



***Plan for Support of Safe Collection and Proper Disposal of
Waste From Self-Injected Home Medications Including Sharps***

***Submitted to the California Department of Resources, Recycling and Recovery
(CalRecycle)
June 30, 2016***

Sanofi-aventis U.S. LLC, on behalf of itself and its affiliate, Sanofi US Services Inc. (f/k/a sanofi-aventis U.S. Inc.) (collectively “the Company”) and Sanofi-Genzyme, submit the following plan describing how the Company supports the safe collection and proper disposal of waste from self-injected at home medications that include sharps.

This report is submitted consistent with the requirements of Chapter 1 of Part 7 of Division 30 of the Public Resources Code, beginning with Section 47115 for the limited number of prescription drug products for at-home use that include, or utilize a separate, hypodermic needle, pen needle, intravenous needle or similar device.

The Company has sought input from patients regarding disposal of medical sharps and suggestions for support of proper disposal. Results of questions relating to sharps disposal from 100 patients in quantitative research conducted for the Company in late 2009 indicated that most of the patients reported proper disposal of their sharps.

The Company markets a line of self-injectable diabetes products. As an initial matter, it is important to note that physicians, health care providers and Certified Diabetes Educators (CDEs) play an important role in instructing patients on self-injection, and routinely include proper needle disposal as part of the education effort.

Information about prescription drugs also appears in the product labeling regulated by the US Food and Drug Administration (FDA), including information about any devices used to deliver medication such as the following examples: “Disposable needles should be used only once. Used needles should be placed in sharps containers (such as red biohazard containers), hard plastic containers (such as detergent bottles), or metal containers (such as an empty coffee can). Such containers should be sealed and disposed of properly.”

The Company has CDEs who also provide a message of proper disposal of sharps as part of new patient training which includes providing this information in disease reference guides given to the patients.

The Company provides a sharps container in its Lovenox starter kit and its product labeling contains a reference to proper safety and disposal of Lovenox sharps.

In connection with a recall of an epinephrine auto-injector, Sanofi US provided to consumers who had purchased the auto-injectors instructions and mail-back containers envelopes designed to secure safe collection for Sanofi's proper disposal of the devices.

The instructions for use for the Genzyme product Kynamro include specific instructions for disposal of needles in an FDA-cleared sharps disposal container, and in accord with state law.

Sanofi and Regeneron Pharmaceuticals, Inc. have an alliance to co-market Praluent, a home injectable. Sharps disposal containers are available to patients upon request through the MyPraluent patient support program. The alliance provides to patients a team of Clinical Nurse Educators (CNEs) who aid in instructing patients on self-injection and include information on proper sharps disposal as part of these efforts

The FDA approved product insert for use of Praluent includes specific instructions for disposal of needles in a puncture resistant container and advises patients and caregivers to be instructed by providers regarding proper pen and syringe disposal. Similarly the booklet "Learn How to Use Praluent" includes greater detail and reiterates that consumers should not to throw away sharps containers in the household trash unless permitted by community guidelines and directs consumers to the FDA sharps disposal site.

Finally, we have a page on our Internet site relating to proper disposal of sharps and prescription medicines: <http://www.sanofi.us/l/us/medias/131FB5D4-CDF5-4AF5-88E4-1581057A1AF2.pdf> This educational effort provides resources for information about sharps disposal, including a link to the CalRecycle website that provides specific information on sharps disposal and a county by county guide for disposal of sharps in California. <http://www.calrecycle.ca.gov/HomeHazWaste/Sharps/Household.htm>

Sanofi is a member of and supports the activities of the Pharmaceutical Product Stewardship Work Group (PPSWG). PPSWG is actively engaged in compliance in counties where county law mandates manufacturer and producer activity with respect to sharps collection and disposal.

We believe that proper sharps disposal is a multi-faceted issue and any comprehensive improvement recommendations should involve input from all stakeholders including patients, healthcare professionals, product manufacturers and waste management/disposal representatives.