

***Kaléo's 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)***

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Kaleo, Inc. ("Kaléo") submits the following plan describing how we support the safe collection and proper disposal of waste from self-injected at home medications that include sharps. This plan 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. It is important to note that physicians, healthcare providers and pharmacists play an important role in instructing patients on the safe collection and proper disposal of needles.

Kaléo sells AUVI-Q® (epinephrine injection, USP), a take-home epinephrine auto-injector. AUVI-Q contains a retractable needle that is designed to eliminate sharps hazards before and after use. The needle is self-contained within the device and is only exposed briefly (less than 1 second) during the activation of the injection. Prior to activation, the needle is completely contained inside the device. After injection, the needle completely retracts into the device, eliminating the sharps hazard.

The AUVI-Q device addresses disposal in its FDA-approved product labeling and patient instructions. The AUVI-Q patient information includes:

Replace the outer case and talk to your healthcare provider about the right way to throw away your AUVI-Q.

AUVI-Q also has audio prompts that tell the user, after injection, to call 911 for emergency medical attention, and instructs the user in how to properly dispose of the unit.

Finally, Kaléo is a member of PPSWG (<https://ppswg.org/>) and participates in Med-Project for the disposal of unwanted or expired pharmaceuticals and sharps disposal program.

Additional Resources

For more information about safe sharps disposal, go to FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

For information on where to safely dispose of sharps in the United States, visit <https://safeneedledisposal.org/>.