Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

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DATE: November 2, 2009

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

ASG

SUBJECT: **FDA Advisory** Amylin Pharmaceuticals Inc

SUGGESTED ACTION: **FDA Advisory; Byetta Label Revised to Include Safety Information on Possible Kidney Problems; In case of consumer inquiry**

The U.S. Food and Drug Administration today acted on new safety information about possible kidney function problems, including kidney failure, in patients taking Byetta (exenatide), a drug used to treat Type 2 diabetes.

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FDA NEWS RELEASE

For Immediate Release: Nov. 2, 2009
Media Inquiries: Sandy Walsh, 301-796-4669, sandy.walsh@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA: Byetta Label Revised to Include Safety Information on Possible Kidney Problems

The U.S. Food and Drug Administration today acted on new safety information about possible kidney function problems, including kidney failure, in patients taking Byetta (exenatide), a drug used to treat Type 2 diabetes.

From April 2005 through October 2008, the FDA received 78 reports of problems with kidney function in patients using Byetta. Some cases occurred in patients with pre-existing kidney disease or in patients with one or more risk factors for developing kidney problems.

Nearly 7 million prescriptions for Byetta were dispensed between April 2005 and September 2008. The 78 cases represent a small percentage of the total number of patients using the drug to control blood sugar (glucose) levels.

The most common side effects associated with Byetta include nausea, vomiting, and diarrhea. These side effects may have contributed to the development of altered kidney function. Kidney malfunction can result in a build-up of waste products in the blood, leading to serious illness or life-threatening conditions.

"Health care professionals and patients taking Byetta should pay close attention to any signs or symptoms of kidney problems," said Amy Egan, M.D. M.P.H., of the Division of Metabolism and Endocrinology Products at the FDA's Center for Drug Evaluation and Research. "Patients also should be aware that problems with kidney function could lead to changes in urine color, frequency of urination or the amount of urine, unexplained swelling of the hands or feet, fatigue, changes in appetite or digestion, or dull ache in mid to lower back."

Patients who experience any of these symptoms should immediately discuss them with their health care professional.

To help health care professionals and patients better weigh the known risks and benefits of Byetta, the FDA worked with the manufacturer to update the drug's prescribing information (label). A description of these label changes can be found online at: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm188656.htm

Byetta is manufactured by San Diego-based Amylin Pharmaceuticals Inc.