DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993-0002

January 23, 2014

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

Re: Order Under Paragraphs XXVIII and 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 XXVIII of the Consent Decree of Permanent Injunction entered on January 26, 2012, in the above-referenced case (decree) provides, in relevant part:

> If, at any time after entry of this Decree, FDA determines, based on the results of an inspection . . . 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 . . .

Paragraph XXIX of the decree provides, in relevant part:

> If FDA inspects any facilities owned and/or operated by Corporate Defendants . . . other than the Covered Facilities, and finds a violation of the 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 Village Toansa, P.O. Rail Majra, District SBS Nagar, Punjab, India (Toansa facility) from January 5-11, 2014. During this inspection, FDA investigators observed and documented significant violations of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, including significant current good

manufacturing practice (CGMP) deficiencies. These observations were documented on a Form FDA-483 issued to Dale Adkisson, Head – Global Quality, at the close of this inspection.

The following observations, among others, were documented by FDA investigators during the January 2014 inspection:

1) Raw materials, intermediates, and finished API analytical results found to be failing specifications or otherwise suspect are retested until acceptable results are obtained. These failing or otherwise suspect results are not reported
2) Appropriate controls are not established over computerized systems
3) Records are not completed contemporaneously

These violations cause drugs manufactured by Ranbaxy at the Toansa 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 during the recent inspection of the Toansa facility, FDA hereby orders, pursuant to Paragraph XXIX of the decree, that the Toansa 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 Toansa facility shall comply with the CGMP injunction provisions in paragraph XVI.A of the decree that apply to the Paonta Sahib and Dewas facilities.[1] Specifically, the Defendants named in the decree are enjoined from manufacturing at the Toansa facility drugs that are the subject of an Application and introducing into interstate commerce any drugs manufactured at the Toansa 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 Toansa facility.[2] In addition to the decree provisions already generally applicable to all Ranbaxy facilities or specifically applicable to the Toansa facility, the following paragraphs of the decree apply to the Toansa 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); XXIV (post FDA notice data audit provisions); XXXII (inspections); XXXIII (cost reimbursement); XXXIV (posting of decree); XXXV (providing copies of the decree to Associated Persons); XXXVI (providing copies of the decree to additional Associated Persons); and XXXVIII (liquidated damages).

In addition, because FDA has determined that Ranbaxy has failed to comply with the law and the decree and additional corrective actions are necessary to achieve compliance with the law and the decree, FDA hereby orders the Defendants named in the decree to immediately:

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[1] Pursuant to our letter to you dated September 12, 2013, these provisions also now apply to the Mohali facility.
[2] Pursuant to paragraph VII.B of the decree, the term "drugs" includes active pharmaceutical ingredients (API) manufactured at Toansa and finished drug products containing API manufactured at Toansa, regardless of where those finished drug products were manufactured.

1) Halt all shipments and stop distribution within the United States of drug products (including drug products manufactured at Ohm Laboratories) containing API that was manufactured at Toansa;
2) Suspend all shipments to the United States of all API manufactured at Toansa and all drug products containing API manufactured at Toansa. Any shipments of such products that already have left India for the United States must be returned to their country of origin or destroyed;
3) Suspend all shipments of API manufactured at Toansa to any third party that Defendants know or have reason to believe will use such API to manufacture drugs for the United States market;
4) Suspend all shipments of API manufactured at Toansa that will be used to manufacture drugs that are the subject of an Application as defined in paragraph VII.D of the decree; and
5) Identify for FDA all third-party manufacturers, whether in the United States or elsewhere, to which Toansa-manufactured API was provided.

In FDA's judgment, the violations at the Toansa 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. If FDA determines that a medically necessary drug is in shortage or at risk of shortage, FDA may modify this order to preserve patient access to drugs manufactured under controls that are sufficient to assure their safety and efficacy.

Also, we remind you that Paragraph XXV of the decree provides, in relevant part:

> 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.

FDA may take additional action under the decree as we continue to review the information and data related to the January 2014 inspection.

Steven J. Lynn, MS, CMQ/OE
Office Director
Office of Manufacturing and Product Quality
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Center for Drug Evaluation and Research

cc: Mr. Dale Adkisson
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