



***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, 2014***

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 “Sanofi US”) and Genzyme, a Sanofi affiliated company, submit the following plan describing how Sanofi US 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.

Sanofi US 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 Sanofi US in late 2009 indicated that most of the patients reported proper disposal of their medical sharps.

Sanofi US 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 (CDE) 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 needle 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.”

Sanofi US 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.

Sanofi markets an epinephrine auto-injector that contains a sharp. That device addresses disposal in its product labeling and patient instructions. Since it has audio capability, it tells the user, when it has been deployed, how to properly dispose of the unit.

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.

Finally, we have a page on our Internet site relating to proper disposal of sharps and prescription medicines: <http://www.sanofi.us/1/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>

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.