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# USFDA Issues

Date: July 28,2008

# Contents

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1. Allegations by USFDA
2. Ranbaxy's Response
3. Chronology of Events

# Allegations by USFDA

- USG is investigating Ranbaxy for possible violations of federal laws. USG feels that these violations have resulted and continue to result in the introduction of adulterated and misbranded products in US.
- The investigation involves baseless allegations of conspiracy, false statements and health care fraud.
- USFDA alleges a pattern of systemic fraudulent conduct on the part of Ranbaxy, including false submissions to FDA about stability & bio-equivalence etc.
- USG is further investigating whether Ranbaxy failed in maintenance and preservation of data wrt Quality Control in manufacture of API & formulations.
- USFDA alleges that Ranbaxy uses API from unapproved sources, blends unapproved API with approved API, and uses less API in its drug than had been approved by the FDA.

## Allegations by USFDA (Contd.....)

- USFDA alleges that Ranbaxy manufactures products at other plants and obtains API from unapproved sources to accommodate corporate convenience, resources and priorities.
- USFDA alleges that Ranbaxy has been selective in releasing information to the FDA and Ranbaxy has been waiving privileges on certain information while asserting privileges on rest of the information.
- Motion moved to seek records (including drafts & audits of Parexel audits) which Ranbaxy has been protecting from production by citing attorney-client and work-product privileges.

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# Ranbaxy's response

Date: July 28,2008

# Ranbaxy's Response

- Ranbaxy has reasons to believe that all the allegations made by DOJ in the Motion of July 3, 2008 are incorrect baseless, and as such, are inflicting serious harm to the reputation and credibility of Ranbaxy's global business, and have a negative effect on its business operations and performance.
- It is to be noted that in interviews with DOJ, many people, which include current and former employees, previous consultants, i.e. Lachman Consultants, have all denied any knowledge of fraud or manipulation of data for products being distributed or filed in the U.S. healthcare system.
- FDA had collected 200 product samples from various Ranbaxy facilities and informed that their testing found them all to be compliant with product specifications.
- The present case is a larger issue – that of providing millions of patients with greater access to affordable high quality generic medicines (alongside expensive innovator medicines), as a means to substantially contain the fast rising cost of healthcare, which is a serious problem worldwide

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# Chronology of Events

Date: July 28,2008

# Chronology of events (by year)

## 2006

- Feb. 25: Paonta Sahib DF Plant inspection - 483 issued (8 observations)
- March 2: Dewas DF Plant inspection – 483 issued (6 observations)
- March 17: Response provided for Dewas inspection
- March 20: Response provided for Paonta Sahib inspection
- April 20: 2nd response provided for Paonta Sahib
- May 25: 3rd response provided for Paonta Sahib
- May 11: Parexel Consulting, USA, engaged by Ranbaxy, led by Mr. Ronald F. Tetzlaff, PhD, a former FDA inspector with 23 years of experience
- June 15: Simvastatin (Tradenname: Zocor – MSD) approval status requested
- June 15: Warning Letter issued for Paonta Sahib Facility



# Chronology of events (by year)

## 2006 contd..

- June 23: Simvastatin approval received for Ranbaxy's ANDA from NJ dosage form facility
- July: Dewas DF Inspection cleared
- August 29: Warning Letter response provided
- Sept 27: 2nd set of FDA questions received, related to Warning Letter
- Oct 13: 2nd set of responses to Warning Letter provided to FDA
- Nov 29: Meeting with FDA to discuss Warning Letter undertaken including members of both Ranbaxy and Parexel with updates provided as to outstanding questions and responsive actions. Previously FDA had collected 200 product samples from various Ranbaxy facilities and in the meeting Ranbaxy was informed that that their testing found them all to be compliant with product specifications.

# Chronology of events (by year)

## 2007

- Jan: Inspection of Paonta Sahib DF and API Facility undertaken
- Feb 1: 483 issued (3 observations for API facility, none for DF facility)
- Feb 14: FDA and DOJ serve warrants at Ranbaxy facilities in Princeton and New Brunswick, NJ. Subsequently the legal services of London & Mead are retained, under the leadership of Mr. Christopher Mead.
- Feb 28: Response provided for 483 for Paonta Sahib API facilities
- March: Inspection cleared for Paonta Sahib API facility
- March: Mr. Mead conducted investigation as to the use of unapproved API source in Indian facilities. No anomalies found
- April: Mr. Mead informs US DOJ that the allegation was investigated by him and was found to be baseless
- June 18: Ranbaxy notifies FDA that stability data has been verified with random checks by Parexel USA

# Chronology of events (by year)

## 2007 contd..

- June 26: Meeting requesting 'hold' be lifted for Paonta Sahib DF facility
- July 27: Ranbaxy stability data provided to FDA through outside counsel: Buc and Beardsley
- Oct 7: Ranbaxy voluntary recalls (Class III – unlikely to cause any adverse health reaction) Gabapentin tablets from the marketplace
- Oct 9: FDA requests additional information on stability verification
- Oct 25: Additional information provided related to stability verification
- Oct 30: FDA inspects Ranbaxy's Princeton office site
- Dec 18: Approval for Clarithromycin XL ANDA requested
- Dec 19: Princeton site inspection completed, 483 issued (2 observations)
- Dec 28: FDA request for audit reports by Parexel which are still underway after denying Ranbaxy's request to remove the 'hold' on the Paonta Sahib facility

# Chronology of events (by year)

## 2008

- Jan 14: 483 response provided for inspection of Princeton office site
- Feb 12: Inspection at Dewas sterile injectable facility - 483 issued (23 observations)
- March 7: Inspection of Bata Mandi facility that is dedicated to the manufacture of Immunosuppressants – 483 (11 observations)
- March 7: CPP facility located at Gurgaon, India, inspected - 483 issued (3 observations)
- March 27: Response for CPP facility provided
- April 3: Response to Dewas inspections 483's provided
- April 10: Paraxel Audit reports requested by FDA provided
- May 1: 483 response for Batamandi facility provided
- May: FDA review not completed for Gabapentin recall or Bata Mandi facility

# Chronology of events (by year)

## 2008 contd..

- June: Ranbaxy announces being acquired by Daiichi-Sankyo (D-S) of Japan that will be consummated by early 2009. US DOJ issues (2) subpoenas for details disclosed during the due diligence process with D-S
- June (early): Meeting requested to lift 'hold' on Paonta Sahib
- June 11, 18, 30: Inquiry into status on Dewas inspection
- June 22: 2nd request for meeting to discuss the Paonta 'hold' and Dewas inspection results
- July 1: 3rd request for meeting
- July 1: Inquiry into status on Dewas
- July 3: US DOJ files motion to compel Ranbaxy to provide information related to the Parexel audits and includes in the Motion many unsubstantiated allegations
- July 22: US House of Representatives Committee on Energy & Commerce chaired by Congressman John Dingell writes to FDA for information on Ranbaxy.

# Request to GoI

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- Going forward, the resolution of issues and concerns remains a critical priority for Ranbaxy. Therefore, Ranbaxy would like USFDA/DOJ to move forward and enter into active discussions with RANBAXY to effectively resolve and bring to conclusion all outstanding issues. *We request Govt. of India to facilitate this.*

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Thank You