FDA Approves Updates to Lilly's HumalogÃ,® (insulin lispro injection rDNA origin) Label

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INDIANAPOLIS, June 8, 2011 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY [1]) today announced that the U.S. Food and Drug Administration (FDA) approved the company's supplemental new drug application (sNDA) with the following updates to the Humalog label:

- continuous insulin infusion pump therapy in children 4 years of age and over with type 1 diabetes
- extension of the time-in-use in the external pump reservoir to a maximum of seven days; and
- extension of the time-in-use of the infusion set and of the infusion set subcutaneous insertion site to a maximum of three days.

Based on the updated label, people with type 1 diabetes using Humalog for pump therapy can use the insulin in the pump reservoir for up to seven days and should change the infusion set and infusion set insertion site at least every three days. The previous label indicated that Humalog in the external insulin pump reservoir should be replaced and a new infusion site selected every 48 hours or less.

Humalog, which contains 100 units per mL, is used to treat people with diabetes for the control of high blood sugar. Humalog should not be taken by someone with low blood sugar (hypoglycemia) or by someone who is allergic to insulin lispro or any of the ingredients in Humalog. Humalog is recommended for use in pump systems indicated for continuous delivery of fast-acting insulin. All people treated with insulin should closely monitor their blood glucose and make changes to their insulin regimen cautiously and only under medical supervision. See Important Safety Information below, and additional information about Humalog is available at www.humalog.com [2].

Insulin pumps deliver insulin 24 hours a day through a catheter placed under the skin. Rapid-acting insulin is delivered continuously to help keep blood
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SOURCE [3]

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http://www.mdtmag.com/news/2011/06/fda-approves-updates-lillys-humalog%C3%A3%E2%80%9A%C2%AE-insulin-lispro-injection-rdna-origin-label

Links:
[1] http://studio-5.financialcontent.com/prnews?Page=Quote&Ticker=LLY
[2] http://www.humalog.com
[3] http://www.bio-medicine.org/medicine-technology-1/FDA-Approves-Updates-to-Lillys-Humalog-AE--28insulin-lispro-injection--5BrDNA-origin-5D-29-Label-17956-1/