International Laboratories – Recall of clopidogrel

- On January 10, 2018, the FDA announced a consumer level recall of one lot of International Laboratories' clopidogrel tablets due to mislabeling. The recalled product is labeled as clopidogrel 75 mg tablets but may contain clopidogrel 75 mg or simvastatin 10 mg tablets.

- The recalled product was distributed nationwide.

Product Description	NDC #	Lot #
Clopidogrel 75 mg tablets, 30-count bottle	54458-888-16	117099A

- Clopidogrel is indicated to reduce the risk of myocardial infarction (MI) and stroke in patients with acute coronary syndrome and in patients with recent MI, stroke or established peripheral artery disease.

- Simvastatin is indicated to reduce the risk of coronary heart disease mortality and cardiovascular events, treat hyperlipidemia, and treat adolescent patients with heterozygous familial hypercholesterolemia.

- Missed doses of clopidogrel increases the risk of heart attack and stroke which can be life threatening. Patients should not stop taking clopidogrel without talking to their prescribing physician.

- Unintentional consumption of simvastatin could include the common side effects associated with its use and may cause fetal harm when administered to a pregnant woman. Simvastatin occasionally causes myopathy. Allergic reactions are also possible and could also be life threatening.

- To date, International Laboratories reports that no complaints have been received related to this event detailing medical illnesses or harmful effects.

- Consumers should contact their healthcare provider if they are experiencing any concern that may be related to taking or using the recalled clopidogrel tablets.

- International Laboratories is notifying distributors and customers by letter and is arranging for return of all recalled products. Consumers who have purchased this product should stop using it and return the product to the location of purchase for a full refund.

- Contact Inmar at **1-855-258-7280** for return information. For general questions regarding this recall, contact International Laboratories at **1-727-322-7146**.