

**Bayer HealthCare, LLC Sharps Disposal Submission to CalRecycle
July 1, 2019**

*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."*¹

Bayer HealthCare, LLC ("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)**, which is indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Patients with multiple sclerosis in whom efficacy has been demonstrated include patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.

Betaseron® is given by injection under the skin (subcutaneous injection) every other day.

b. **BETACONNECT™** Autoinjector, which aids in the injection of Betaseron® as prescribed.

c. **JIVI® [antihemophilic factor (recombinant) PEGylated-aucl]**, is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age or older) with hemophilia A (congenital Factor VIII deficiency) for:

- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes.

d. **KOGENATE® FS antihemophilic factor (recombinant)**, which is a recombinant factor VIII treatment indicated for the control and prevention of bleeding episodes and peri-operative management in adults and children (0-16 years) with hemophilia A. **Kogenate® FS** is also indicated for routine prophylaxis to reduce the frequency of bleeding episodes and the risk of joint damage in children with hemophilia A with no preexisting joint damage.

Dosage and duration of treatment depend on the severity of the factor VIII deficiency, the location and extent of bleeding, and the patient's clinical condition. Careful control of replacement therapy is especially important in cases of major surgery or life-threatening bleeding episodes.

It is recommended to use the IV administration set provided. A dose of Kogenate® FS may be administered over a period of 1 to 15 minutes. The rate of administration, however, should be adapted to the response of each individual patient. The pulse rate should be determined before and during administration of Kogenate® FS. If there is a significant increase in pulse rate, reducing the rate of administration or temporarily halting the injection allows the symptoms to disappear promptly.

Bayer supports the safe collection and proper disposal of any used hypodermic needle, pen needle, intravenous needle, or any other similar device by several means, including among others as described below, clear instructions in each relevant product's accompanying package insert and other product labeling.

e. **KOVALTRY® antihemophilic factor (recombinant)**, which is a recombinant full-length Factor VIII concentrate indicated in the use in adults and children with Hemophilia A for:

- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes

Dosage and duration of treatment depend on the severity of the factor VIII deficiency, the location and extent of bleeding and the patient's clinical condition. Careful control of replacement therapy is especially important in cases of major surgery or life-threatening bleeding episodes.

Kovaltry® is a lyophilized product and must be reconstituted before administration. The reconstituted product is indicated for intravenous administration only. Infuse Kovaltry® intravenously over a period of 1 to 15 minutes. Adapt the rate of administration to the response of each individual patient.

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

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

i. As for **BETASERON®**:

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.

In addition, many of Bayer's contracted specialty pharmacies which provide Betaseron also provide sharps containers or needle clips to safeguard used sharps.

Further, prescribing and patient information gives additional direction about proper sharps disposal: Statement made in Patient Package Insert Step 6 and Injection Training Guide Step 6:

Step 6: Disposing of used syringes, needles, and vials

- To prevent needle-stick injury and spread of infection, do not try to re-cap the needle.
- Place used needles, syringes, and vials in a closeable, puncture-resistant container.
- For a free sharps container, please call BETAPLUS® at 1-800-788-1467. When the container is full, ask your pharmacist, healthcare provider, or BETA Nurse how to dispose of it.
- You may use a sharps container (such as a red biohazard container), hard plastic container (such as a detergent bottle), or metal container (such as an empty coffee can). Do not use glass or clear plastic containers. Ask your healthcare provider for instructions on the right way to throw away (dispose of) the container. There may be state and local laws about how you should throw away used needles and syringes.

- **Do not throw used needles, syringes, or vials in your household trash or recycle.**
- Throw away any unused medicine. Do not save any unused BETASERON for a future dose.
- Keep the disposal container, needles, syringes, and vials of BETASERON out of the reach of children.
- Never hesitate to ask questions! It's important that you know how to take your BETASERON—so please don't let your questions go unanswered. If you have any questions at all about BETASERON, or need a new sharps container, call BETAPLUS at 1-800-788-1467 and speak with a BETA Nurse.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

ii. As for **BETACONNECT™**:

Through Bayer's BETAPLUS™ patient support program, available to all Betaseron® patients, BETA Nurses are available to patients 24/7. After the expiration date, the Betaconnect® autoinjector has to be replaced. The patient can ask a BETA Nurse or healthcare provider for a new Betaconnect® autoinjector. The expiration date can be located inside the lid indicated by year (YYYY) and month (MM) printed as YYYY-MM. BETACONNECT autoinjector should not be used after the expiration date. When expired, Betaconnect® autoinjector will be shipped back to the manufacturer for recycling.

Betaseron® syringes are the only product used with the Betaconnect® autoinjectors. The BETA nurses provide proper disposal instructions of Betaseron® syringes, 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. In addition, many of Bayer's contracted specialty pharmacies which provide Betaseron® also provide sharps containers or needle clips to safeguard used sharps. [see (2)(a)(i) above]

iii. As for **JIVI®**:

Many entities in Bayer's specialty provider network (i.e. home health care, hemophilia treatment centers) provide sharps disposal containers directly to Jivi® patients.

Note: Section 16, page 15:

Jivi is available as a lyophilized powder in single-use glass vials, one vial per carton. It is supplied with a sterile vial adapter with 15-micrometer filter and a prefilled diluent glass barrel syringe, which together serve as a needleless reconstitution system. [emphasis added]

Further, prescribing and patient information gives additional direction about proper disposal:

Section 17 "Patient Counseling Information" page 16:

Advise patients to discard all equipment, including any unused product, in an appropriate container.

“FDA-Approved Patient Labelling” page 19:

Carefully handle Jivi. Dispose of all materials, including any leftover reconstituted Jivi product, in an appropriate container.

“Resources at Bayer available to the patient:” page 20:

For Adverse Reaction Reporting contact Bayer Medical Communications 1-888-84-BAYER (1-888-606-3780)

To receive more product information, contact Jivi Customer Service 1-888-606-3780

For more information, visit <http://www.Jivi.com>

iv. As for **KOGENATE® FS:**

Many entities in Bayer's specialty provider network (i.e. home health care, hemophilia treatment centers) provide sharps disposal containers directly to Kogenate® FS patients.

Further, prescribing and patient information gives additional direction about proper sharps disposal:

Section 17 "Patient Counseling Information" page 18:

Carefully handle Kogenate® FS. Dispose of all materials, including any leftover reconstituted Kogenate® FS product, in an appropriate container.

Resources at Bayer available to the Patient:

For Adverse Reaction Reporting contact:

Bayer Medical Communications 1-888-84-BAYER (1-888-842-2937)

Contact Bayer to receive more product information:

Kogenate FS Customer Service 1-888-606-3780

For more information, visit www.kogenatefs.com

v. As for **KOVALTRY®**

Many entities in Bayer's specialty provider network (i.e. home health care, hemophilia treatment centers) provide sharps disposal containers directly to Kovaltry® patients.

Prescribing Information page 20:

Carefully handle KOVALTRY®. Dispose of all materials, including any leftover reconstituted KOVALTRY® product, in an appropriate container.

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

i. As for **BETASERON®:**

As described above, patient education is the focus of the BETAPLUS™ program, building upon the prescribing and patient information that gives additional direction about proper sharps disposal:

Statement made in Patient Package Insert:

"Used needles and syringes may be placed in a container made specially for disposing of used syringes and needles (called a "Sharps" container), or a hard plastic container with a screw-on cap or metal container with a plastic lid labeled "Used Syringes". Do not use glass or clear plastic containers. You should always check with your healthcare provider for instructions on how to properly dispose of used vials, needles and syringes. You should follow any special state or local laws regarding the proper disposal of needles and syringes.

DO NOT throw the needle or syringe in the household trash or recycle.

Always keep the disposal container out of the reach of children.

ii. As for **BETACONNECT™**:

This unit is to be used with **Betaseron®** only.

Section 3.3 Step 3 of the Patient Instruction for Use and Injecting with Betaconnect section of Injection Training Guide:

Important: Take care to avoid the needle when you remove the empty syringe. It could injure you or others. Do not put the needle cap back on the syringe. Always dispose of your empty syringe promptly, using an appropriate sharps container.

Step 3: Disposing of Used Needles and Syringes

Put your used BETASERON® syringe and needle in a FDA-cleared sharps disposal container right away after use.

Do not throw away (dispose of) your used syringes and needles in your household trash.

If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- upright stable during use
- leak-resistant
- properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should dispose of used syringes. For more information about the safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container. **Keep the disposal container out of the reach of children**

Patient Training Guide Page 10:

Be sure to have a disposable sharps container (not included) available. If you need a sharps container, call 1-800-788-1467 to request one.

Page 26:

Tip – For a free sharps container please contact BETAPLUS® at 1-80078801467. When the container is full, ask your pharmacist, healthcare provider or BETA Nurse how to dispose of it.

iii. As for **JIVI®**:

Note: Section 16, page 15:

Jivi is available as a lyophilized powder in single-use glass vials, one vial per carton. It is supplied with a sterile vial adapter with 15-micrometer filter and a prefilled diluent glass barrel syringe, which together serve as a needleless reconstitution system. [emphasis added]

Section 17 "Patient Counseling Information" page 16:

Advise patients to discard all equipment, including any unused product, in an appropriate container.

“FDA-Approved Patient Labelling” page 19:

Carefully handle Jivi. Dispose of all materials, including any leftover reconstituted Jivi product, in an appropriate container.

“Resources at Bayer available to the patient:” page 20:

For Adverse Reaction Reporting contact Bayer Medical Communications 1-888-84-BAYER (1-888-606-3780)

To receive more product information, contact Jivi Customer Service 1-888-606-3780

For more information, visit <http://www.Jivi.com>

iv. As for **KOGENATE® FS**:

Section 17 "Patient Counseling Information":

Dispose of all materials, including any leftover reconstituted Kogenate® FS product, in an appropriate container.

The Kogenate® FS Prescribing Information contains the following guidance statements:

Section 2.2 Preparation & Reconstitution:

Product reconstitution, administration, and handling of the administration set and needles must be done with caution because percutaneous puncture with a needle contaminated with blood can transmit infectious viruses, including HIV(AIDS) and hepatitis. Place needles in a sharps container after single use. Discard all equipment, including any reconstituted Kogenate® FS product, in an appropriate container. Obtain immediate medical attention if injury occurs. For any questions about the handling, reconstitution and administration of Kogenate® FS, contact Bayer Medical Communications at 1-888-84-BAYER (1-888-842-2937).

v. As for **KOVALTRY®**:

Prescribing information page 20:

Carefully handle KOVALTRY®. Dispose of all materials, including any leftover reconstituted KOVALTRY® product, in an appropriate container.

“(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.”

i. As for **BETASERON®**:

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. All patients are advised, “Place your used syringe and needle in a sharps container. DO NOT throw them in the household trash or recycle bin. To request a free sharps container, please call BETAPLUS® at 1-800-788-1467.” In addition, many of Bayer's contracted specialty pharmacies which provide Betaseron® provide sharps containers or needle clips to safeguard used sharps.

ii. As for **BETACONNECT™**:

Section 3.3 Step 3 of the Patient Instruction for Use:

Important: Take care to avoid the needle when you remove the empty syringe. It could injure you or others. Do not put the needle cap back on the syringe. Always dispose of your empty syringe promptly, using an appropriate sharps container.

Step 3: Disposing of Used Needles and Syringes:

Put your used BETASERON® syringe and needle in a FDA-cleared sharps disposal container right away after use.

Do not throw away (dispose of) your used syringes and needles in your household trash.

If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
- upright stable during use
- leak-resistant
- properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should dispose of used syringes. For more information about the safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at:

<http://www.fda.gov/safesharpsdisposal>.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container. **Keep the disposal container out of the reach of children**

iii. As for **JIVI®**:

Note: Section 16, page 15:

Jivi is available as a lyophilized powder in single-use glass vials, one vial per carton. It is supplied with a sterile vial adapter with 15-micrometer filter and a prefilled diluent glass barrel syringe, which together serve as a needleless reconstitution system. [emphasis added]

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iv. As for **KOGENATE® FS**:

Many entities in Bayer's specialty provider network (i.e. home health care, hemophilia treatment centers) provide sharps disposal containers directly to Kogenate® FS patients.

v. As for **KOVALTRY®**:

Many entities in Bayer's specialty provider network (i.e. home health care, hemophilia treatment centers) provide sharps disposal containers directly to Kovaltry® patients.

Prescription Information Page 20:

Carefully handle KOVALTRY®. Dispose of all materials, including any leftover reconstituted KOVALTRY® product, in an appropriate container.

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 26, 2019, to the California Department of Resources, Recovery and Recycling (CalRecycle) in care of its designated e-mail contact, pharmasharps@calrecycle.ca.gov, with a copy to:

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