IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	Hon.
	)	
v.	)	Civil Action No.:
	)	
RANBAXY LABORATORIES, LTD., RANBAXY, INC.,	)	
	)	
corporations, and	)	
	)	
DALE ADKISSON, ARUN SAWHNEY, VENKATACHALAM KRISHNAN,	)	
	)	
individuals,	)	
	)	
Defendants.	)	

CONSENT DECREE OF PERMANENT INJUNCTION

The United States of America, plaintiff, by its undersigned attorneys, having filed its complaint for injunctive relief against defendants, Ranbaxy Laboratories, Ltd. and Ranbaxy, Inc., corporations ("Corporate Defendants"), and Dale Adkisson (who was hired by Ranbaxy Laboratories Ltd., and assumed the position of Senior Vice President, Head Global Quality in January 2010, after all of the activities alleged in the complaint had occurred), Arun Sawhney (who assumed the position of Managing Director of Ranbaxy Laboratories, Ltd. on August 20, 2010, after all the activities alleged in the complaint had occurred), and Venkatachalam Krishnan, Regional Director Americas (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the "Decree"), without contest and before any testimony has been taken and without admitting or denying any allegation of the complaint and disclaiming any liability in connection therewith, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

I. This Court has jurisdiction over the subject matter and over all parties to this action.

II. The complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (the "Act").

III. The complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities or controls used for, the manufacture and processing of the drugs do not comply with the current good manufacturing practice requirements to assure that they meet the requirements of the Act as to their safety and that they have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

IV. The complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing drugs to be adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) while the drugs are held for sale after shipment of one or more of their components in interstate commerce.

V. The complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(d), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce new drugs in violation of 21 U.S.C. § 355.

VI. The complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(e), by failing to make reports required under 21 U.S.C. § 355(k).

DEFINITIONS

VII. For purposes of this Decree, the following definitions shall apply:

A. "Application" means any application or other submission made by Defendants to the Food and Drug Administration ("FDA" or "Agency") in support of or in connection with an approved or pending new drug application ("NDA") or abbreviated new drug application ("ANDA"), including any post-marketing submissions with respect to such Application except field alerts required under 21 C.F.R. § 314.81(b)(1), adverse drug experience reports required under 21 C.F.R. § 314.80, and labeling supplements and amendments made solely to comply with the "same labeling requirement" found in 21 U.S.C. § 355(j)(2)(A)(v) and 21 C.F.R § 314.94(a)(8), when the reference listed drug has made labeling changes.

B. "Drug(s)" refers to any product that meets the definition in 21 U.S.C. § 321(g), including, but not limited to, finished drugs, drug components, and active pharmaceutical ingredients ("APIs").

C. "Interstate commerce" is defined as set forth in 21 U.S.C. § 321(b).

D. The term "drugs that are the subject of an Application" includes drugs that may not be intended for introduction into interstate commerce, but are the subject of an Application and must be manufactured in conformity with such Application, such as drugs associated with the President's Emergency Plan for AIDS Relief ("PEPFAR") program.

E. "Covered Facilities" means: (1) Ranbaxy Laboratories, Ltd., Sirmour District, Himanchal Pradesh, India (hereafter, "Paonta Sahib"); (2) Ranbaxy Laboratories, Ltd., Industrial Area-3, Dewas, India (hereafter, "Dewas"); and (3) any facility added to this Decree pursuant to paragraph XXIX. Defendant Ranbaxy Laboratories, Ltd. has represented to FDA and now

represents to this Court that: (1) the Ohm Laboratories, 34 West Fulton St., Gloversville, NY, facility (hereafter, "Gloversville") was officially closed on Thursday, October 13, 2011; and (2) they have withdrawn the FDA site registration for the Ranbaxy Laboratories, Ltd., Unit II, P.O. Batamandi, Paonta Sahib, Dirst Sirmour, Batamandi, Himanchal Pradesh, India facility (hereafter, "Batamandi"). Corporate Defendants shall withdraw all NDAs and ANDAs that contain data or other information generated or developed at Batamandi, and shall never submit another Application to FDA for any drug that is the subject of the withdrawn Batamandi NDAs and ANDAs and shall never transfer such NDAs and ANDAs to a third party. If Corporate Defendants submit notice under paragraph XVI.B that they intend to resume manufacturing drugs at Gloversville and/or intend to resume manufacturing drugs that are the subject of an Application and/or are intended for introduction into interstate commerce at Batamandi, such facility shall thereafter be included in the definition of "Covered Facilities" and be fully subject to the provisions of this Decree.

F. An Application "contain(s)" data or other information generated or developed at a facility if such data or other information were submitted to or incorporated by reference into the Application(s) at any time, regardless of whether such data or other information were subsequently replaced by a supplement or amendment. However, if Corporate Defendants believe that: (1) the amount of data or information generated or developed at a facility is de minimis; or (2) that FDA's approval of an Application was not based on any data or information generated or developed at a Covered Facility, and their Data Integrity Expert described in paragraph XI certifies to FDA that the data is de minimis and/or irrelevant to FDA's approval, they may petition FDA for a determination that the Application does not contain data or

information from such facility.

G. "Affected Application" means: (1) any Application that, at the time of entry of this Decree, is pending or approved and contains any data or other information generated or developed at Paonta Sahib and/or Dewas; (2) all Applications that contain data or other information generated or developed at Paonta Sahib and were withdrawn between February 25, 2009 and the entry of this Decree; and (3) all Applications that contain data or other information generated or developed at Dewas and were withdrawn between August 1, 2003 and the entry of this Decree. For purposes of this Decree, ANDA 76-477 for Atorvastatin Calcium is not an Affected Application. Within ninety (90) days after entry of this Decree, Corporate Defendants may, in writing, withdraw from FDA's consideration for approval any pending Affected Application(s) and/or request that FDA withdraw approval of any approved Affected Application(s). If Corporate Defendants withdraw an Affected Application(s) in accordance with the preceding sentence, Corporate Defendants shall never submit another Application to FDA for the drug that is the subject of the withdrawn Application(s) and shall never transfer such Application(s) to a third party, and such withdrawn Affected Application(s) will be exempt from the requirements of this Decree. If Corporate Defendants submit or transfer an Application for a drug that is the subject of an Affected Application withdrawn under this provision, FDA will not review any resubmitted or transferred Application(s) and will have no obligation to do so. Within five (5) days after entry of this Decree, Corporate Defendants shall provide to FDA: (1) a complete list of all Applications that Corporate Defendants believe meet this paragraph's definition of Affected Application; and (2) a complete list of all pending or approved Applications that contain data or other information generated or developed at Batamandi;

however, such lists do not preclude FDA from determining that other Applications meet the definition of Affected Application or contain data or other information generated or developed at Batamandi.

H. Notwithstanding subparagraph G of this paragraph, the following Applications will be referred to as "Excepted Applications" and will not be considered Affected Applications under this Decree unless deemed to be such under paragraph XIV.A.2 of this Decree: ANDA 1; ANDA 2; ANDA 3; ANDA 4; and ANDA 5.

I. "CGMP" means the current good manufacturing practice requirements for drugs. See 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. Parts 210 and 211.

J. "CGMP Requirements" means both CGMP and the CGMP provisions of this Decree.

K. "Corrective Action Operating Plan" ("CAOP") means Corporate Defendants' written operating plan that describes their procedures, actions, and controls to ensure data integrity in their Applications. Corporate Defendants shall have one CAOP, which they shall update as set forth in paragraphs XVII.G and XIX.

L. "Days" shall refer to calendar days unless otherwise stated.

M. "Untrue statement" means a Defendant's untrue statement of material fact in an Application or a Defendant's material omission from an Application. An untrue statement of fact is material if it reasonably could be expected to affect FDA's decision with respect to the matter for which the fact was submitted and it is: (1) required under applicable law and regulations; (2) requested by FDA to be included in the Application; or (3) submitted by Defendants in support of an Application. An omission is material if the omitted information

could reasonably be expected to affect FDA's decision with respect to the matter about which the fact was omitted.

N. "Data irregularity" means data in one or more Applications, other than untrue statements, that raise a question as to whether the data are reliable. Data irregularities will be evaluated by Corporate Defendants' Chief Data Reliability Officer (see paragraph IX.B), Data Integrity Expert (see paragraphs XI, XIV.B, XVII.G.1.b, XIX), and Data Quality Auditor (see paragraph XXIV.A) as specified in the Decree to determine whether they occur with sufficient frequency and/or are sufficiently similar to constitute a pattern or practice of data irregularities that call into question the reliability of the data in an Application. Upon receipt of such a determination, FDA will evaluate the data to determine whether, in the exercise of its discretion, such pattern or practice of data irregularities causes FDA to believe that it should not approve and/or should not have approved the Application under 21 U.S.C. § 355(b) (for NDAs) and/or 21 U.S.C. § 355(j) (for ANDAs) (hereafter, "pattern(s) or practice(s) of data irregularities affecting approval"). If FDA makes the determination that there is a pattern or practice of data irregularities affecting approval, it will advise Corporate Defendants of its decision and reasons therefore in writing, and the Application shall be withdrawn according to the procedures set forth in paragraphs XV, XVII.H and I, XIX, and XXIV.A.

O. The terms "manufacture," "manufactured," and "manufacturing" refer to manufacturing, processing, packing, repacking, labeling, holding, and/or distributing drugs.

P. "Quality assurance" ("QA") includes, but is not limited to, the systemic review and approval of procedures, review of records, auditing, and monitoring the performance of all operations to assure consistent product quality.

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Q. "Quality control" ("QC") includes, but is not limited to, assessing the suitability of incoming components, containers, closures, labeling, in-process materials, and finished products; evaluating the performance of the manufacturing process and laboratory controls to ensure adherence to proper specifications and limits; and determining the acceptability of each batch for release.

R. "Wrongful Act" includes both untrue statements and data irregularities.

S. "Validity Assessment" means FDA's determination of the nature and extent of Defendants' Wrongful Acts based on: FDA's inspection of Defendants' Corporate facilities; FDA's review of data or information in Applications, Defendants' internal review(s) and/or audit(s); and/or any other information.

T. The term "affiliates" does not include Daiichi Sankyo Co., Ltd., or its subsidiaries not named as a defendant in this Decree nor previously owned by a named defendant in this Decree.

QUALITY ASSURANCE AND QUALITY CONTROL MANAGEMENT

VIII. Defendants shall establish and document management control over QA and QC at the Covered Facilities for all drugs that are the subject of an Application and/or intended for introduction in interstate commerce, to ensure continuous compliance with the Act, its implementing regulations, and this Decree (hereafter, collectively, "the law and/or this Decree"). Corporate Defendants shall vest responsibility for QA and QC in an individual who shall be authorized and responsible for all QA and QC functions at the Covered Facilities, including establishing, implementing, and maintaining a comprehensive written QA and QC program ("QA/QC program") to ensure that all drugs that are the subject of an Application and/or

intended for introduction in interstate commerce manufactured by Corporate Defendants have the safety, identity, strength, quality, purity, and potency that they purport or are represented to possess, and are in compliance with the law and this Decree.

DATA INTEGRITY MANAGEMENT

IX. Within one-hundred twenty days (120) after entry of this Decree, Corporate Defendants shall establish in the United States an Office of Data Reliability, which shall be responsible for conducting pre-submission audits of all Applications from all facilities owned and/or operated by Corporate Defendants and/or their subsidiaries and/or affiliates, including but not limited to: the Covered Facilities; Ohm Laboratories, 14 Terminal Road, New Brunswick, NJ; Ohm Laboratories, Van Dyke Ave., New Brunswick, NJ; Ohm Laboratories, 1385 Livingston Ave., North Brunswick, NJ; Ranbaxy, Inc., 600 College Road East, Princeton, NJ; Ranbaxy Laboratories, Ltd., P.O. Rail Majra, Dist. Nawanshahar, Punjab, India (also known as Toansa); Ranbaxy Laboratories, Ltd., Phase III Ind. Area, Sas Nagar and Unit III, A41, Phase VIIIA, Mohali, Punjab, India; Ranbaxy Laboratories, Ltd., Sector 18 Udyog Vihar Ind Area, Gurgaon, India; and/or any new facilities. Corporate Defendants shall not submit to FDA any Applications until such Office of Data Reliability is established and operating in compliance with this paragraph, except that Corporate Defendants may make submissions as required by law for approved Applications, or submissions that are requested by FDA for pending Applications, provided that such submission is accompanied by a certification: (1) from the Data Integrity Expert described in paragraph XI that the data in the submission are accurate and complete in all material respects to the best of his/her knowledge; or (2) from Corporate Defendants, certifying that they were unable to secure the foregoing certification from the Data Integrity Expert in time

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to meet its legal obligations and providing a time, not to exceed ninety (90) days, by which they will provide to FDA the foregoing Data Integrity Expert's certification for such submission. FDA will have no obligation to review any submissions made without a certification from the Data Integrity Expert until after it has received the Data Integrity Expert's certification. The Office of Data Reliability shall be headed by a Chief Data Reliability Officer who shall report directly to the Managing Director of Ranbaxy Laboratories, Ltd., and shall have the authority to recommend to the Managing Director of Ranbaxy Laboratories, Ltd., that individual employees be disciplined or terminated and that any of Corporate Defendants' Applications be withdrawn from FDA consideration for approval. The Chief Data Reliability Officer shall report to FDA all such recommendations within five (5) days of making such recommendations to the Managing Director. The Chief Data Reliability Officer shall have the authority to review, and to approve or prohibit the submission to FDA of all of Corporate Defendants' Applications, and is responsible for ensuring that:

A. Pre-submission audits include an audit trail (i.e., a complete record within a closed system that ensures the integrity, trustworthiness, and reliability of records and raw data within the system) and certifications from all employees of Corporate Defendants and/or their subsidiaries and/or affiliates involved in Application-related data generation or processing. The audit trail and certifications shall be maintained in a form electronically available to FDA for as long as the product covered in the Application is pending approval or approved in the United States;

B. Prior to submitting any Application to FDA, the Chief Data Reliability Officer or his/her designee has reviewed the audit trails to determine whether one or more Wrongful Acts

has occurred in the Application(s). Within fifteen (15) days after review of the audit trails is complete, the Chief Data Reliability Officer shall identify all untrue statements and data irregularities and determine whether the data irregularities occur with sufficient frequency and/or are sufficiently similar to constitute a pattern or practice of data irregularities that call into question the reliability of the data in the Application(s), and shall submit to FDA all audit trails identifying untrue statements and/or data irregularities in or affecting the Application(s);

C. Each Application submitted to FDA includes a certification by the Chief Data Reliability Officer that, after diligent investigation, the Chief Data Reliability Officer has, to the best of his/her knowledge, determined that the data in the Application are accurate and complete in all material respects; and

D. The Chief Data Reliability Officer reports in writing and in person to Ranbaxy Laboratories, Ltd.'s Board of Directors at least annually, and also at the next scheduled Board meeting following identification of an untrue statement and/or a pattern or practice of data irregularities that call into question the reliability of the data in an Application(s).

X. Within seventy-five (75) days after entry of this Decree, Defendants shall establish a disclosure program that includes both a worldwide toll-free compliance telephone line and a system to receive and maintain written submissions from individuals who wish to disclose to the Chief Data Reliability Officer any issues or questions associated with Defendants' policies, conduct, practices, or procedures believed by the individual to be a potential violation of the Act. Defendants shall publicize the existence of the disclosure program by sending, semi-annually, e-mails to employees, posting the information prominently on the Corporate Defendants' websites, and posting in employee common areas. The disclosure program shall

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emphasize a non-retribution, non-retaliation policy, and shall facilitate anonymous and confidential communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Chief Data Reliability Officer or his/her designee shall gather all relevant information from the disclosing individual. The Chief Data Reliability Officer or his/her designee shall make a diligent, good faith inquiry into the allegations set forth in every disclosure to ensure that he/she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific to: (a) permit a determination of the appropriateness of the alleged improper practice; and (b) provide an opportunity for taking corrective action, Defendants shall conduct a review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted. The Chief Data Reliability Officer or his/her designee shall maintain a disclosure log, which shall include a record and an accurate and complete summary of each disclosure received (whether anonymous or not), the status of the respective reviews, and any corrective action taken in response to the reviews. All information gathered by the disclosure program shall (a) be maintained for at least four years following closure of the review and corrective action, and (b) be provided to FDA upon request.

XI. Within thirty (30) days after entry of this Decree, Corporate Defendants shall retain, at their expense, an independent person or persons (the "Data Integrity Expert(s)"), who has no personal or financial ties (other than the consulting agreement between the parties) to Defendants or their immediate families, and who, by reason of background, experience, education, and training, is qualified to conduct complete reviews ("internal reviews") and audits of the Excepted and Affected Applications to identify all instances of Wrongful Acts at

Corporate Defendants' facilities and to establish the reliability and integrity of the data contained in the Excepted and Affected Applications. Corporate Defendants shall notify FDA in writing of the identity of the Data Integrity Expert(s) within fifteen (15) days after retaining such expert(s). Corporate Defendants shall give the Data Integrity Expert(s) the freedom to conduct independent and adequate internal reviews and audits, as set forth in paragraphs XIV.B and XVII.A-F of this Decree, and to determine, in consultation with FDA and Corporate Defendants, the appropriate scope of the audits. Corporate Defendants' consulting agreement with the Data Integrity Expert(s) shall require the Data Integrity Expert(s) to: (1) notify FDA, within fifteen (15) days, of any disputes he or she has with Defendants regarding the scope, conduct, findings, or any other aspect of the internal reviews and audits; (2) upon FDA's request, meet directly with FDA without Defendants present; and (3) meet with FDA without Defendants present any time the Data Integrity Expert(s) deems it necessary, to discuss the Data Integrity Expert(s)'s internal reviews of Corporate Defendants' facilities and audits of Corporate Defendants' Applications.

PENDING APPLICATIONS

XII. Upon entry of this Decree, Defendants shall be deemed to have relinquished any claim to 180-day exclusivity for the following Affected Applications, and shall not interpose any objection in any forum to FDA's approval of any other ANDAs held by other sponsors for the drugs subject to such Affected Applications: ANDA 6; ANDA 7; and ANDA 8.

XIII. If Corporate Defendants have not received final approval of ANDA 3 by March 25, 2013, Corporate Defendants shall, upon written notification from FDA, be deemed to have relinquished any claim to 180-day exclusivity for such Application, and shall not interpose any objection in any forum to FDA's approval of any other ANDAs held by other sponsors for such

drug. If Corporate Defendants have not completed their substantial completeness submissions pursuant to paragraph XIV.A, audit plans pursuant to paragraph XIV.B.1, and audits pursuant to paragraph XIV.B.2, for each of the following Excepted Applications by the following dates, Corporate Defendants shall, upon written notification from FDA, be deemed to have relinquished any claim to 180-day exclusivity for such Excepted Application(s) and shall not interpose any objection in any forum to FDA's approval of any other ANDAs held by other sponsors for the drugs subject to such Excepted Application(s) after such date: ANDA 1, by December 31, 2012; ANDA 2, by January 31, 2013; ANDA 5, by July 31, 2013; and ANDA 4, by September 30, 2014.

EXCEPTED APPLICATIONS

XIV. Within thirty (30) days after entry of this Decree:

A. Defendants shall submit to FDA detailed written submissions, with all available supporting data, to demonstrate whether the Excepted Applications were substantially complete, within the meaning of 21 U.S.C. § 355(j)(5)(B)(iv)(II)(cc) and 21 C.F.R. § 314.101(b)(1), at the time they were initially filed.

1. Following FDA's review of such submissions, which will be completed within sixty (60) days, the Agency will provide Corporate Defendants with written notice whether each ANDA appears to have been substantially complete at the time it was filed. FDA's substantial completeness determination may be based on any information, including, but not limited to, the submissions required under this paragraph.

2. If FDA determines that an ANDA does not appear to have been substantially complete at the time of filing, Corporate Defendants shall be ineligible for

exclusivity for such ANDA, and such ANDA shall be deemed to be an Affected Application; and

B. The Data Integrity Expert shall develop plans to audit the Excepted Applications (hereafter, "EA audit plan(s)"). The EA audit plans shall be designed to determine, based on all information available to Defendants, whether any Excepted Application contains untrue statements or data irregularities and whether data irregularities occur with sufficient frequency and/or are sufficiently similar to constitute a pattern or practice of data irregularities that call into question the reliability of the data in the Excepted Application, and to identify all such untrue statements and/or data irregularities. With respect to data generated by third parties and included in an Excepted Application, the Data Integrity Expert shall not be required to visit a third party's facility as a part of his or her audit of the third party data; however, if the Data Integrity Expert attempts to visit a third party's facility and is refused access by the third party, Corporate Defendants shall promptly notify FDA of such refusal. The Data Integrity Expert shall audit: (1) all data generated by third parties that are in the possession or control of Corporate Defendants and/or their subsidiaries and/or affiliates, and (2) all records of Corporate Defendants and/or their subsidiaries and/or affiliates related to such data. While auditing such information related to data generated by third parties, the Data Integrity Expert shall verify that the processing of such third-party data by Corporate Defendants and/or their subsidiaries and/or affiliates (including, but not limited to, handling, analysis, and transmission of such data) was done properly and in a manner that would not affect the reliability and integrity of data received from the third party. The Data Integrity Expert shall not be required to audit data supporting the Application that is no longer in the possession or control of Corporate Defendants and/or their subsidiaries and/or affiliates on the date of entry of this Decree (hereafter, "third party data

auditing requirements").

1. Defendants shall submit the EA audit plans to FDA, which shall have thirty (30) days to provide written notification that it has accepted or identified deficiencies in the EA audit plans. Any deficiencies identified by FDA will be provided to Defendants, together with a rationale for FDA's conclusion. If deficiencies are identified, the Data Integrity Expert and Defendants shall revise the EA audit plans and Defendants shall resubmit the revised EA audit plans to FDA, which will have an additional twenty (20) days to accept or identify deficiencies in the revised EA audit plans;

2. After Defendants receive written notification from FDA that the EA audit plans are acceptable, the Data Integrity Expert shall begin auditing the Excepted Applications in accordance with the FDA-approved EA audit plans. The Data Integrity Expert shall submit all audit reports (whether interim or final), as well as individual reports regarding any Excepted Application, simultaneously to FDA and Defendants.

Nothing in this paragraph shall require FDA to review such audit reports for an Excepted Application that FDA determines does not appear to have been substantially complete at the time of its filing.

XV. For all Excepted Applications found by FDA under paragraph XIV.A.1 to have been substantially complete at the time they were initially filed, FDA will, within sixty (60) days after receipt of an audit report for an Excepted Application under paragraph XIV.B.2, evaluate the data to determine whether such Excepted Application contains any untrue statements, and/or whether, in the exercise of FDA's discretion, such Excepted Application contains a pattern or practice of data irregularities affecting approval. If FDA determines that there is an untrue

statement and/or pattern or practice of data irregularities affecting approval, Corporate Defendants shall, in writing, withdraw such Excepted Application, except that Corporate Defendants shall not be required to withdraw any Excepted Application for which the Data Integrity Expert certifies to FDA in writing that Corporate Defendants had replaced all untrue statements and/or such patterns or practices of data irregularities in such Excepted Application prior to February 25, 2009. If Defendants dispute FDA's determination, they shall submit, in writing within twenty (20) days of receiving FDA's determination, their reasons why FDA's determination is incorrect. FDA will provide Defendants with a final written determination regarding any disputed Excepted Application within fifteen (15) days of receipt of Defendants' dispute. Upon FDA's final determination that an Excepted Application contains an untrue statement and/or patterns or practices of data irregularities affecting approval, Corporate Defendants shall, in writing, withdraw such Excepted Application(s). If FDA does not determine that an Excepted Application contains untrue statements and a pattern or practice of data irregularities affecting approval, FDA will begin or resume reviewing that Excepted Application.

Nothing in this paragraph shall restrict FDA's ability to raise additional data integrity concerns regarding the Excepted Applications during the review process.

CGMP INJUNCTION PROVISIONS

XVI. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing the following: (1) manufacturing any drugs

at or from Gloversville, unless and until Defendants have satisfied all of the requirements of subparagraph B of this paragraph applicable to Gloversville; (2) manufacturing at Batamandi drugs that are the subject of an Application that contains data or other information generated or developed at Batamandi and introducing into interstate commerce any drugs manufactured at Batamandi, unless and until Defendants have satisfied all of the requirements of subparagraph B of this paragraph applicable to Batamandi; (3) manufacturing at Paonta Sahib drugs that are the subject of an Application that contains data or other information generated or developed at Paonta Sahib and introducing into interstate commerce any drugs manufactured at Paonta Sahib, unless and until Defendants have satisfied all of the requirements in subparagraph A of this paragraph applicable to Paonta Sahib and have received notification of CGMP compliance from FDA under paragraph XVI.A.6 for Paonta Sahib; and (4) manufacturing at Dewas drugs that are the subject of an Application that contains data or other information generated or developed at Dewas and introducing into interstate commerce any drugs manufactured at Dewas, unless and until Defendants have satisfied all of the requirements in subparagraph A of this paragraph applicable to Dewas and have received notification of CGMP compliance from FDA under paragraph XVI.A.6 for Dewas.

A. The following provisions apply to the Paonta Sahib and Dewas facilities and relate solely to those facilities' manufacture of drugs that are the subject of an Application and/or that are intended for introduction into interstate commerce:

1. Corporate Defendants' methods, facilities, and controls used to manufacture drugs are established, operated, and administered in conformity with CGMP Requirements;

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2. Corporate Defendants retain, at their expense, an independent person or persons (the "CGMP Expert"), who has no personal or financial ties (other than the consulting agreement between the parties) to Defendants or their immediate families and who, by reason of background, experience, education, and training, is qualified to inspect Corporate Defendants' drug production facilities to determine whether their methods, facilities, and controls are operated and administered in conformity with CGMP Requirements. Corporate Defendants' consulting agreement with the CGMP Expert shall require the CGMP Expert to: (1) notify FDA, within fifteen (15) days, of any disputes he or she has with Defendants regarding the scope, conduct, findings, or any other aspect of the CGMP review; (2) upon FDA's request, meet directly with FDA without Defendants present; and (3) meet with FDA without Defendants present any time the CGMP Expert deems it necessary, to discuss the CGMP Expert's review of Corporate Defendants' facilities. Defendants shall notify FDA in writing of the identity of the CGMP Expert within fifteen (15) days after retaining such expert. The CGMP Expert shall:

a. Perform a comprehensive inspection of the facilities, methods, and controls used to manufacture drugs. The CGMP Expert shall determine whether Corporate Defendants' facilities, methods, and controls used to manufacture drugs are in compliance with CGMP Requirements;

b. Evaluate whether Defendants have established and implemented a comprehensive written QA/QC program that is adequate to ensure continuous compliance with CGMP Requirements. The CGMP Expert, at a minimum, shall determine whether the QA/QC program:

i. Addresses all elements of Corporate Defendants' quality system including, but not limited to, compliance monitoring, trend analyses, internal audit procedures, and whether

the personnel in Corporate Defendants' QA and QC units (hereafter, collectively "QA/QC Unit") are adequately trained and staffed to evaluate Defendants' continuous compliance with CGMP Requirements and to prevent and correct deviations from CGMP Requirements;

ii. Includes the QA and QC management controls and the disclosure program described in paragraphs VIII and X of this Decree, and assures that Corporate Defendants' organization infrastructure and policies are designed to support quality, including, but not limited to, effective management monitoring and review systems and reporting structures;

iii. Includes procedures to ensure that Defendants: (a) promptly and thoroughly investigate product deviations, reports of complaints regarding Corporate Defendants' products, and all unexplained discrepancies and failures of a batch of drug or any of its components to meet all of the applicable specifications; the procedures shall include extending such investigation to other batches of the same drug and other drugs and components that may have been associated with or affected by the specific failure or discrepancy; (b) take required and prompt corrective actions for all products and components that fail to meet their specifications; and (c) determine whether a complaint represents a serious and unexpected adverse drug experience that is required to be reported to FDA under 21 C.F.R. §§ 310.305 or 314.80;

iv. Establishes procedures to ensure that written standard operating procedures ("SOPs") are periodically re-evaluated so that they remain in continuous compliance with the law and this Decree, and that the SOPs address all aspects of CGMP Requirements and are reviewed and controlled by the QA/QC Unit; and

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v. Includes written SOPs to ensure that: (a) QA personnel are promptly notified in writing of all deviations from CGMP Requirements (including, but not limited to, out-of-specification results, laboratory and/or manufacturing deviations, and/or problems that could affect the safety, identity, strength, quality, and purity of any drug); (b) Corporate Defendants' QA personnel participate in and/or closely monitor the implementation and verification of corrective actions to prevent future occurrences of such similar deviations and/or problems; and (c) there are systems to ensure that such written SOPs are continuously followed;

c. Evaluate whether Defendants have established and implemented an adequate stability program that accurately measures the stability characteristics of drug products using the following:

i. appropriate stability test methods;

ii. appropriate equipment appropriately maintained;

iii. appropriate laboratory control systems to track stability samples; and

iv. appropriate record control systems to ensure authenticity, reliability, and retention of all data;

d. Evaluate whether Defendants have established and implemented a comprehensive quality assurance system for both process validation and analytical method validation including, but not limited to, change management and timely revalidation of changes in packaging, formulation, equipment, and processes that may affect the drug product's effectiveness, quality, or purity attributes;

e. Evaluate whether Defendants have established and implemented a comprehensive written program to maintain the production, control, and other records and ensure the

authenticity and reliability of all data reflected in those records; and

f. Evaluate whether Defendants have established and implemented the Office of Data Reliability discussed in paragraph IX and the disclosure program discussed in paragraph X of this Decree and a comprehensive written program to ensure the authenticity and reliability of all Application data provided to FDA.

3. The CGMP Expert certifies to FDA that:

a. The CGMP Expert has inspected Corporate Defendants' facilities, methods, and controls used to manufacture drugs;

b. All deviations from CGMP Requirements brought to Defendants' attention by FDA, the CGMP Expert, and/or any other source since August 2003 have been corrected; and

c. Such facilities, methods, processes, and controls are adequate to ensure continuous compliance with CGMP Requirements. As part of this certification, the CGMP Expert shall include a detailed and complete report of the results of the CGMP Expert's inspections;

4. Defendants report to FDA in writing the actions they have taken to:

a. Correct the CGMP deviations brought to their attention by FDA, the CGMP Expert, and/or through any other means; and

b. Ensure that the methods used in, and the facilities and controls used for manufacturing drugs are operated and will be continuously administered in compliance with CGMP Requirements.

5. FDA representatives may begin an inspection of a facility within ninety (90) days after receipt of the certification described in paragraph XVI.A.3 or the Defendants'

report described in paragraph XVI.A.4 for that facility, whichever is later, or at any time under paragraph XXXII of this Decree, to determine whether the requirements of this Decree have been met, and whether that facility is otherwise operated in conformity with CGMP Requirements.

6. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in paragraphs XVI.A.1-4, which notification, if appropriate, will be issued no later than one hundred twenty (120) days after conclusion of any inspection or, if FDA does not inspect Defendants' facilities pursuant to paragraph XVI.A.5, within ninety (90) days after receiving the certification described in paragraph XVI.A.3 or the Defendants' report described in paragraph XVI.A.4, whichever is later. When a notification is issued under this subparagraph, FDA will terminate any import alert associated with the facility that is the subject of the notification and remove that facility from Official Action Indicated status, and Defendants may introduce into interstate commerce any FDA-approved drugs manufactured at such facility after the date of such notification.

B. If Corporate Defendants intend to resume manufacturing drugs at Gloversville, they shall notify FDA in writing and paragraph XVI.A shall immediately apply to Gloversville. FDA will not use Gloversville's past non-compliance with the CGMP requirements as the sole basis for withholding approval of requests to transfer the manufacture of products from Gloversville to a site other than Gloversville, including, but not limited to, any third party site. If Corporate Defendants intend to resume the manufacture at Batamandi of drugs that are the subject of an Application and/or are intended for introduction into interstate commerce, they shall notify FDA in writing and paragraph XVI.A shall immediately apply to Batamandi.

DATA INTEGRITY PROVISIONS FOR AFFECTED APPLICATIONS

XVII. FDA has halted and will not resume or begin reviewing Affected Applications, unless and until: (1) for Affected Applications that contain data generated or developed at Paonta Sahib, Defendants have fully and satisfactorily completed the requirements of paragraphs XVII.A-L, and FDA has issued written notification to Defendants in accordance with paragraph XVII.O that the Agency's concerns regarding the reliability of the data in all such Affected Applications appear to be resolved; and (2) for Affected Applications that contain data generated or developed at Dewas or at another facility (excluding Paonta Sahib), Defendants have fully and satisfactorily completed the requirements of paragraph XVII.A-E and have completed the audit under paragraph XVII.F for a specific Affected Application, and FDA has notified Defendants under paragraph XVII.N that the Agency's concerns regarding the reliability of the data in that specific Affected Application appear to be resolved. If Corporate Defendants notify FDA under paragraph XVI.B that they intend to resume the manufacture at Batamandi of drugs that are the subject of an Application and/or intended for introduction into interstate commerce, the provisions of this paragraph and paragraph XXIV pertaining to Paonta Sahib shall be immediately applicable to Batamandi.

A. The Data Integrity Expert shall develop, in consultation with the Defendants as necessary, internal review protocols for Paonta Sahib and Dewas, that shall include, but not be limited to:

1. identifying an historical period (hereafter, "relevant period") during which Wrongful Acts occurred in the Affected Applications from such facility;

2. identifying and interviewing current employees who were employed prior to, during, or immediately after the relevant period to identify activities, systems, procedures, and management behaviors that may have resulted in or contributed to Wrongful Acts;

3. identifying former employees who departed prior to, during, or after the relevant period and making diligent efforts to interview them to determine whether they possess any relevant information regarding any Wrongful Act;

4. based on the information identified from the foregoing interviews, collecting data and information that may be related to Wrongful Acts, determining whether other evidence supports the information gathered during the interviews, and determining whether additional facilities were involved in or affected by Wrongful Acts;

5. using organizational charts and SOPs to identify the specific managers in place when Wrongful Acts were occurring;

6. determining whether any individual managers identified in item (5) of this subparagraph are still in a position to influence data integrity with respect to CGMP Requirements or the submission of Applications; and

7. establishing procedures to expand the internal review to any other facilities determined to be involved in or affected by Wrongful Acts;

B. Defendants shall submit the internal review protocols to FDA, which shall have sixty (60) days to provide written notification that it has accepted or identified deficiencies in the protocols. Any deficiencies identified by FDA will be provided to Defendants, together with a written rationale for FDA's conclusion. If deficiencies are identified, the Data Integrity Expert shall revise the internal review protocols and Defendants will resubmit the revised internal

review protocols to FDA, which shall have an additional thirty (30) days to accept or identify deficiencies in the revised internal review protocols;

C. After Defendants receive written notification from FDA that the internal review protocols are acceptable, the Data Integrity Expert shall begin the internal reviews in accordance with the FDA-approved protocols. In conducting the internal reviews, the Data Integrity Expert may consider data and information generated by third party experts prior to the entry of this Decree. The Data Integrity Expert shall submit all internal review reports (whether interim or final) simultaneously to FDA and Defendants;

D. Based upon the results of the internal reviews, the Data Integrity Expert and Defendants shall develop plans for Paonta Sahib and Dewas, designed as set forth in paragraph XIV.B of this Decree, to audit all Affected Applications that contain data generated or developed at each facility (hereafter, "audit plan(s)"). The Data Integrity Expert's audit of data generated by third parties and included in an Affected Application audited under this paragraph shall be conducted pursuant to the third party data auditing requirements set forth in paragraph XIV.B. If the Data Integrity Expert's internal reviews determine that an untrue statement and/or a pattern or practice of data irregularities occurred at one or more facilities other than Paonta Sahib and/or Dewas, the Data Integrity Expert shall develop audit plan(s) to audit any additional Applications identified by the internal reviews as being potentially affected by such untrue statement and/or a pattern or practice of data irregularities, and such Applications shall be deemed to be Affected Applications;

E. Defendants shall submit the audit plans to FDA for review and acceptance according to the procedures set forth in paragraph XIV.B.1 of this Decree;

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F. After Defendants receive written notification from FDA that the audit plans are acceptable, the Data Integrity Expert shall begin the audit in accordance with the FDA-approved audit plans. The Data Integrity Expert shall submit all audit reports (whether interim or final and including reports for withdrawn Applications), as well as individual reports regarding any Affected Application, simultaneously to FDA and Defendants;

G. Within ninety (90) days after the Data Integrity Expert has completed all of the audits required at Paonta Sahib and/or Dewas, whichever is first, Defendants shall submit to FDA an initial CAOP addressing the internal review findings from such facility and each Affected Application from any facility audited at that time. When the Data Integrity Expert completes all audits required at a subsequent facility, Defendants shall update the CAOP submitted previously to include information regarding each internal review completed and/or each Affected Application audited from any facility since submission of the initial CAOP or since the last update to the CAOP. The CAOP shall ensure the integrity of data submitted to FDA. The CAOP, initially, and as supplemented by each of the CAOP updates, shall be based on the completed internal review(s), and shall, at minimum, include the following:

1. For each audited Affected Application: (a) identification of all untrue statements; (b) identification of all data irregularities, including a determination as to whether such data irregularities occur with sufficient frequency and/or are sufficiently similar to constitute a pattern or practice of data irregularities that call into question the reliability of the data in the Application; (c) identification of all individuals who were involved in, aware of, or responsible for untrue statements and/or patterns or practices of data irregularities; and (d) identification of practices or procedures that contributed to any untrue statements and/or patterns

or practices of data irregularities;

2. A detailed description of the disposition by Defendants of all recommendations made by the Data Integrity Expert;

3. A description of the actions taken and to be taken by Defendants, including time frames, to address and correct all untrue statements and/or patterns or practices of data irregularities identified by FDA and/or discovered by the internal reviews and/or audit;

4. Identification of the individuals responsible for addressing and correcting untrue statements and/or patterns or practices of data irregularities;

5. A description of a comprehensive ethics and data integrity program that describes standards for employees, procedures for training employees about the program, procedures for regularly evaluating the effectiveness of the training, and procedures to enforce the program; and

6. A description of the procedures to monitor the effectiveness of the CAOP and to ensure that Corporate Defendants will manufacture products in continuous compliance with the law and this Decree.

H. After Defendants submit the CAOP and updates to the CAOP ("CAOPs") described in paragraph XVII.G, FDA will have sixty (60) days to provide written notification that it has accepted or identified deficiencies in the CAOPs. For each Affected Application identified in the CAOPs to contain data irregularities that occur with sufficient frequency and/or sufficient similarity to constitute a pattern or practice of data irregularities, FDA will evaluate the data to determine whether, in the exercise of its discretion, the Application contains a pattern or practice of data irregularities affecting approval. Any deficiencies identified in the CAOP and a

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list of any Affected Applications that FDA determines contain a pattern or practice of data irregularities affecting approval will be provided to Defendants in writing by FDA, together with a rationale for FDA's conclusions. If deficiencies are identified, the Defendants shall revise the CAOPs and resubmit the revised CAOPs to FDA, which shall have an additional forty-five (45) days to accept or identify deficiencies in the revised CAOPs. If Defendants disagree with FDA's determination that an Affected Application contains a pattern or practice of data irregularities affecting approval, they shall submit, in writing within twenty (20) days after receiving FDA's determination, their reasons why FDA's determination is incorrect. FDA will provide Defendants with a final written determination regarding any disputed Affected Application within fifteen (15) days after receiving Defendants' statement of disagreement.

I. Within thirty (30) days after receiving FDA's final determination that an Affected Application contains a pattern or practice of data irregularities affecting approval, Corporate Defendants shall:

1. in writing, withdraw all pending Affected Applications that contain any untrue statements and those Affected Applications that FDA determines contain a pattern or practice of data irregularities affecting approval, except that Corporate Defendants shall not be required to withdraw any pending Affected Applications that contain data or other information generated or developed at Paonta Sahib for which the Data Integrity Expert certifies to FDA in writing that Corporate Defendants had replaced all untrue statements and/or pattern or practice of data irregularities in such Affected Application prior to February 25, 2009; and

2. request in writing that FDA withdraw approval of all approved Affected Applications that contain any untrue statements and those Affected Applications that FDA

determines contain a pattern or practice of data irregularities affecting approval, except that Corporate Defendants shall not be required to withdraw any approved Affected Applications that contain data or other information generated or developed at Paonta Sahib for which the Data Integrity Expert certifies to FDA in writing that Corporate Defendants had replaced all untrue statements and/or pattern or practice of data irregularities in such Affected Application prior to February 25, 2009.

J. After Defendants receive written notification from FDA that the CAOP (as updated, if applicable) is acceptable, Defendants shall implement the CAOP.

K. Within thirty (30) days after Defendants identify an individual(s) who knowingly directed or condoned Wrongful Acts, Corporate Defendants shall remove from positions of authority on matters under FDA's jurisdiction such individual(s) and shall advise FDA, in writing within fifteen (15) days after the removal, of the identity and position of the person(s) removed, and the reasons for the removal.

L. Upon completion of the obligations in paragraphs XVII.A-K, Defendants shall provide FDA with a written report of the actions taken under this paragraph.

M. At any time, FDA may begin a Validity Assessment of Corporate Defendants' Application(s).

N. With respect to Affected Applications that contain data or other information generated or developed at Dewas, after FDA has determined that Defendants have fully and satisfactorily completed all of the requirements in paragraphs XVII.A-E (relating to the Data Integrity Expert's internal review and audit plans), and the Data Integrity Expert has audited a specific Affected Application and submitted all audit reports regarding such Affected

Application to FDA under paragraph XVII.F, FDA will determine whether such Affected Application contains an untrue statement and/or a pattern or practice of data irregularities affecting approval. If FDA does not determine that such Affected Application contains an untrue statement and/or pattern or practice of data irregularities affecting approval:

1. For a pending Affected Application, FDA will begin or resume review of that Affected Application and notify Defendants in writing that the Agency's concerns regarding the reliability of the data in that pending Affected Application appear to be resolved;

2. For an approved Affected Application, FDA will notify Defendants in writing that the Agency's concerns regarding the reliability of the data in the approved Affected Application appear to be resolved.

FDA will provide notification of its determination within sixty (60) days after receiving the Data Integrity Expert's final report with respect to such Application; however, if there are more than five (5) final reports on Affected Applications under simultaneous FDA review, the timeframe for the Agency's response under this paragraph shall increase in increments of ten (10) days per such Affected Application. Any determination that FDA's concerns regarding an Affected Application are not resolved shall include in the notification a rationale for such determination. Nothing in this paragraph shall restrict FDA's ability to raise additional data integrity concerns regarding an Affected Application during the review process.

O. With respect to Affected Applications that contain data or other information generated or developed at Paonta Sahib, after FDA has, based upon its review of Corporate Defendants' submissions, determined that Defendants appear to have fully and satisfactorily completed all of the requirements in paragraphs XVII.A-L for all such Affected Applications,

FDA will promptly decide whether it needs to inspect Paonta Sahib to determine whether to revoke the Application Integrity Policy at such facility. If no inspection is necessary, FDA will promptly revoke the Application Integrity Policy at Paonta Sahib, notify Defendants in writing of the revocation, and resume review of all such Affected Applications. If FDA decides an inspection is necessary, it will notify Defendants of its decision in writing and begin such inspection within ninety (90) days after making such decision. If FDA's inspection reveals that Corporate Defendants have fully and satisfactorily implemented all of the requirements in paragraphs XVII.A-L applicable to Paonta Sahib, FDA will, within ninety (90) days after the inspection is complete, promptly revoke the Application Integrity Policy at Paonta Sahib, notify Defendants in writing of the revocation, and resume review of all Affected Applications that contain data or other information generated or developed at Paonta Sahib. Any determination that Corporate Defendants have not fully and satisfactorily implemented all of the requirements in paragraphs XVII.A-L applicable to Paonta Sahib shall include in the notification a rationale for such determination. Nothing in this paragraph shall restrict FDA's ability to raise additional data integrity concerns regarding any Affected Application during the review process.

EXCLUSIONS

XVIII. Notwithstanding paragraphs XVI and XVII, Defendants may continue the following activities as set forth below. None of the products manufactured under subparagraphs A-C of this paragraph may be offered for sale or commercially distributed in the United States.

A. Manufacturing investigational drugs for the sole purpose of conducting clinical trials under investigational new drug applications or for bioavailability or bioequivalence testing, provided Defendants comply with all applicable laws and regulations.

B. Manufacturing limited quantities of drugs that are necessary for the sole purpose of preparing or supporting an Application.

C. Manufacturing products for the sole purpose of conducting non-clinical laboratory studies or other research and testing that does not involve exposure to human research subjects.

D. Distributing in the United States any lawful drugs: (1) that are manufactured solely by a third party or parties; and (2) for which Defendants perform no manufacturing (other than distributing) functions with respect to such drugs.

ADDITIONAL REQUIREMENTS FOR DEWAS AFFECTED APPLICATIONS

XIX. If Defendants have not completed the internal review under paragraph XVII.C at Dewas and/or audited all Affected Applications that contain data or other information generated or developed at Dewas before they submit the CAOP and/or updates required under paragraph XVII.G, Defendants shall, within thirty (30) days after completing the Dewas internal review and/or auditing an Affected Application(s) that contains data or other information generated or developed at Dewas, update the CAOP to include information regarding the internal review and/or Affected Application(s) audited after submission of the initial CAOP or since the last update to the CAOP. For each Affected Application identified by the Data Integrity Expert to contain data irregularities that occur with sufficient frequency and/or sufficient similarity to constitute a pattern or practice of data irregularities, FDA will evaluate the data to determine whether, in the exercise of its discretion, such Affected Application contains a pattern or practice of data irregularities affecting approval. If Defendants dispute FDA's determination that an Affected Application contains a pattern or practice of data irregularities affecting approval, they shall submit, in writing within twenty (20) days of receiving FDA's determination, their reasons

why FDA's determination is incorrect. FDA will provide Defendants with a final written determination regarding any disputed Affected Application within fifteen (15) days of receipt of Defendants' dispute. Within thirty (30) days after receiving an audit showing that an Application contains any untrue statement or receiving FDA's final determination that an Application contains a pattern or practice of data irregularities affecting approval, Corporate Defendants shall: (1) in writing, withdraw such pending Application(s); and/or (2) request in writing that FDA withdraw approval of such approved Application(s).

Updates of the CAOP under this paragraph shall continue until all audits of Affected Applications that contain data or other information generated or developed at Dewas are complete or until all remaining unaudited Affected Applications are withdrawn under paragraph XX.

WITHDRAWAL OF UNAUDITED AFFECTED APPLICATIONS

XX. If, within four (4) years after entry of this Decree, the Data Integrity Expert has not completed auditing all Affected Applications that contain data or other information generated or developed at Paonta Sahib and/or Dewas, Corporate Defendants shall withdraw, in writing, any such unaudited pending Affected Applications, and any such unaudited approved Affected Applications from such facilities will be deemed to be withdrawn. Corporate Defendants shall not re-submit any Affected Applications withdrawn under this paragraph, except in full accordance with paragraph XXVII.

ADDITIONAL INJUNCTION PROVISION

XXI. Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or

participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done, at any Covered Facility or at any other facility added to this decree through paragraph XXIX, any act that:

A. Violates 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce, any article of drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Violates 21 U.S.C. § 331(k) by causing any drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), while such drug is held for sale after shipment in interstate commerce;

C. Violates 21 U.S.C. § 331(d) by introducing into interstate commerce any new drug that does not comply with 21 U.S.C. § 355; and

D. Violates 21 U.S.C. § 331(e) by failing to make reports required under 21 U.S.C. § 355(k).

If, and for as long as, an individual Defendant ceases to be employed by or act on behalf of Corporate Defendants or any of their subsidiaries, franchises, affiliates and/or "doing business as" entities, then that individual Defendant shall not be subject to the terms of this Decree except as to such individual Defendant's act(s) or failure(s) to act under this Decree prior to the time such individual ceased to be employed by or to act on behalf of Corporate Defendants or their subsidiaries, franchises, affiliates, and/or "doing business as" entities.

XXII. Defendants shall not receive, hold, or distribute any Desquam X Wash products that do not comply with the requirements and timelines set forth in "Classification of Benzoyl

Peroxide as Safe and Effective and Revision of Labeling to Drug Facts Format; Topical Acne Drug Products for Over-The-Counter Human Use" Final Rule ("Final Rule"), 76 Fed. Reg. 9767 (Mar. 4, 2010), and any subsequent amendments thereto.

POST FDA NOTICE CGMP AUDIT PROVISIONS

XXIII. For the Covered Facilities, within thirty (30) days after Defendants have received FDA's notice under paragraph XVI.A.6 for a facility, Corporate Defendants shall retain an independent person (the "CGMP Auditor"), who meets the criteria set forth in, and may be the same person identified in, paragraph XVI.A.2, and whose consulting agreement shall contain the provisions identified in paragraph XVI.A.2, who shall inspect such facility no less frequently than once every six (6) months for a period of no less than one (1) year and annually thereafter for an additional period of not less than four (4) years.

A. At the conclusion of each of the audit inspections described in this paragraph, the CGMP Auditor shall prepare a written audit report ("CGMP audit report") certifying whether Defendants are in compliance with CGMP Requirements for all drugs that are the subject of an Application and/or intended to be introduced into interstate commerce and identifying all deviations therefrom ("CGMP audit report observations"). Beginning with the second audit report, the CGMP Auditor shall also assess the adequacy of all actions taken by Defendants to correct all previous CGMP audit report observations, and include this information in the CGMP audit report. The CGMP audit reports shall be delivered simultaneously to Defendants and FDA, no later than thirty (30) days after the date each inspection is completed. Defendants shall maintain the original CGMP audit reports in a separate file at the facility to which the report pertains and a copy at a Ranbaxy, Inc., office located in the United States, and shall promptly

make the CGMP audit reports available to FDA upon request.

B. If a CGMP audit report contains any CGMP audit report observations, Defendants shall, within thirty (30) days after receipt of the CGMP audit report, correct those deviations at the Covered Facilities, unless FDA notifies Defendants in writing that a shorter time period is necessary. If, after receiving the CGMP audit report, Defendants believe that correction of the deviations will take longer than thirty (30) days, Defendants shall, within ten (10) business days after receipt of the CGMP audit report, propose a schedule for completing corrections. FDA will, within ten (10) days after receiving the proposed schedule, review and approve or disapprove the proposed schedule in writing. Defendants shall complete all corrections according to the FDA-approved correction schedule.

C. Within thirty (30) days after Defendants' receipt of any CGMP audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the CGMP Auditor shall review the actions taken by Defendants to correct the CGMP audit report observations. Within ten (10) business days after completing that review, the CGMP Auditor shall report in writing to FDA whether each of the CGMP audit report observations has been fully corrected and, if not, which CGMP audit report observations remain uncorrected.

POST FDA NOTICE DATA AUDIT PROVISIONS

XXIV. For Paonta Sahib, within thirty (30) days after Defendants have received FDA's notice under paragraph XVII.O, and for Dewas, within thirty (30) days after the first time Defendants receive notice that FDA's concerns regarding the reliability of the data in either a pending or approved Affected Application appear to be resolved pursuant to paragraph XVII.N.1

or 2, Corporate Defendants shall retain an independent person (the "Data Quality Auditor"), who meets the criteria set forth and may be the same person identified in paragraph XI, and whose consulting agreement shall contain the provisions identified in paragraph XI, who shall inspect that facility no less frequently than once every six (6) months for a period of no less than two (2) years and annually thereafter for an additional period of not less than three (3) years. For Dewas, audits conducted under this paragraph may exclude Affected Applications that have not yet been audited by the Data Integrity Expert under paragraph XVII.F. The Data Quality Auditor's audit of data generated by third parties and included in an Application audited under this paragraph shall be conducted pursuant to the third party data auditing requirements set forth in paragraph XIV.B.

A. At the conclusion of each of the audit inspections described in this paragraph, the Data Quality Auditor shall prepare a written audit report ("data quality audit report"): addressing whether or not Defendants are continuing to ensure the validity of all data developed at the facility; identifying all Wrongful Acts at the facility ("data quality audit report observations"); identifying all managers in a position to influence data integrity with respect to the submission of Applications; identifying all Applications that contain untrue statements and/or data irregularities; and, if data irregularities are found, determining whether they occur with sufficient frequency and/or are sufficiently similar to constitute a pattern or practice of data irregularities that call into question the reliability of the data in an Application or other Applications. Beginning with the second audit report, the Data Quality Auditor shall also assess the adequacy of all corrective actions taken by Defendants to correct all previous data quality audit report observations, and shall include this information in the data quality audit report. The data quality

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audit reports shall be delivered simultaneously to Defendants and FDA, no later than thirty (30) days after the date each inspection is completed. For each Application identified by the Data Quality Auditor to contain a pattern or practice of data irregularities, FDA will evaluate the data to determine whether, in the exercise of its discretion, the Application contains a pattern or practice of data irregularities affecting approval. A list of any Application(s) that FDA determines contains a pattern or practice of data irregularities affecting approval will be provided to Defendants in writing by FDA, together with a rationale for FDA's conclusions. If Defendants disagree with FDA's determination, they shall submit in writing, within twenty (20) days of receiving FDA's determination, their reasons why FDA's determination is incorrect. FDA will provide Defendants with a final written determination regarding any disputed Application within fifteen (15) days of receipt of Defendants' statement of disagreement. Defendants shall maintain the original data quality audit reports in a separate file at the facility to which the report pertains and a copy at a Ranbaxy, Inc. office in the United States, and shall promptly make the data quality audit reports available to FDA upon request.

B. Defendants shall, within thirty (30) days after receipt of the data quality audit report, report to FDA the responsive actions that Defendants are taking to address all data quality audit report observations. Corporate Defendants shall also, within thirty (30) days after receiving an audit showing that an Application contains any untrue statement or receiving FDA's final determination that an Application contains a pattern or practice of data irregularities affecting approval: (1) in writing, withdraw such pending Application(s); and/or (2) request in writing that FDA withdraw approval of such approved Application(s).

C. If a data quality audit report contains any additional data quality audit report observations, Defendants shall, within thirty (30) days after receipt of the data quality audit report, correct those deviations at all implicated facilities, unless FDA notifies Defendants in writing that a shorter time period is necessary. If, after receiving the data quality audit report, Defendants believe that correction of the deviations will take longer than thirty (30) days, Defendants shall, within ten (10) days after receipt of the data quality audit report, propose a schedule for completing corrections. FDA will, as it deems appropriate, review and approve or disapprove the proposed schedule in writing. Defendants shall complete all corrections according to the approved correction schedule. Within sixty (60) days after Defendants' receipt of any data quality audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Data Quality Auditor shall review the actions taken by Defendants to correct the data quality audit report observations. Within ten (10) business days after completing that review, the Data Quality Auditor shall report in writing to FDA whether each of the data quality audit report observations has been fully corrected and, if not, which data quality audit report observations remain uncorrected.

GENERAL PROVISIONS

XXV. After entry of this Decree, Defendants shall retain, and make available for FDA inspection upon request, all data existing at the time of entry of this Decree or created thereafter in any pending, approved, or withdrawn Application as follows:

A. If the Application is pending or has been approved, the data shall be retained and be provided to FDA upon request for at least two (2) years after the drug product(s) covered by

the Application ceases to be distributed in the United States, by Corporate Defendants or by anyone else.

B. If the Application has been withdrawn, the data shall be retained and be provided to FDA upon request for at least two (2) years after the Application was withdrawn.

C. Notwithstanding the provisions in paragraphs XXV.A, if the Application has been transferred to a third party, Corporate Defendants shall retain a copy of the data only if the Application is an Affected or Excepted Application.

XXVI. After entry of this Decree, Defendants shall submit to FDA all adverse drug experience and post-marketing reports in full compliance with 21 U.S.C. § 355(k) and 21 C.F.R. § 310.305 and Part 314.

XXVII. After entry of this Decree, Defendants shall not submit a new Application for any drug that was the subject of an Affected Application unless either: (A) the Affected Application has been withdrawn; (B) for Affected Applications that contain data or other information generated or developed at Paonta Sahib, FDA has notified Defendants under paragraph XVII.O that the Agency's concerns regarding the reliability of the data appear to be resolved; or (C) for Affected Applications that contain data or other information generated or developed at Dewas, FDA has notified Defendants under paragraph XVII.N that the Agency's concerns regarding the reliability of the data in the Affected Application for that drug appear to be resolved. Any new Application for a drug that was the subject of a withdrawn Affected Application, shall, in addition to undergoing the pre-submission audit and certification set forth in paragraphs IX.A-C of this Decree, identify the parts of the original Application that remain in the new Application and, if any, the parts that were found to contain or be affected by untrue

statements and/or a pattern or practice of data irregularities, and include a certification from the Chief Data Reliability Officer that the new Application does not contain any such data from the original Application.

XXVIII. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analyses of samples, a report or data prepared or submitted by Defendants, the expert(s), or the auditor(s), or any other information, that Defendants have failed to comply with the law or this Decree or that additional corrective actions are necessary to achieve compliance with the law or this Decree with respect to any of Defendants' products and/or Applications, and/or the Covered Facilities, and/or any new facilities, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing all drugs intended for introduction into interstate commerce and/or importing into the United States any or all drug(s);

B. Recall specified drugs manufactured by Defendants. The recall(s) shall be initiated within five (5) business days after receiving notice from FDA that a recall is necessary. Upon written request by FDA, Defendants shall destroy all articles of drugs that are in Defendants' possession, custody, or control, for which a recall was initiated. Corporate Defendants shall bear the costs of such recall(s), including the costs of destruction and the cost of FDA's supervision at the rates prevailing at the time of the recall. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state law;

C. Submit additional reports or information to FDA;

D. Revise, modify, expand, and/or extend any report(s) or plan(s) prepared or audit conducted under this Decree, regardless of whether previously accepted or approved by FDA;

E. Issue a safety alert; and/or

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants into compliance with the law and this Decree or to protect the public health.

XXIX. If FDA inspects any facilities owned and/or operated by Corporate Defendants and/or their subsidiaries and/or affiliates, other than the Covered Facilities, and finds a violation of the Act and/or FDA's regulations, and/or finds that an untrue statement and/or pattern or practice of data irregularities affecting approval originated at one or more facilities, FDA may order that such facility or facilities shall thereafter be fully subject to the provisions of this Decree as though it or they were listed as a Covered Facility in paragraph VII.E when the Decree was entered, and FDA may order Defendants to take any or all of the actions described in paragraph XXVIII.

XXX. The following process and procedures shall apply when FDA issues an order under paragraphs XXVIII or XXIX, except as provided in subparagraph D below:

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the complete

basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as the Agency deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order while the matter is before the Court and unless and until the Court reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph XLVI of this Decree.

D. The process and procedures set forth in subparagraphs A-C shall not apply to any order issued pursuant to paragraph XXVIII or XXIX if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall, upon receipt of such an order, immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief.

XXXI. Any cessation of operations described in paragraphs XXVIII, XXIX, and XXX, shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the law and this Decree. Upon Defendants' written request to resume operations, FDA will promptly determine whether it needs to inspect any of Defendants'

facilities to determine Defendants' compliance with the law and this Decree. If FDA determines that an inspection is necessary, it shall conduct the inspection within one hundred twenty (120) days after such determination, and, within sixty (60) days following the close of the inspection, determine whether Defendants appear to be in compliance with the law and this Decree and, if so, FDA will issue to Defendants a written notification permitting resumption of operations. If no inspection is necessary, FDA will decide within forty-five (45) days after receipt of the request whether Defendants appear to be in compliance and, if so, issue to Defendants a written notification permitting resumption of operations.

XXXII. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of any of the Covered Facilities, collect samples, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted: access to Defendants' facilities and other place(s) of business including, but not limited to, all buildings, equipment, in-process or unfinished and finished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, and labeling; to interview employees; and to examine and copy all records relating to the receipt, development, and manufacturing of any and all drugs. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

XXXIII. Corporate Defendants shall reimburse FDA for the costs of all FDA inspections, sampling, testing, travel, time spent traveling, reviewing documents, consulting with Defendants' experts and/or auditors, supervising this Decree, and subsistence expenses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections and other activities shall be borne by Corporate Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour or fraction thereof per representative for analytical or review work; $.51 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

XXXIV. Within twenty (20) days after entry of this Decree, Corporate Defendants shall post a copy of this Decree on a bulletin board in the employee common areas at the Covered Facilities. Corporate Defendants shall ensure that the Decree remains posted for a period of at least twelve (12) months at each Covered Facility.

XXXV. Within fifteen (15) days after the entry of this Decree, Corporate Defendants shall provide a copy of the Decree, by personal service, personal delivery via electronic mail with acknowledgment of receipt, return receipt email, or certified mail (restricted delivery, return receipt requested), to each of their officers, directors, agents, representatives, successors, assigns,

(Para. XXXV)

attorneys, and to those employees at the Covered Facilities and all other persons no matter where they are located who participate with Corporate Defendants in the submission of Applications for drugs from the Covered Facilities and/or their manufacture at the Covered Facilities of drugs that are the subject of an Application and/or are intended to be introduced into interstate commerce (collectively referred to as "Associated Persons"). Within thirty (30) days after the date of entry of this Decree, Corporate Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

XXXVI. In the event that any of the Defendants becomes associated with any additional Associated Person(s) with respect to Defendants' activities relating in any way to Corporate Defendants' submission of Applications for drugs from the Covered Facilities and/or their manufacture of drugs at the Covered Facilities that are the subject of an Application and/or are intended to be introduced into interstate commerce at any time after entry of this Decree, Corporate Defendants shall, within twenty (20) days after such association, provide a copy of this Decree, by personal service, personal delivery via electronic mail with acknowledgment of receipt, return receipt email, or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Corporate Defendants shall, on a quarterly basis, furnish FDA with an affidavit of compliance identifying the names, addresses, and positions of all new Associated Persons who receive a copy of the Decree.

XXXVII. Corporate Defendants shall notify FDA in writing at least fifteen (15) days before any: change in ownership, character, or name of their businesses, including

incorporation, reorganization, bankruptcy, assignment, or sale resulting in the emergence of a successor business or corporation; creation or dissolution of subsidiaries or any other change in the corporate structure or identity of any Corporate Defendant; sale, assignment, or any transfer of ownership of an Application; purchase or sale of any new facilities; or sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Corporate Defendants shall provide a copy of this Decree to any potential successor or assign at least ten (10) days before any sale, assignment, or transfer of any kind. Corporate Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) days prior to such assignment or change in ownership.

XXXVIII. If Defendants fail to comply with any provision of the law or this Decree at any Covered Facility and/or with respect to any Affected Application, then, on motion of the United States in this proceeding, Corporate Defendants shall pay to the United States of America: fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues and an additional sum of fifteen thousand dollars ($15,000) in liquidated damages for each violation of the law and this Decree (e.g., if two violations occur for two business days, the liquidated damages shall be $60,000). In addition, should Defendants distribute from the Covered Facilities any drug after entry of this Decree that violates the law or this Decree, Corporate Defendants shall, in addition to the foregoing, also pay upon motion of the United States as liquidated damages a sum equal to two times the retail value of such drug(s). The amount of liquidated damages imposed under this paragraph shall not exceed ten (10) million dollars ($10,000,000.00) in any one calendar year. The remedy in this paragraph shall be in addition to any other remedies available to the United States under law or this Decree.

XXXIX. In addition, if, after entry of this Decree, Defendants submit an untrue statement in connection with any Application, then, on motion of the United States in this proceeding, Corporate Defendants shall pay to the United States of America up to three million dollars ($3,000,000) in liquidated damages for each such statement. The amount of liquidated damages imposed under this paragraph shall not exceed thirty million dollars ($30,000,000.00) in any one calendar year. The remedy in this paragraph shall be in addition to any other remedies available to the United States under law or this Decree.

XL. If FDA determines that an untrue statement appears in any Application(s) submitted by Defendants after entry of this Decree and for which Corporate Defendants may be eligible for 180-day exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv), Corporate Defendants shall, upon written notification from FDA, be deemed to have lost any claim to 180-day exclusivity for such Application(s), and Corporate Defendants shall waive all rights to sue FDA regarding any and all claims to 180-day exclusivity for such Application(s). FDA shall halt its review of any such Application(s) and Corporate Defendants shall, in writing, withdraw such Application(s) from FDA consideration for approval. Any new Application for a drug that was the subject of an Application withdrawn under this paragraph shall, in addition to undergoing the pre-submission audit and certification set forth in paragraphs IX.A-C of this Decree, identify the parts of the original Application that were found to contain or be affected by untrue statements and include a certification from the Chief Data Reliability Officer that the new Application does not contain any such data or information from the original Application. The remedy in this paragraph shall be in addition to any other remedies available to the United States under law or this Decree.

XLI. If any deadline in this Decree falls on a weekend or federal holiday, the deadline shall be continued to the next business day.

XLII. The parties may at any time petition each other in writing to modify any deadline provided herein, and if the parties mutually agree in writing to modify a deadline, such extension may be granted without seeking leave of Court.

XLIII. Notwithstanding any other provision of this Decree, Corporate Defendants may submit and FDA may review and approve, if appropriate, the following submissions for drugs in commercial distribution in the United States: (a) supplements for class labeling, or changes that enhance the labeling or are protective in nature; (b) supplements for changes for post-approval applications that do not require pre-approval, such as "changes being effected" supplements; (c) annual reports; and (d) adverse experience/event reports.

XLIV. In the event Defendants replace any third party expert required under this Decree, Defendants shall notify FDA in writing of any such successor and Defendants' reasons for replacing the expert within ten (10) business days after such replacement. In satisfying the requirements of this Decree, any third party expert may review the previous expert's work, and refer to such work to satisfy the requirements of the Decree; however, when such work is referenced by the new expert, he or she shall identify the specific prior work referenced.

XLV. Corporate Defendants understand that FDA may need to postpone inspecting Corporate Defendants' facilities located in India if safety or security concerns warrant such postponement. If such need arises, FDA will provide Corporate Defendants with written notice within five (5) days of making such postponement decision.

XLVI. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

XLVII. Should the United States of America bring, and prevail in, a contempt action to enforce the terms of this Decree, Corporate Defendants agree to pay all attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such action.

XLVIII. Unless otherwise specified, all notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be addressed to the Director, Office of Compliance, CDER, Building 51, Room 5270, 10903 New Hampshire Ave., Silver Spring, MD 20993. Unless otherwise specified, all notifications, certifications, reports, correspondence, and other communications to Defendants required by the terms of this Decree shall be addressed to Mr. Arun Sawhney, CEO and Managing Director, Ranbaxy Laboratories Limited, Plot No. 90, Sector 32, Gurgaon – 122001, with copies to Mr. Dale Adkisson, Ranbaxy Laboratories Limited, 77B IFFCO Road, Sector 18, Udyog Vihar Industrial Area, Gurgaon, 122015, India, and to Lavesh Samtani, Esq., Vice President, Legal-Americas and Venkatachalam Krishnan, Ranbaxy, Inc., 600 College Road East, Suite 2100, Princeton, NJ 08540.

XLIX. If Defendants have maintained at the Covered Facilities a state of continuous compliance with the law and this Decree for at least sixty (60) months after satisfying all of their obligations under paragraphs XVI and XVII, Defendants may petition this Court for relief from this Decree, and the United States will not oppose such petition.

L. In all instances where FDA is required to provide written notification to Defendants under this Decree, FDA's silence shall not be construed as a substitute for written notification.

LI. Notwithstanding FDA's February 25, 2009 letter placing Paonta Sahib and Batamandi on the Application Integrity Policy (AIP), the provisions of this Decree with respect to such facilities constitute the full requirements that Corporate Defendants must satisfy to address FDA's concerns set forth in its February 25, 2009 AIP letter.

LII. This Court retains jurisdiction of this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED, this ____ day of _____, 2011.

_____
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree:

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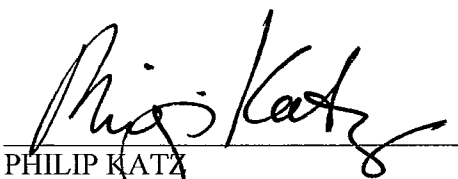

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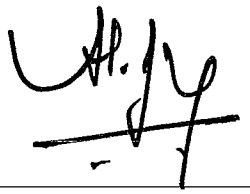

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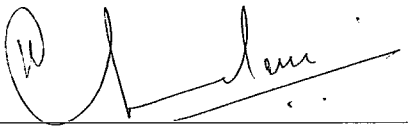

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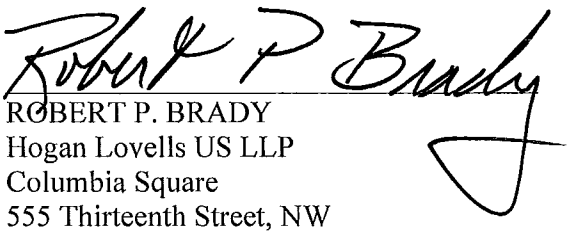

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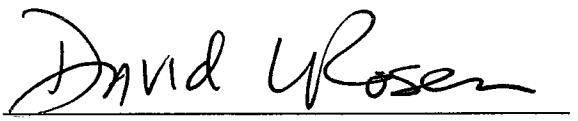

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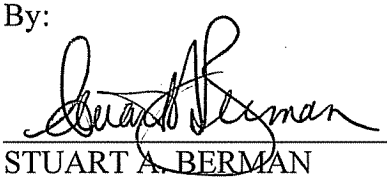

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA

*

vs. * **Case No. JFM-12-cv-250**

RANBAXY LABORATORIES, LTD., et al.

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NOTICE OF FILING ATTACHMENT UNDER SEAL

☒ Appendix A, which is an attachment to Consent Decree of Permanent Injunction, is filed under Seal