The US Food and Drug Administration (FDA) has approved labeling changes to the entire **statin class**. These clarifications include but are not limited to:

- Use may be associated with hyperglycemia and elevated A1c;
- Use may be associated with the potential for cognitive adverse effects;
- Periodic monitoring of liver function tests is no longer required.

Lovastatin labeling was revised to include contraindications and dose limitations for certain drug interactions which can increase drug exposure and subsequent risk for rhabdomyolysis.

Lovastatin is contraindicated with strong cytochrome (CYP) 3A4 inhibitors, such as clarithromycin and ketoconazole. Daily doses should not exceed 20 mg with diltiazem, verapamil, and danazol. Daily doses should not exceed 40 mg with amiodarone.

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For more information, see FDA Adds Warnings to Statin Label.

Mifepristone (Korlym™, Corcept Therapeutics Incorporated, Menlo Park, California) was approved to manage hyperglycemia in patients with endogenous Cushing's syndrome and type 2 diabetes mellitus or glucose intolerance who are not candidates for surgery or in whom surgical treatment has failed. This cortisol receptor blocker has potent antiprogestational properties and should **never be used in pregnant women due to risk for pregnancy termination**. Pregnancy must be excluded in women of reproductive age prior to initiation of therapy or if treatment is interrupted for more than 14 days. The manufacturer will distribute Korlym through a central pharmacy; retail pharmacies are unlikely to supply this drug adequately due to the rare nature of the condition.

For more information, see Mifepristone Okayed for Adults With Cushing's Syndrome.

The FDA has approved a once-weekly, extended-release formulation of exenatide injection (**Bydureon**™, Amylin Pharmaceuticals, Inc., San Diego, California). This glucagon-like peptide-1 receptor agonist is indicated as an adjunct to diet and exercise in adult patients with type 2 diabetes mellitus (DM) and is administered subcutaneously once every 7 days. Bydureon is not recommended as first-line therapy and should not be used to treat type 1 DM or diabetic ketoacidosis. Use with insulin and in patients with a history of pancreatitis is not recommended. A Risk Evaluation and Mitigation Strategy (REMS) is required with Bydureon to help ensure that the benefits outweigh the risks for medullary thyroid carcinoma and acute pancreatitis. Insulin de

For more information, see Once-Weekly Exenatide Okayed by FDA for T2DM After Long Look.

The FDA changed the pregnancy category for **insulin detemir** (rDNA origin) injection (Levemir®, NovoNordisk A/S, Bagsvaerd, Denmark) from C to B. No increased fetal risk was found in a randomized controlled trial of pregnant women with type 1 diabetes mellitus who were taking Levemir during pregnancy.

For more information, see Levemir Assigned More Reassuring Pregnancy Risk Category.

The FDA approved a combination of the dipeptidyl peptidase-4 (DPP-4) inhibitor **linagliptin and biguanide** metformin hydrochloride (Jentadueto™, Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut; and Eli Lilly and Company, Indianapolis, Indiana) as an adjunct to diet and exercise in adult patients with type 2 DM. Jentadueto should be given twice daily with meals, using slow dose escalation to decrease the adverse gastrointestinal effects associated with metformin. Jentadueto should not be used for type 1 DM or diabetic ketoacidosis, and use has not been evaluated in combination with insulin. Labeling contains a black box warning about the risk for lactic acidosis associated with metformin accumulation. For more information, see Combination Type 2 Diabetes Pill Gets FDA Nod.

Once-daily **Janumet® XR** (Merck & Co., Inc, Whitehouse Station, New Jersey) was approved by the FDA for adjunct management of type 2 DM in combination with diet and exercise in adults. Janumet XR is the combination of the DPP-4 inhibitor sitagliptin and extended-release metformin. Janumet XR is not indicated for type 1 DM or diabetic ketoacidosis and has not been evaluated in patients with a history of pancreatitis. To decrease the adverse gastrointestinal effects of metformin, administration with the evening meal is preferred, and dosing should be gradually escalated. Labeling contains a black box warning regarding the risk for lactic acidosis associated with metformin accumulation. Decrease of insulin or insulin secretagogue (eg, sulfonylurea) dose requirements may be needed with concomitant use of Janumet XR to minimize risk for hypoglycemia.

For more information, see FDA Approves Once-A-Day Drug for Type 2 Diabetes.