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Ranbaxy Overview

Situation Analysis

On September 16, 2008, the U.S. Food and Drug Administration (FDA) issued two Warning Letters related to Current Good Manufacturing Practice violations (CGMP) and an Import Alert that blocked thirty generic drugs manufactured at Ranbaxy Laboratories Limited's Paonta Sahib and Dewas facilities.

In conjunction with the release of the Warning Letters, on September 19, 2008, Rep. John Dingell, Chairman of the House Energy and Commerce Committee, sent a letter to Secretary of State Rice requesting an examination of Ranbaxy's HIV/AIDs drugs which Ranbaxy supplies to Africa through various aid programs. Both of these announcements generated considerable negative news coverage worldwide. Three additional drugs utilized by the President's Emergency Plan for AIDS Relief, or PEPFAR were then blocked. The World Health Organization (WHO) and other countries have also followed the FDA's lead.

Ranbaxy's methods and corrective actions to date have not been well received by the FDA. Cooperation issues related to a Department of Justice (DOJ) investigation has caused additional negative brand integrity focus.

The FDA has stated that all drugs manufactured by Ranbaxy have repeatedly tested safe and effective with no adverse incidents reported. Ranbaxy is committed to a swift resolution to address these issues and to continuing to supply the global marketplace with safe and effective pharmaceuticals.

Analysts predict that Ranbaxy will suffer an estimated revenue loss of approximately Rs 300 crore ($106MM) in 2008, or about 5% of its 2007sales as a result of the Import Alert. Ranbaxy's U.S. revenues account for about 24% of its total sales (Rs 6,690 crore in 2007); the FDA decision is impacting about ½ of U.S. sales.

It is estimated that Ranbaxy has lost millions of dollars and market share due to the Import Alert and will continue to loose millions until these issues are resolved.

Project Goals & Deliverables:

- Ranbaxy will become FDA compliant at the Panota Sahib, Batamandi (Unit II) and Dewas manufacturing facilities. Measures will be put into place which will allow products identified on the Import Alert to be released back into the U.S. marketplace.
- Ranbaxy will eliminate the FDA's perception that Ranbaxy's issues are systemic in nature.
- Ranbaxy will pass the FDA re-inspection of the facilities.
- The Import Alert issued in September, 2008 will be lifted.
- Ranbaxy's will be able to seek new pharmaceutical approvals currently on hold.
- Ranbaxy will proactively and positively reinforce its corporate image and reestablish confidence it its products with customers, employees, shareholders and regulatory agencies world-wide.

Next Steps

Giuliani Partners, initial review has determined that since February, 2006 the FDA perceives that Ranbaxy has had significant systemic CGMP compliance and FDA regulatory issues. Ranbaxy must fully commit to a shift in corporate culture as it relates to total quality control measures and CGMP compliance. The FDA has the most stringent laws and regulations for pharmaceutical imports. It is worth noting that, the FDA can inspect Ranbaxy's other worldwide manufacturing sites at any time.

Giuliani Partners recognizes that Ranbaxy has made efforts to resolve these issues via internal mechanisms, as well as, through the use of external agencies. Based on the outcomes to date and Ranbaxy's desire to regain its competitive advantage and reentry into the U.S. Market, Giuliani Partners recommends the following immediate actions take place:

- A Giuliani Partners led team with strong FDA regulatory industry and operations backgrounds will visit the Ranbaxy facilities in India. Our team's initial focus will be to conduct an analysis of current state operations. Assessing Ranbaxy's status as it relates to the CGMP deficiencies identified in the (2) warning letters, as well as, a review of global operations at the sites in question in anticipation of a requested FDA re-inspection. Once we analyze Ranbaxy's issues and have fully assessed the appropriate facilities, the next step is to prepare a detailed implementation plan to design new solutions and prioritize improvement opportunities.

- The FDA will not consider an organization to be compliant without:

    - Identification of the underlying cause
    - Resolve and correction of the underlying cause, systemically
    - Preventing recurrence of the problem

- Therefore, implementation of the following is critical:

    - A functional Corrective and Preventive Action program (CAPA)

- Functional Management Controls
- Ongoing critical improvement initiatives

- Ranbaxy, along with Giuliani Partners will create a long-term Quality and Regulatory Compliance Program. This will be a detailed implementation plan that will address and remedy all outstanding issues, prioritize actions, include technical aspects and staff training/education components. The FDA clearly stated in the (2) Warning Letters;

> ***"…If you wish to continue to ship your products to the United States, it is the responsibility of your firm to assure compliance with all U.S. standards for Current Good Manufacturing Practices. The CGMP deviations identified at your firm are not to be considered an all-inclusive list of the deficiencies at your facility..."***

- Only upon Ranbaxy passing mock inspections conducted via the Giuliani Partners team, should the FDA be invited back to the facilities. The FDA Warning Letters clearly state;

> ***"…To schedule a re-inspection of your facility, after corrections have been completed and your firm is in compliance with CGMP requirements..."***

- Ranbaxy's overall public relations strategies, as well as, statements to the media, must be focused and well-executed. One voice, one consistent message must be delivered. The FDA's Import Alert that has blocked 33 of Ranbaxy's products, the issuance of (2) recent Warning Letters, additional potential legal issues as it relates to the DOJ investigation, along with the continued involvement of Rep. John Dingell are all serious concerns and need to be handled both delicately and appropriately.

High-Level Action Steps

1) Notify the FDA that Ranbaxy has a fundamental understanding of the issues and is committed to rectifying and becoming fully compliant and transparent to the agency. Inform the FDA that Ranbaxy has begun a reorganization process to address all issues, has hired external, objective third-party experts to assist with the reorganization and is in the process of creating short term interim controls. A longer term approach is also part of Ranbaxy's renewed vision and will be solution oriented, keeping "the patient" in mind throughout the process.

2) Ranbaxy will submit its Action Plan to the FDA and would like to continue a positive dialogue with the FDA by conducting monthly meetings or conference calls to keep the FDA apprised of Ranbaxy's Action Plan status. Ranbaxy will submit Monthly reports to compliment their ongoing efforts to regain a positive and open working relationship with the FDA.

High-Level Action Steps cont'd

3) An Initial "Current State" Assessment will be conducted and improvement opportunities prioritized globally within the Ranbaxy facilities. Warning Letter observations will be the basis/starting point and will expand to address ALL areas that will come under FDA evaluation.

4) Post Assessment, a detailed Implementation Plan will be delivered to the Ranbaxy Executive Team.

5) Implementation of "Best Practices". Train/Educate/Culture Shift/Alignment of Internal Employee and Management Teams for sustainability.

6) Test/Pilot and conduct Mock Inspections.

7) Evaluate and make adjustments as needed/required for full compliance.

8) Roll-out NEW and/or enhanced policies/procedures/systems and create "New History" for the FDA to review.

9) Create, update weekly and/or monthly Performance Measurement Tools for continued improvement opportunity evaluation, as well as, continued monitoring of goals.

10) Invite the FDA to return to the facilities and conduct re-inspections.

11) Ongoing monitoring

Team Actions-to-Date

DATE	ACTION	OWNER	COMMENTS
PRIOR TO	Ranbaxy addressing allegations/issues presented by the FDA/DOJ		
SEPTEMBER			
Sept, 2008	Ranbaxy retained the services of former New York City Mayor Rudy Giuliani and Giuliani Partners to assist in reviewing policies and procedures to ensure complete compliance with the FDA	GP, RB	
	GP orients to current team members	GP, BM, RB, WR, BB, V	
	GP begins document & data review	GP and requests	
	GP meets with B & M (Burson Marsteller) re: RB Press positioning	GP, BM	
	BM develops FAQ document, GP review and edit	BM, GP	
	GP begins FDA Business Partner Review	GP	
	GP develops Ranbaxy Project Plan	GP	
9/16/2008	(2) FDA warning letters issued	RB	
9/26/2008	GP& Team members conduct status review conf call	GP, BM, RB, WR, BB, V	
OCTOBER			
Oct, 2008	GP continues document & data review	GP	
	GP to schedule on-site tour/mtg of Princeton, NJ site and other US sites TBD	GP, RB	
	GP to schedule on-site visit to India	GP, RB	
	Conduct in-person strategy session	GP, BM	
	Establish weekly update meetings	GP,RB,BM,WR,BB,V	
10/1/2008	BM returns Final draft of FAQ doc to GP for review	BM	
10/7/2008	GP meets w/ potential FDA BP	GP	
10/8/2008	GP meets w/ potential FDA BP	GP	
10/8/2008	GP & Team members conduct status review conf call	GP, BM	
10/10/2008	GP and team members conduct BP review call	GP, RB, BB, WR	
	Ranbaxy strategy session	RB, GP, RR	
NOVEMBER			
Nov, 2008	Bring Daiichi Sankyo into crisis response strategy (Date TBD)	GP, RB, BM	
	Conduct survey of key customers for their attitudes toward Ranbaxy	GP, RB, BM	
	GP arrives in India - TBD	GP, RB	
DECEMBER	TBD		
JANUARY	TBD		