

**Bayer HealthCare, LLC Sharps Disposal Submission to CalRecycle
July 1, 2021**

1. *“A pharmaceutical manufacturer that sells or distributes a medication in California that is usually intended to be self-injected at home through the use of a hypodermic needle, pen needle, intravenous needle, or any other similar device, shall, on or before July 1, 2010, and annually thereafter, submit to the board, or its successor agency, a plan that describes how the manufacturer supports the safe collection and proper disposal of the waste devices.”*

2. *“The plan required...shall include, at a minimum, a description of the actions, if any, taken by the manufacturer to do the following,*

“(a) Provide for the safe collection and proper disposal of the waste devices.”

“(b) Educate consumers about safe management and collection opportunities.”

“(c) Support efforts by retailers, pharmaceutical distributors, manufacturers of injection devices, and other partners, including local governments, health care organizations, public health officers, solid waste service providers, and other groups with interest in protecting public health and safety through the safe collection and proper disposal of waste devices.”

BAYER HEALTHCARE, LLC

Bayer HealthCare, LLC (“Bayer”) is committed to our purpose of “Science for a Better Life” and to operating sustainably and addressing our social and ethical responsibilities.

Bayer has five (5) products within its portfolio of prescription medications that are “usually intended to be self-injected at home through the use of a hypodermic needle, pen needle, intravenous needle, or any other similar device....” These include:

- a. **BETASERON® (interferon beta-1b)**
- b. **BETACONNECT™ Autoinjector**
- c. **JIVI® [antihemophilic factor (recombinant) PEGylated-aucl**
- d. **KOGENATE® FS antihemophilic factor (recombinant)**
- e. **KOVALTRY® antihemophilic factor (recombinant)**

Patients who self-administer these therapies at home should adhere to safe disposal practices for sharps.

EDUCATION AND RESOURCES

Many of Bayer's contracted specialty pharmacies provide sharps containers and needle clips for patients to safeguard used sharps. In addition, many entities in Bayer's specialty provider network (i.e. home health care, hemophilia treatment centers) provide sharps disposal containers directly to patients.

The table below highlights, by product, the resources available to educate the patient about proper sharps disposal.

BETASERON® (interferon beta-1b) and BETACONNECT™ Autoinjector
<ul style="list-style-type: none">• Through Bayer's BETAPLUS™ patient support program, available to all Betaseron® patients, BETA Nurses are available to patients 24/7. Newly diagnosed patients or patients new to Betaseron® therapy are provided direct information by the BETA Nurses about proper disposal of used containers or needle clips to safeguard used sharps, through referral to designated sharps take-back locations, based upon the individual patient's area of residence.• Prescribing and patient information gives additional direction about proper sharps disposal. The Betaseron® prescribing information and patient medication guide and the Betaconnect™ autoinjector instructions for use may be found at www.betaseron.com.• The above website also includes an injection training guide and a video with instructions for proper disposal of used syringes, needles and vials.
JIVI® [antihemophilic factor (recombinant) PEGylated-aucl
<ul style="list-style-type: none">• Prescribing and patient information gives direction about proper disposal. The FDA-approved prescribing information and patient labeling may be accessed at www.jivi-us.com.
KOGENATE® FS antihemophilic factor (recombinant)
<ul style="list-style-type: none">• Prescribing and patient information gives direction about proper disposal. The FDA-approved prescribing information and patient labeling may be accessed at www.kogenatefs.com.
KOVALTRY® antihemophilic factor (recombinant)
<ul style="list-style-type: none">• Prescribing and patient information gives direction about proper disposal. The FDA-approved prescribing information and patient labeling may be accessed at www.kovaltry-us.com.

OTHER RESOURCES

Patients and caregivers may also access information about safe sharps disposal at the sites below.

- U.S. Food and Drug Administration - <https://www.fda.gov/medical-devices/consumer-products/safely-using-sharps-needles-and-syringes-home-work-and-travel>
- CalRecycle - <https://www.calrecycle.ca.gov/HomeHazWaste/sharps>

3. (a) *Posted on Bayer HealthCare, LLC website (www.pharma.bayer.com) and a copy of same is maintained at 100 Bayer Blvd. Whippany NJ 07981*

(b) The above was submitted on June 25, 2021, to the California Department of Resources, Recovery and Recycling (CalRecycle) in care of its designated e-mail contact, pharmasharps@calrecycle.ca.gov.