Corporate Profile

a report by
Biocodex, Inc.

Biocodex is a family business that started in France more than 50 years ago. Its innovative drug for the treatment of diarrhea, Florastor®, has seen widespread acceptance in Europe and is now marketed in approximately 85 countries.

Florastor is a probiotic, thus a natural product. It is very safe, producing virtually no side effects. While the parent company has diversified and has developed other products in the field of neurology, psychiatry and pain treatment, the American subsidiary dedicates 100% of its efforts to Florastor and Florastor® Kids. Biocodex believes that Florastor fills an important niche in the rapidly growing market for many groups of people who suffer with gastrointestinal (GI) problems. Nicolas Coudurier, General Manager, US Subsidiary, says,

> *Our corporate philosophy is to find products that are as strong as possible in treating GI health disorders, but at the same time have the fewest possible side effects.*

History

Biocodex traces its roots to the early 1920s in Indo-China, where French microbiologist Henri Boulard made a fascinating discovery during an outbreak of cholera. To treat their diarrhea, the local people cooked the skins of the lychee fruit then drank the tea. Boulard was able to isolate the agent, which he named *Saccharomyces boulardii* (SB).

In 1947, Michel Hublot, a doctor of pharmacy, founded Biocodex along with François Vallet, a lawyer. Boulard sold them the rights to his strain of yeast and the fermentation process. Research then began on Biocodex's strain of *Saccharomyces boulardii lyo*. The drug they developed is Florastor (called Ultra-Levure in Europe).

In 1966, the company built a factory and research center near Beauvais, France, and in 1987 established a research center in Seattle, Washington, where they studied *Clostridium difficile*, antibiotic-associated diarrhea, and other intestinal health problems. Growing steadily, in 2000 they opened a new corporate office and distribution center in Creswell, Oregon. Currently, Biocodex is a US$80 million company with three subsidiaries, in France, Belgium, and the US of which Coudurier says,

> *Biocodex wanted to make sure Florastor was strong in Europe and elsewhere before moving into the very demanding American marketplace.*

The Number One Probiotic Worldwide

Over 50 years of international use has shown that Florastor is safe and effective for the treatment of diarrhea. Extensive clinical trials have been conducted in the US and Europe in patients of all ages.

Florastor is a natural probiotic, that is, a live micro-organism that produces therapeutic or preventive health benefits. By destroying pathogenic bacteria, it decreases abdominal discomfort, reduces the number of stools and improves the consistency of stools, enabling patients to better manage their bowel movements.

Florastor also protects the intestinal wall, and maintains intestinal function. "In the US, probiotics are considered dietary supplements," Coudurier points out, "But in Europe, Florastor is not a dietary supplement—it is a drug."

Florastor is made of live freeze-dried yeast cells of the species *S. boulardii*. Each capsule contains 250mg of *S. boulardii*. Florastor has a three-year shelf life and does not need to be refrigerated. It is non-pathogenic yeast and not bacterium, brewers or bakers yeast, thus it is resistant to antibiotics as well as to low pH and bile salts. Florastor is resistant to all antibiotics but not to antifungals or antimycotics. It can be taken with standard antibiotics without any loss of effect.

Taking Florastor

Florastor capsules are available in bottles of 10 or 50. The capsules dissolve and release the yeast cells within 30 minutes of ingestion. Florastor Kids is available as

10 sachets (or packets) in a box. Florastor clears the body within five to seven days.

Florastor should not be taken if a person has a yeast allergy or is currently taking any antifungal products. Individuals with a lactose intolerance can take Florastor. The agent does not contain any milk protein, but it does contain a very small amount of lactose monohydrate.

Florastor has an excellent side effect profile. Gas, constipation and thirst have been reported infrequently. Individuals with a central venous catheter should consult their physician before taking Florastor, as fungemia has been observed in very rare cases.

Effect on the GI Tract

Pre-clinical and experimental studies of Florastor confirm its anti-inflammatory, antimicrobial, enzymatic, metabolic, and antitoxinic activity. Florastor secretes a 54KD2 protease which has been shown to neutralize certain bacterial toxins. It has been shown to stimulate an immune response in the intestinal mucosa and it increases a trophic effect by enhancing the metabolic structure of the mucosa. Florastor releases polyamines, which are implicated in stimulating the enzymatic activity of the colonic mucosa.

Distribution

Florastor is marketed through key wholesalers throughout the US. Pharmacists can find the product numbers on the Florastor website. Currently, the company has 25 sales consultants. Florastor brands are currently not available via the Internet.

The Future

Biocodex anticipates major growth with the introduction of Florastor Kids to support the current growth of Florastor in the American marketplace. Florastor Kids is in powder form and has a fruit flavor. Children respond better to products with a pleasing aroma and taste, so compliance is expected to be excellent. As Coudurier says,

> *Our philosophy is to develop products that are as strong as possible in treating health disorders, but with the fewest possible side effects.* ■