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ASIA EDITION

FDA warns of potential contamination in multiple brands of drugs, dietary supplements

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Recalled products from Rugby Laboratories, Major Pharmaceuticals, Leader Brands all manufactured by PharmaTech

Singapore - The U.S. Food and Drug Administration is advising consumers and health care professionals not to use any liquid drug or dietary supplement products manufactured by PharmaTech LLC of Davie, Florida, and labeled by Rugby Laboratories, Major Pharmaceuticals and Leader Brands, due to potential contamination with the bacteria*Burkholderia cepacia (B. cepacia)* and the risk for severe patient infection.

The drug and dietary supplement products made by PharmaTech include liquid docusate sodium drugs (stool softeners), as well as various dietary supplements including liquid vitamin D drops and liquid multivitamins marketed for infants and children.

"*B. cepacia* poses a serious threat to vulnerable patients, including infants and young children who still have developing immune systems," said FDA Commissioner Scott Gottlieb, M.D. "These products were distributed nationwide to retailers, health care facilities, pharmacies and sold online – making it important that parents, patients and health care providers be made aware of the potential risk and immediately stop using these products."

According to the Centers for Disease Control and Prevention (CDC), *B. cepacia* poses the greatest threat to hospitalized patients, critically ill patients and people with health problems such as weakened immune systems and chronic lung diseases. The symptoms of *B. cepacia* infections vary widely from none to serious respiratory infections. It can spread from person-to-person by direct contact and is often resistant to common antibiotics.

Consumers, pharmacies and health care facilities should immediately stop using and dispensing all liquid drug and dietary supplement products manufactured by PharmaTech and labeled by Rugby Laboratories, Major Pharmaceuticals and Leader Brands.