U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

March 13, 2017

Stephen J. Manzano
Group Vice President, General Counsel, Secretary & Corporate Compliance
Sun Pharmaceutical Industries, Ltd.
Tara Pharmaceutical Industries, Ltd.
3 Skyline Drive
Hawthorne, New York 10532

PJ Deepak
Corporate Quality Project Management & CD Office Commitments
Sun Pharmaceuticals Industries, Ltd.
Plot No. 90, Sector 32
Institutional Area
Gurgaon 122001 India

Re: Decision Under Paragraph XVI.A.6 of the Consent Decree of Permanent Injunction entered in *United States v. Ranbaxy Laboratories, Ltd., et al.*, Civ. No JMF-12-250 (D. Md.) (Jan. 26, 2012)

Dear Messrs. Manzano and Deepak:

On September 12, 2013, under paragraph XXIX of the Consent Decree of Permanent Injunction (decree) entered by the District Court of Maryland on January 26, 2012, in the above-referenced case, FDA issued an order requiring that Ranbaxy's facility in Mohali, Punjab, India 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. That order required the Mohali facility to comply with, among other things, the current good manufacturing practice (CGMP) injunction provisions in paragraph XVI.A of the decree. Subsequently, Ranbaxy notified FDA that it selected (b) (4) as its independent CGMP Expert for the Mohali site. Sun Pharmaceutical Industries, Ltd. (Sun) acquired Ranbaxy in 2015.

On August 16, 2016, FDA received (b) (4) certification and report of its inspections at the Mohali facility as required under paragraph XVI.A.3 of the decree. On August 24, 2016, pursuant to paragraph XVI.A.4 of the decree, Sun notified FDA that it had corrected all CGMP deviations brought to its attention by FDA, the CGMP expert, and other sources. Pursuant to decree paragraph XVI.A.5, FDA conducted an inspection of the Mohali facility on November 11-17, 2016.

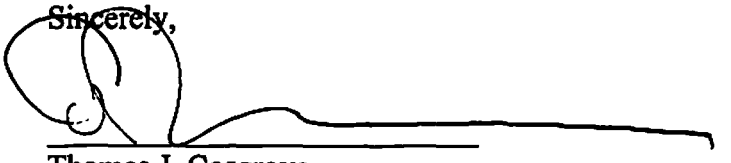
CDER has received and carefully reviewed the following submissions relating to FDA's November 11-17, 2016 inspection at the Mohali facility:

- Sun's 483 response dated December 8, 2016, and all attachments
- Sun's February 3, 2017 submission in response to FDA's request for additional information.
- Sun's February 10, 2017 submission in response to FDA's request for additional information.
- Sun's February 15, 2017 submission in response to FDA's request for additional information.

FDA hereby notifies you under paragraph XVI.A.6 of the decree that the Agency has determined that Sun's facility in Mohali, Punjab, India, appears to be in compliance with the requirements set forth in paragraphs XVI.A.1-4 of the decree. Accordingly, FDA will terminate any import alert associated with the Mohali facility and remove that facility from Official Action Indicated status. Upon such removal and subject to otherwise applicable requirements, including with respect to pre-approval facility inspections in the normal course, Defendants may resume introducing into interstate commerce FDA-approved drugs manufactured at the Mohali facility.

We remind you that the Mohali facility continues to be a "Covered Facility" as defined in decree paragraph VII.E, and therefore, the following paragraphs of the decree continue to apply to the Mohali facility: 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).

Sincerely,



Thomas J. Cosgrove
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

cc: (b) (4)