International Laboratories – Recall of pravastatin

- On August 10, 2017, the FDA announced the voluntary consumer-level recall of one lot of International Laboratories' pravastatin sodium tablets due to mislabeling.

- The affected product below is labeled as pravastatin sodium 40 mg tablets but contained bupropion hydrochloride extended-release (XL) 300 mg tablets.

Product Description	NDC #	Lot #
Pravastatin sodium 40 mg in bottles of 30 tablets	54458-925-16	115698A

- Pravastatin is indicated as an adjunctive therapy to diet when the response to a diet restricted in saturated fat and cholesterol and other non-pharmacologic measures alone has been inadequate. It is used to treat children and adolescent patients ≥ 8 years of age with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy.

- If a patient mistakenly takes bupropion, common side effects include: nausea, vomiting, dry mouth, headache, constipation, sweating, sore throat, diarrhea, dizziness, restlessness, and blurry vision. These are typically minor and reversible issues. However, individuals with epilepsy are at higher risk of seizure on bupropion due to it lowering the seizure threshold. Also, people on monoamine oxidase inhibitors can experience a hypertensive crisis, a risky drug interaction with bupropion. Finally, allergic reactions are also possible and could be life threatening.

    — Bupropion hydrochloride XL 300 mg tablets are an aminoketone antidepressant, indicated for the treatment of major depressive disorder and prevention of seasonal affective disorder in children, adolescents, young adults and adults.

- Anyone with an existing inventory of the recalled lots should stop use and distribution, and return all recalled product.

- Consumers who have purchased this product should not open the package or use the contents. They should return the product to the location of purchase for a full refund, or contact International Laboratories at **1-727-322-7146**.

- Consumers who have experienced problems that may be related to taking or using this drug product should contact their physician or healthcare provider.