1001
18 U.S.C. § 2

FORFEITURE ALLEGATION

The United States Attorney for the District of Maryland further charges that:

1. Pursuant to Federal Rule of Criminal Procedure 32.2, notice is hereby given to the defendant that the United States will seek forfeiture as part of any sentence in accordance with Title 21, United States Code, Section 334, and Title 28, United States Code, Section 2461(c).

FDCA Forfeiture

2. As a result of the violations of Title 21, United States Code, Sections 331(a), 333(a)(2), and 351(a)(2)(B) set forth in Count One of this Information, the defendant,

RANBAXY USA, INC.,

shall forfeit to the United States pursuant to Title 21, United States Code, Section 334 and Title 28, United States Code, Section 2461(c), 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), during the period January 1, 2005 through December 31, 2006, including Ciprofloxacin, Gabapentin, and Sotret (Ranbaxy brand for Isotretinoin).

Substitute Assets

3. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), incorporated by reference in Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture, in the form of a money judgment in the amount of $20 million.

21 U.S.C. § 334
28 U.S.C. § 2461(c)

SENTENCING ALLEGATION

The United States Attorney for the District of Maryland further charges that:

With respect to the charges in this Information, for purposes of determining the alternative maximum fine pursuant to Title 18, United States Code, Section 3571(d), defendant **RANBAXY USA, INC.** derived gross gains of less than $100 million.

Rod J. Rosenstein
United States Attorney
District of Maryland

Stuart F. Delery
Acting Assistant Attorney General
Civil Division
U.S. Department of Justice

By:

Michael S. Blume
Director, Consumer Protection Branch
U.S. Department of Justice

Date: May 13, 2013