California SB-486 Plan Revision Date: June 2021 for 2022 Requirements

Plan for Supporting Safe Collection and Proper Disposal of

Home Generated Sharps July 2016 – CA California SB-486 Plan Revision

Date: June 2021

Background:

The State of California enacted two laws to address home generated sharps disposal. The first law (SB 1305), makes it illegal for any person in the state of California to dispose of home generated sharps waste in the trash or recycling containers, and requires that all sharps waste be transported to a collection center in an approved sharps container. This law became effective September 1, 2008. In 2009, California enacted (SB 486) which requires any pharmaceutical manufacturer that sells or distributes medication that is self-injected at home through the use of hypodermic needles and other similar devices to submit to the board, or its successor agency, a plan that describes how the manufacturer supports the safe collection and proper disposal of waste devices.

GlaxoSmithKline Pharmaceuticals (GSK) Self – Injectable Products Subject to these Regulations

- GSK currently markets, distributes, and/or sells self-injectable products including
- BENLYSTA SUBCUTANEOUS Pre-Filled syringe and Autoinjector,
- NUCALA SUBCUTANEOUS Pre-Filled syringe and Autoinjector,
- Imitrex STAT dose

GSK Supports Safe Collection and Proper Disposal of Home Generated Sharps GSK has demonstrated a commitment to the safe and proper use and disposal of its self-injectable medications.

The GSK Response Center provides instructions for consumers Instructions to Patients on the Safe Storage and Disposal of Home Generated Sharps.

Collection and Storage

- Place used needles, syringes, lancets and sharp devices in a container approved for storage of sharps.
- When your sharps disposal container is about three-quarters (3/4) full, follow your community
- guidelines for proper disposal methods. Do not throw sharps in the trash in the State of California.
- Keep sharps storage containers away from children and pets
- Do not place loose needles or other sharps in the household or public trash cans or recycling
- Do not flush loose needles and other sharps down the toilet
- Do not attempt to remove the needle without a proper needle destruction device

Sharps Disposal Options

Current best practices have been recommended by the EPA1, FDA2, and state and local municipalities throughout the United States. Current disposal options generally accepted for home generated sharps waste include the following:

- **Drop-Off Collection Sites** Where available, home generators take filled sharps containers or other appropriate rigid storage container, to appropriate collection sites. These may include
- California SB-486 Plan Revision Date: July 1, 2016 doctors' offices, hospitals, health clinics, pharmacies, police and fire stations, and medical waste facilities.
- Household Hazardous Waste Collection Sites Where available, home generators take filled sharps containers or other appropriate rigid storage container to municipal household hazardous waste/recyclable waste collection sites for proper disposal.
- Needle Exchange Programs Used sharps are exchanged for clean unused devices and the used sharps are properly managed and disposed of by the clinic or exchange venue. These programs are

intended for illicit drug users and are not typically used by a prescription patient to obtain an injection device. However, the exchange venue can serve as a disposal location for a prescription patient. Additionally, patients or Healthcare professionals may call the GSK Response Center to receive disposal information through a number provided in the medication guide.

Return Goods Vendor - GSK retains a Return Goods Vendor, Inmar to ensure all returned and unused product is properly and appropriately destroyed for customers. This is a service GSK provides all customers. GSK provides a vehicle for proper destruction. GSK provides safe vehicle for retail pharmacy, HCPs and all customer types

Return Goods Policy - GSK makes it Return Goods Policy publicly available on www.gsk-ecs.com website under Trade Information. This Policy includes appropriate guidance for the customers on how, where and when to return eligible product to Inmar, GSK's return goods vendor, for appropriate product destruction. Under the Policy customers may return product for replacement

PPSWG - GSK is a participating member of PPSWG.

Disaster Policy- GSK maintains a disaster policy designed to help customers in the event of a persona, natural or FEMA declared disaster to safely return damaged product for appropriate and safe product destruction. GSK provides this vehicle as a service to customers.

In summary, GlaxoSmithKline supports the safe collection and proper disposal of home generated sharps by providing at no cost to the patient, educational materials on proper sharps disposal. Patients may contact our Toll-Free GSK Response Center to obtain California specific disposal information including the locations of sharps collection facilities near their homes where they can dispose of their sharps free of charge.

1 EPA Website http://www.epa.gov/wastes/nonhaz/industrial/medical/disposal.htm

2. FDA Website:

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/default.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=sharps_disposal_content=1