

Par to Make Cutbacks

Par Pharmaceutical Cos. is reducing the size of its workforce by about 190. Those cutbacks are part of the company's strategy to reap annualized savings of \$45 million to \$55 million.

RX Generic Drugs

Generic Razadyne

Barr Pharmaceuticals Inc. has been given approval for its generic version of Razadyne ER capsules. The brand version is marketed by Ortho-McNeil Janssen. Barr's clearance is for 8-, 16- and 24-mg strengths.

Ranbaxy Record Shows Commitment to Quality

Focus

By Robert Coopman

As this is being written, the front-line news story about Ranbaxy generic medication manufacturing procedures in India not meeting United States Food and Drug Administration standards has faded into the background — that is, as a news story, not the practical reality of medications no longer in U.S. distribution because their importation from manufacturing units in India has been suspended.

The news story itself was an interesting one. In typical fashion, the story's lead-in was one of quality not being assured because certain manufacturing standards were not being met. For the casual listener or reader taking generic medications, the story may have been alarming. If one stayed with the story to the end it was mentioned that



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routine testing of actual medications in distribution in the U.S. had shown no quality deviations. This time it was about Ranbaxy and India, not China and Chinese manufacturers, as had been in the news in previous months.

Impressions can and do become re-

ality. Probably good news to American consumers was that the FDA was on the ground in India performing quality assurance audits of a foreign manufacturer. Following previous stories in recent months stating an absence of such audits of Chinese manufacturers, the Ranbaxy story likely provided some redemptive value inuring to the Food and Drug Administration.

The Ranbaxy story was of special interest to this writer because of previous experience working with retail chain pharmacies in India. I have consulted with GNRC MediShops in Guwahati and Guardian LifeCare Pharmacies in Gurgaon, very near New Delhi. It was because of this work assisting in the development of these retail pharmacy chains that Dr. William Rifee, dean of the College of Pharmacy at the University of Florida, contacted me. Rifee and his staff at Florida had been asked to evaluate pharmacy education in India and to

consult with private investors on raising the general standards of pharmacy education in the country.

In mid-2007, along with Dr. Rifee and three of his University of Florida staff, we met for a half-day in New Delhi with senior executives of Ranbaxy, including the president and chief executive officer. To say that Ranbaxy enjoys a high profile in India and other parts of the world and that the executive staff is impressive is to understate their case. Along with a major presence in manufacturing, Ranbaxy has a large clinical division that owns and operates some of the most respected hospitals in India.

As is typical of wealthy Indian families, the Ranbaxy family has an interest in funding and developing private education facilities in the country. In fact, such private educational institutions are credited with providing some of the most respected education curricula in the country.

Not meeting U.S. Food and Drug Administration manufacturing standards is not only a province of foreign manufacturers. U.S.-based major pharmaceuticals have had similar experiences.

This is not to excuse whatever manufacturing shortcomings Ranbaxy may have had. But it is to suggest that Ranbaxy is a generics manufacturer with respectable quality standards and a mentality of raising the bar in the work they do in manufacturing, in education and in owning and operating clinical health care businesses.

It is also to suggest that fairness and accuracy of reporting may have been better served if the fact that no quality abnormalities of Ranbaxy medications tested in the U.S. were shown had been a more prominent part of the story.

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Greenstone Momentum Continues

PEAPACK, N.J. — First established in 1993 as a subsidiary of Upjohn Co., Greenstone LLC — formerly called Greenstone Ltd. — offers a continuous and growing line of high-quality generic pharmaceuticals.

In 2003 Greenstone became the generics subsidiary of Pfizer Inc., and today the company is considered one of the longest-running and most respected marketers of innovator authorized generics in the United States. Greenstone provides a vigorous product pipeline that highlights quality generic equivalents to some of the best-selling branded pharmaceuticals on the market.

In addition to its name change, Greenstone has embarked on an aggressive new corporate strategy. Specifically, Greenstone has become part of a separate and distinct profit center within Pfizer — Global Established Products.

For the second consecutive year the Healthcare Distribution Management Association (HDMA) awarded Greenstone a DIANA (Distribution Industry Awards for Notable Achievements in Healthcare) as the "best overall generic pharmaceutical products manufacturer with sales to health care distributors of more than \$100 million."

The announcement of the DIANA awards was made by the HDMA at its October 2007 Annual Leadership Forum awards banquet, which was held in Phoenix.

The DIANA, which has been awarded to health care and consumer products manufacturers since 1959, honors those companies that have developed creative and results-oriented programs that set the standard for excellence in new-product introductions and/or product promotions, as

'We're building an ... organization that will serve its customers and partners better'

well as having benefited health care distributors.

The award recognizes those manufacturers who serve as models for leadership and innovation in the health care marketplace.

Criteria used by the HDMA for judging pharmaceutical products companies include:

- Demonstrating flexibility and creativity in meeting the needs of health care distributors and their customers.
 - A product line and marketing plan that contribute to sales growth.
 - Salespeople empowered to provide business solutions.
 - Support of distributor promotional programs.
 - High product service levels.
 - A high level of customer service.
- This commitment to customers car-

ries over to all segments of the pharmaceutical industry.

Greenstone's customers have come to rely on the decades of experience represented by the Greenstone national accounts team, a dedicated support staff, a strong supply chain and distribution services to support a continuous supply of generic pharmaceutical products that benefit patients, physicians, pharmacies and partners.

Greenstone aspires to be the industry's most respected generics supplier while continuing to promote the value of authorized generics.

"Greenstone LLC is building a broader, more nimble and more aggressive organization that will serve its customers and partners better," says Bill Kennally, president of Greenstone.

Two Intros Help Harris Achieve Goal

FORT MYERS, Fla. — Harris Pharmaceutical is focused on doing one thing and doing it well: becoming a preferred provider of generic products with dermatological indications.

To that end, Harris has launched two new products: Metronidazole Topical Cream 0.75% and Hydroxyzine HCl Tablets in 10-, 25- and 50-mg strengths.

Citing figures from IMS Health, Harris says Metronidazole Topical Cream 0.75% had total sales of about \$12 million for the year ended August

2008. Sales of Hydroxyzine HCl Tablets exceeded \$70 million for the same period.

The addition of these two products has increased the total number of new products launched in 2008 to five, with a total of seven new products since late 2007. The line now comprises several first-time generics, including Terbinafine HCl Tablets and Clotripropol Nail Lacquer as well as Mometasone and Benzoyl Peroxide products.

Harris Pharmaceutical was founded in 2002 with a mission to provide

Heritage Rolls Out Propranolol Tablets

EDISON, N.J. — Heritage Pharmaceuticals Inc. has announced the availability of propranolol HCl oral tablets in 10-, 20-, 40-, 60- and 80-mg strengths. Heritage's development and manufacturing partner, Ipca Laboratories Ltd., received final approval of its abbreviated new drug application for an AB-rated equivalent of Inderal in June.

Propranolol tablets are the generic equivalent of Inderal tablets, formerly marketed by Wyeth. Propranolol has multiple cardiovascular-related indications, including the management of hypertension and treatment of angina.

Citing figures provided by IMS Health, Heritage says propranolol had United States brand and generic sales of about \$25 million for the 12-month period ending December 31, 2007.

"The launch of propranolol represents the first vertically integrated product from our strategic alliance with Ipca and will enable us to leverage the economies of scale of products made abroad while continuing to provide customers with high-quality, cost-efficient generic pharmaceutical products," says Heritage president and chief executive officer Jeffrey Glazer.



dermatologists and their patients with safe, effective and affordable generics that offer the same therapeutic benefits as branded products but at a fraction of the cost.

Harris' initial years were spent focusing on its primary strategy: to develop, manufacture and commercialize its own abbreviated new drug applications (ANDAs). Its first ANDA, Terbinafine HCl Tablets, was launched in July 2007, and in order to offer patients and customers a broad dermatological product portfolio,

Harris has been acquiring and licensing additional products in its niche.

Through these collaborations Harris has quickly increased its product line over the past 18 months to now represent a variety of dosage forms, including oral solids, topical creams, ointments, liquids, and washes, all targeted toward the dermatology market.

Besides the multiple new products already launched, Harris has further ANDAs pending Food and Drug Administration approval, with additional products in development.