



**SB 486 Safe Needle Disposal Plan for 2013 – 2014  
Second Amendment Date February 26, 2014  
to First Amendment of November 25, 2013 to:**

**Department of Resources Recycling and Recovery  
(CalRecycle)**

## **Background**

The State of California has 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. This plan is due on July 1, 2010 and annually thereafter.

### **Dr. Reddy's Laboratories, Inc. Self-Injectable Products**

#### **Subject To These Regulations In California**

Dr. Reddy's Laboratories, Inc. currently markets, distributes, and/or sells two self-injectable products in the State of California. The generic names of these products are fondaparinux sodium injection (subcutaneous) and sumatriptan injection (subcutaneous).

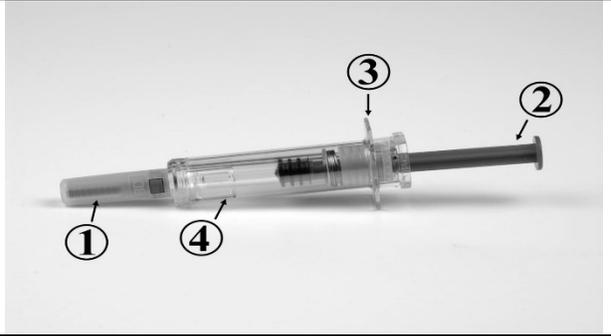
### **Dr. Reddy's Laboratories, Inc. Supports Safe Collection and Proper Disposal of Home Generated Sharps**

Dr. Reddy's Laboratories, Inc. supports appropriate and safe disposal of home-generated waste sharps. Patient safety and needle stick injury prevention were given serious consideration as the above-mentioned products were being developed.

#### **Fondaparinux**

During the development of fondaparinux sodium injection (subcutaneous), Dr. Reddy's Laboratories, Inc. employed safe needle technology in order to protect patients and those assisting in the disposal of waste sharps. Specifically, fondaparinux sodium injection uses a 27 gauge needle that is only a half-inch long and an automatic needle protection system covers the needle after the injection. The steps to activate the automatic needle protection system are described in the fondaparinux sodium injection (subcutaneous) Patient Information Leaflet.

Automatic Needle Protection System:

<p>The different parts of fondaparinux sodium safety syringe are:</p>	
<ol style="list-style-type: none"><li>1. Rigid Needle Shield</li><li>2. Plunger</li><li>3. Finger-grip</li><li>4. Safety shield</li></ol>	
<p>Syringe BEFORE USE</p> 	<p>Syringe AFTER USE</p> 

**Sumatriptan**

Sumatriptan injection autoinjector system is available for use with a 6 mg prefilled syringe to facilitate self-administration in patients using the 6 mg dose. With this device, the needle penetrates approximately ¼ inch (5 to 6 mm). The steps to activate the autoinjector system are described in the sumatriptan injection (subcutaneous) Patient Information and Instructions for Use.

About the Autoinjector Pen

The parts of the pen are shown in this picture.



**Cap**  
The pen will not work until the cap is taken off.

**Medicine Window**  
Use the window to check that the liquid is clear.

**Button**  
The button must be pressed firmly down for the injection to start.

### Patient Education Materials:

Patients who self-inject Dr. Reddy's Laboratories, Inc. products at home should receive instructions from their healthcare professionals on how to use these products properly. The full prescribing information for is available to healthcare professionals. Patients should read the Patient Information Leaflet that comes with each product before they start taking each product and each time the prescription is refilled as there may be new information.

Dr. Reddy's Laboratories, Inc. has also created a patient specific website for sumatriptan injection (subcutaneous) at [www.drreddys.com/products/NA/sumatriptan](http://www.drreddys.com/products/NA/sumatriptan). This website provides patients with the most important information they need to know from Dr. Reddy's Laboratories. The information on this website does not take the place of talking with the patient's doctor about the medical conditions or treatments. Patients can view sumatriptan self-administration instructions in English in text or as a video.

Patients and caregivers can also contact a Dr. Reddy's Laboratories, Inc. representative at 1-888-375-3784. Pharmacists are available Monday through Friday 9:00 am to 7:00 pm EST to assist with questions about these products.

### Disposal:

Patients and consumers have several options available to them to safely dispose sharps waste.

Patients may visit California's CalRecycle website at <http://www.calrecycle.ca.gov/HomeHazWaste/Sharps/Household.htm> to become familiar with all disposal options available and select the option that is most convenient. Below is a summary of the disposal options detailed on the California CalRecycle website:

1. Patients may use the *The Sharps and Medication Disposal Directory* to identify the locations of sites where sharps containers can be properly disposed. Patients can access this searchable database via the California CalRecycle website at: <http://www.calrecycle.ca.gov/HomeHazWaste/HealthCare/Collection/>
2. Patients may contact their health care provider or pharmacist for information on where to bring waste sharps.
3. Patients may contact their local household hazardous waste agency and ask if they collect sharps at their collection facilities or on household hazardous waste days.

### Company Contact Information:

If you would like assistance from Dr. Reddy's Laboratories, Inc. in identifying your disposal options, please contact a Dr. Reddy's Laboratories, Inc. representative at 1-888-375-3784. Representatives are available to assist patients with questions about each of these products, including product administration and medical waste disposal.

Dr. Reddy's Laboratories, Inc. remains committed to help facilitate the safe disposal of its products and will continue to evaluate feedback and make modifications to this plan as needed.