

## Supplemental NDA for Exenatide Submitted

Amylin Pharmaceuticals (San Diego) and Eli Lilly and Company (Indianapolis, Ind) have submitted a supplemental New Drug Application (NDA) to the Food and Drug Administration (FDA) to seek approval for expanded use of exenatide injection (Byetta) as add-on therapy to thiazolidinediones (TZD) in people with type 2 diabetes who are not achieving acceptable blood sugar control.

Byetta was approved by the FDA in April 2005 for the treatment of type 2 diabetes as add-on therapy in patients who are not achieving acceptable blood sugar

control despite using the commonly prescribed diabetes medications metformin, sulfonylurea or a combination.

Byetta is the first in a new class of drugs for the treatment of type 2 diabetes called incretin mimetics (which works to mimic the antidiabetic or glucose-lowering actions of incretins) and exhibits many of the same effects as the human incretin hormone glucagon-like peptide-1 (GLP-1). GLP-1, secreted in response to food intake, has multiple effects on the intestine, liver, pancreas and brain that work in concert to regulate blood sugar.

For more information, visit [www.byetta.com](http://www.byetta.com).

## GlucoBurst Diabetic Drink With Beta-Carotene and DHA

PBM Products LLC (Gordonsville, Va) has introduced GlucoBurst Diabetic Drink to help people better manage diabetes. Enriched with beta-carotene and DHA, GlucoBurst Diabetic Drink helps maintain blood glucose levels and provides nutrients beneficial for visual and circulatory health. A portion of the proceeds will be donated to diabetes research.



In consideration of a recent American Diabetes Association (ADA) recommendation, GlucoBurst Diabetic Drink does not contain fructose. The drink has a high fiber content and may improve cholesterol levels and/or reaction to carbohydrates, according to a news release.

type 2 diabetes whose treatment includes a combination of rosiglitazone and sulfonylurea; those who are not adequately controlled on a sulfonylurea alone; or for those patients who have initially responded to rosiglitazone alone and require additional blood sugar control.

Avandaryl is available in three tablet strengths of rosiglitazone/glimepiride, respectively: 4 mg/1 mg, 4 mg/2 mg and 4 mg/4 mg. It may cause low blood sugar; patients with kidney problems may need a lower dose to reduce this side effect. Some patients may experience tiredness, weight gain or swelling (which could lead to or worsen heart failure). Avandaryl is not approved for use with insulin and is not recommended for patients with NYHA Class 3 and 4 cardiac status or active liver disease.

For more information, visit [www.avandia.com](http://www.avandia.com) or call 888-825-5249.

## Fixed-Dose Combination Tablet Treats Type 2 Diabetes

Avandaryl (rosiglitazone maleate and glimepiride; GlaxoSmithKline, Philadelphia), is now available as a fixed-dose combination product for type 2 diabetes. Recently approved by the FDA, Avandaryl is the first tablet to combine a TZD (rosiglitazone maleate; separately marketed as Avandia) with a sulfonylurea (glimepiride; separately marketed as Amaryl) to help improve blood sugar control.

As an adjunct to diet and exercise, Avandaryl is indicated to improve blood sugar control in patients with

## FDA Accepts First-in-Class NDA for Januvia

Sitagliptin phosphate (Januvia; Merck, Whitehouse Station, NJ) is an investigational one-daily medicine with a novel mechanism of action for the treatment of type 2 diabetes. According to Merck, if approved the drug would potentially be the first in a new class of oral medications (DPP-IV inhibitors) that enhances the body's ability to lower blood sugar when it is elevated.

The NDA has been accepted for review by the FDA and action should be taken by mid-October.

According to a news release, Merck took the lead over Switzerland-based Novartis in the race to get the new class of diabetes treatments to market. Novartis is developing a DPP-IV drug called Galvus. Both companies are expected to present data at the ADA meeting in June. ■