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U.S. Food and Drug Administration
5630 Fishers Lane
Rockville, MD

In light of your review of diabetes prevention and treatment this week, we are writing this letter in support of approval for pramlintide.

Our office serves as a site for Amylin's 155 trial involving pramlintide treatment of type 1 and type 2 diabetes mellitus. We currently have 7 patients actively on drug. Overall, we have seen a decrease in insulin requirement, improved diabetes control, reduction or stabilization of weight (despite improved control), and increased feelings of well being in patients who are taking pramlintide with insulin to manage their blood glucose. Severe hypoglycemia due to pramlintide has not been an issue in our patients. The incidence of hypoglycemia in our patients has not increased over pre-pramlintide events.

As you are well aware, in the Diabetes Control and Complications Trial (DCCT), improved diabetes control with insulin was accompanied by significant weight gain and an increase in hypoglycemia over baseline. Following the instructions set out by Amylin in the 155 protocol, we decreased insulin dosage in our patients anywhere from 30-50% at initiation of pramlintide (depending upon type of insulin and pre-pramlintide glycemic control), titrated both the insulin and pramlintide appropriately, and have not seen this effect.

We do realize that our patient population is small, but each one of the patients is doing well on treatment. Patients with diabetes mellitus ought to have all missing hormones replaced in order to better manage glucose. For this reason, pramlintide has an important place in the treatment of diabetes mellitus.

Sincerely,

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