DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993-0002

September 12, 2013

Mr. Arun Sawhney, CEO and Managing Director
Ranbaxy Laboratories Limited
Plot No. 90, Sector 32
Gurgaon, 122001, India

Re: Order Under Paragraph XXIX of the Consent Decree of Permanent Injunction entered in *United States v. Ranbaxy Laboratories, Ltd., et al.* (Civ. No. JMF-12-250 (D. Md.)

Dear Mr. Sawhney:

Paragraph XXIX of the Consent Decree of Permanent Injunction (decree) entered on January 26, 2012, in the above-referenced case provides, in relevant part:

> If FDA inspects any facilities owned and/or operated by [Ranbaxy], other than the Covered Facilities, and finds a violation of the [Federal Food, Drug, and Cosmetic] Act and/or FDA's regulations . . . 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.

FDA investigators inspected Ranbaxy's facility located at SEZ Unit 1, Plot No. A-41, Industrial Area Phase VIII, SAS Nagar, Mohali, Punjab, India (hereafter, Mohali facility) in September and December 2012. During both inspections, FDA investigators observed and documented significant violations of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and FDA's regulations, including significant violations of the current good manufacturing practice (CGMP) requirements for drugs. These observations were documented on Form FDA-483s issued to Naresh K. Gaur, Plant Head, at the close of these inspections.

The following observations, among others, were documented by FDA investigators during the September 2012 inspection:

1) Failure to conduct adequate investigations (21 C.F.R. § 211.192)
2) Lack of production control procedures to limit batch variation (21 C.F.R. § 211.110)
3) Lack of written control procedures (21 C.F.R. § 211.80)

The following observations were documented by FDA investigators during the December 2012 inspection:

1) Failure to conduct adequate investigations (21 C.F.R. § 211.192)
2) Incomplete laboratory records (21 C.F.R. § 211.194)
3) Lack of production control procedures to limit batch variation (21 C.F.R. § 211.110)

These violations cause Ranbaxy's drug products manufactured at the Mohali facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Act [21 U.S.C. § 351(a)(2)(B)] in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP.

Because FDA found violations of the Act and its regulations during inspections of the Mohali facility, FDA hereby orders, pursuant to Paragraph XXIX of the decree, that the Mohali facility be fully subject to the provisions of the decree as though it were listed as a Covered Facility in paragraph VII.E when the decree was entered. The Mohali facility shall comply with the CGMP injunction provisions in paragraph XVI.A of the decree that apply to the Paonta Sahib and Dewas facilities. Specifically, the Defendants named in the decree are enjoined from manufacturing at the Mohali facility drugs that are the subject of an Application and introducing into interstate commerce any drugs manufactured at the Mohali facility, unless and until Defendants have satisfied all of the requirements in paragraph XVI.A of the decree and have received notification of CGMP compliance from FDA under paragraph XVI.A.6 for the Mohali facility. In addition to the decree provisions already generally applicable to all Ranbaxy facilities or specifically applicable to the Mohali facility, the following paragraphs of the decree apply to the Mohali facility which is now a "Covered Facility" under the decree: VIII (quality assurance and quality control management); XXI (additional injunction provision); XXIII (CGMP audit provisions); XXVIII (corrective actions); XXXII (inspections); XXXIII (cost reimbursement); XXXIV (posting of decree); XXXV (providing copies of the decree to Associated Persons); XXXVI (providing copies of decree to additional Associated Persons); and XXXVIII (liquidated damages).

In FDA's judgment, the violations observed at the Mohali facility raise significant public health concerns because those violations relate to the operation of the facility's quality system, which plays a critical role in ensuring the quality of drug products manufactured at the facility. Thus, pursuant to paragraph XXX.D of the decree, Defendants shall,

upon receipt of this order, immediately and fully comply with its terms.

Steven Lynn
Office Director
Office of Manufacturing and Product Quality
Office of Compliance
Center for Drug Evaluation and Research

cc: Mr. Dale Adkisson
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