The Promise of Science
Serialized

Drug Name Here

Galaxy™
Single Dose
Container   100 mL
Iso-osmotic   NDC 000-0000-00
XXXXX
Sterile nonpyrogenic

Each 100 mL contains: Experimental not for human use. Experimental not for human use. Experimental not for human use.

Dosage: Experimental not for human use.

Cautions: Experimental not for human use. Experimental not for human use. Experimental not for human use. Federal (USA) law prohibits dispensing without prescription.

Do not store above -20°C. Experimental not for human use. Experimental not for human use. Experimental not for human use. Experimental not for human use. Experimental not for human use. Do not release.

Baxter Healthcare Corporation
Deerfield, IL 60015 USA
Made in USA
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Definitions:

Serialization: Process of assigning a unique identification number to the lowest saleable unit or immediate container.

Pedigree: Electronic record containing information regarding each transaction resulting in a change of ownership of a drug.

Commitment

Baxter views serialization as a critical element of our supply chain security program, and is taking a proactive approach across our global manufacturing and distribution network.

We follow GS1 standards for healthcare to fulfill global serialization and DSCSA (US) requirements. We believe that industry-wide adoption of these standards will:

- – Improve patient safety through integrity of supply
- – Support initiatives to drive increased efficiency
- – Satisfy regulatory and governing agency requirements
- – Provide an effective method for sharing product tracking and pedigree data

As our customer, you can be confident that BioPharma Solutions is implementing the proper systems and processes to adhere to global requirements in a timely manner.

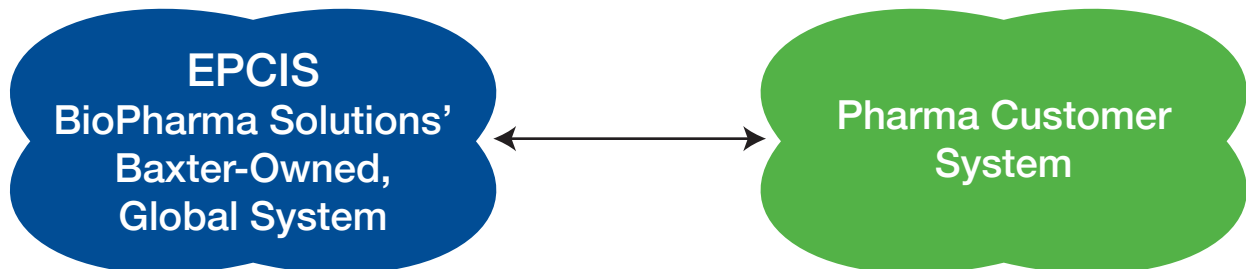We are equally committed to the safety of our patients and yours.

Background: Serialization Requirements

In 2008, California passed legislation (SB1307: Ridley-Thomas, Chapter 713) that requires pharmaceutical companies to implement Pedigree systems. Pedigree is an electronic system that tracks the origin and supply history of a drug. The intent is to protect consumers from counterfeit drugs and contaminated medicine.

On November 27, 2013, the Drug Quality and Security Act (DQSA), was enacted by Congress. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines requirements for drug manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers (trading partners). Some requirements began in November 2014 and several key requirements began at various stages in 2015. The requirements, development of standards, and the system for product tracing under the DSCSA will continue to be phased in until 2023.

Since then, several other countries have issued their own serialization requirements. With the exception of China, all countries are following the GS1 standard. A number of countries have set different "go live" dates for these requirements, with some of them already online (e.g., Korea, Saudi Arabia) and others following soon (such as the EU in 2019).

Our Approach

EPCIS
**BioPharma Solutions'
Baxter-Owned,
Global System**

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**Pharma Customer
System**

Plant

Line

Product

- Baxter systems follow GS1 and EPCIS standards to manage serialization and communicate Pedigree data.

- Our EPCIS system will be able to communicate with your system to help ensure the proper information exchange.