

SB 486 Safe Needle Disposal Plan

July 1, 2023



Background

The State of California enacted two laws to address home generated sharps disposal. The first law, Senate Bill 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 Senate Bill 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. In compliance with these laws, GSK submits the following Safe Needle Collection and Disposal Plan.

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

GSK currently markets, distributes, and/or sells the following self-injectable products:

- 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

Patients are instructed to:

- 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 US Environmental Protection Agency (EPA)ⁱ, US Food and Drug Administration (FDA)ⁱⁱ, 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 container 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 container or other appropriate rigid storage container to municipal household hazardous waste/recyclable waste collection sites for proper disposal.

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- **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. GSK provides safe vehicle for proper and safe destruction for all customers, including retail pharmacies and HCPs.

Return Goods Policy

GSK makes its Return Goods Policy publicly available at www.gsk-ecs.com 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 if certain conditions are met.

Pharmaceutical Product Stewardship Work Group

GSK is a participating member of PPSWG, a membership association for producers of branded and generic prescription and non-prescription pharmaceutical products and sharps. PPSWG's mission is to provide infrastructure, guidance, and subject matter expertise to support member compliance and improve awareness of existing pharmaceutical disposal options.

Disaster Policy

GSK maintains a disaster policy designed to help customers in the event of a persona, natural, or Federal Emergency Management Agency (FEMA) declared disaster to safely return damaged product for appropriate and safe product destruction. GSK provides this option as a service to customers.

In summary, GSK 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 at 1-888-825-5249 to obtain California specific disposal information, including the locations of sharps collection facilities near their homes where they may dispose of their sharps free of charge.

ⁱ EPA Website <http://www.epa.gov/wastes/nonhaz/industrial/medical/disposal.htm>

ⁱⁱ 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](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/default.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=sharps%20disposal%20content=1)