“Household Generated Sharps Management Plan”

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Bristol-Myers Squibb Company Sharps Management Plan for the Continental United States, Alaska and Hawaii.

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Introduction

As some states have approved regulation for the management of household generated sharps waste during the past years, Bristol Myers Squibb Company has prepared

the following “Household Generated Sharps Management Plan” to support the safe collection and proper disposal of these waste sharps. Under various state-sanctioned regulations, pharmaceutical manufacturers that sell or distribute a medication that is self-administered through the use of hypodermic needles or other self-injectable devices have to prepare and/or submit to these states, or the state responsible agency, a plan that describes how the manufacturer supports the safe collection and proper disposal of waste sharps.

These regulations require the manufacturer to post and maintain their plans on their respective websites . Currently two states, California and Minnesota, have issued pharmaceutical manufacturer requirements for Household Generated Sharps management. For California, the plan must be submitted to the California Integrated Waste Management Board for posting, and also posted on Bristol Myers Squibb Company website. The State of Minnesota only requires that the plan is posted on the Bristol Myers Squibb Company website.

The “Household Generated Sharps Management Plan” and some related reference guidance are available at the following Internet website:

- *https://www.bms.com/assets/bms/us/en-us/pdf/household-generated-sharps-management-plan.pdf*

Additional sharps disposal guidance for all states is available at the following webpages:

- http://www.safeneedledisposal.org/
- https://www.epa.gov/rcra/community-options-safe-needle-disposal

Elements of the Bristol Myers Squibb Company Plan

Safe Collection and Proper Disposal of the Waste Devices from Clinical Trials

Sharps waste generated by self-administration of an injectable drug occurs throughout the United States. Bristol Myers Squibb Company has been conducting several clinical trials in various states, which involve subcutaneous injection of our pharmaceuticals. These clinical trials are administered by third parties at clinical investigative sites, located throughout California, Minnesota, and elsewhere. In each of these trials, the patients may be provided injectable sharps to self-administer the medication in a home environment, and puncture-resistant containers for the safe collection of the used sharps. As an element of the clinical trial, patients are provided with instructions on the proper administration of the medicine and are requested to return the used sharps materials to these investigative sites using the puncture-resistant containers. The investigative sites ultimately dispose of these sharps and containers in accordance with applicable regulatory requirements. These home-generated sharps materials are not expected to enter the pertinent municipality trash cycle.

Safe Collection and Proper Disposal of the Waste Devices from Commercially Available Products

For household sharp waste generated by prescribed self-injectable drugs administered at home, customers are provided with reference guidance on how to handle the "Household Generated" sharps. Recommended FDA handling and disposal is described in Appendix A of this document.

In 2011, Bristol Myers Squibb Company initiated the commercial distribution of a medicinal product ORENCIA® (abatacept) that is self-injected at home. Under the Bristol Myers Squibb Company "Household Generated Sharps Management Plan", Bristol Myers Squibb Company offers customers that utilize self-injectable sharps, guidance, instructions and/or recommendations on how to handle the used sharp and how to properly dispose of these materials. A copy of this guidance can be obtained at Orencia-SC-Self-Injection-Digital.pdf and Orencia-ClickJectTm-Digital.pdf

In addition, our product, ORENCIA® (abatacept), currently offers our customers the convenient option to participate in a program, which allows for both the safe disposal of needles and patient convenience, at no cost to the customer. The program mails participating customers an empty Sharps container with a return-mail box for when the

Sharps container is full. This Sharps container mail-back program is managed by a third-party but is fully funded by Bristol Myers Squibb Company. Bristol Myers Squibb Company has contracted the services of this third-party service provider that will ensure the supply of the sharps container, will arrange for the proper shipment, and disposal of the sharps in compliance with applicable regulations. When a patient registers for the service by calling Bristol Myers Squibb Company Customer Service at 1-800-ORENCIA, a Sharps container with instructions and mail-return back box is sent. When the Sharps container is full, patients can return the Sharps container in the return-mail box. The mail-back box contains all necessary return shipping address labels/materials and postage, pre-paid by Bristol Myers Squibb Company. Questions about the program and additional containers and return boxes can be requested for patients who take ORENCIA® (abatacept) by calling the Bristol Myers Squibb Company Customer Service line at 1-800-ORENCIA.

Consumers Education on Safe Management and Collection Opportunities

The patients enrolled in applicable Bristol Myers Squibb Company clinical trials involving self-injectables are provided with a puncture-resistant Sharps container marked with the biohazard label for the safe collection of the used sharps. The patients are provided with written instructions on the proper use and disposal of the Sharps container.

Patients receiving a Bristol Myers Squibb Company commercially supplied self-injectable product (prefilled syringe or autoinjector pen) receive Patient Prescribing Information with every new package of the product which includes Instructions For Use information on the proper handling and disposal of waste sharps. This pamphlet also instructs patients on the basic disposal requirements.

The specific product webpages, with applicable content, are included in Appendix B. In general, the guidance states that when disposing of Sharps you should:

- Ask your State or local environmental agencies, or your healthcare provider for instructions on the right way to discard (dispose of) your used sharps and the container. There may be state and local laws regulating how you should dispose of used sharps.

- Place used needles in a closeable, puncture-resistant container. Use a Sharps container (such as a red biohazard container) or when allowed by your local or state regulations, a hard, plastic container (such as a detergent bottle labeled as “Do Not Recycle”).

- Do not throw the disposal container in the household trash unless it is allowed by your local or state regulations.

- For additional information you may contact the Coalition for Safe Community Needle Disposal at 800-643-1643 or www.safeneedledisposal.org.

Additional education and supporting information on Waste Sharps Management and for the States of California and Minnesota can be found Appendix Appendices C and D.

Efforts in Protecting Public Health and Safety Through the Safe Collection and Proper Disposal of Waste Devices

Bristol Myers Squibb Company continues to evaluate employing “safe needle technologies” (i.e., retractable needles; use of a blunting media) for our future products. Such technologies/approaches aim to further reduce the potential for inadvertent “sticks”.

Guidance links on sharps management are listed in Appendix C. The current guidance (webpages) for the States of California and Minnesota are listed in Appendix D. Additional collection and disposal information may be obtained at most pharmacies and at state environmental agency websites .

Appendix A:

Handling and Disposal of Household Sharps

Always follow the local regulations regarding disposal of Household Generated Sharps. The following website will provide access to state-by-state requirements:
http://www.safeneedledisposal.org/

FDA Guidance from the following website:

http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/Sharps/default.htm

Needles and Other Sharps (Safe Disposal Outside of Health Care Settings) The above webpage gives tips for safely disposing (getting rid of) needles and other sharp devices that are used outside of health care settings. Patients and caregivers should keep these tips in mind when at home, at work, and while traveling.

What are Sharps?

"Sharps" is a medical term for devices with sharp points or edges that can puncture or cut skin.

Examples of Sharps include:

- **Needles** – hollow needles used to inject drugs (medication) under the skin
- **Syringes** – devices used to inject medication into or withdraw fluid from the body

- **Lancets,** also called “fingerstick” devices – instruments with a short, two- edged blade used to get drops of blood for testing
- **Auto Injectors,** syringes pre-filled with fluid medication designed to be self-injected into the body
- **Infusion sets** – tubing systems with a needle used to deliver drugs to the body.
- **Connection needles/sets** – needles that connect to a tube used to transfer fluids in and out of the body.

Sharps may be used at home, at work, and while traveling to manage the medical conditions of people.
There are about 9 million Americans who use needles or other sharps to manage their medical conditions at home. This amounts to more than 3 billion used needles and other sharps that must be disposed of outside health care settings each year.

Importance of Safe Sharps Disposal

Used needles and other sharps are dangerous to people if not disposed of safely because they can injure people and spread infections that cause serious health conditions. The most common infections are:

- Hepatitis B (HBV),
- Hepatitis C (HCV), and
- Human Immunodeficiency Virus (HIV).

Safe sharps disposal is important whether you are at home, at work, at school, traveling or in other public places such as hotels, parks, and restaurants.

Never place loose needles and other sharps (those that are not placed in a sharps disposal container) in the household or public trash cans, recycling bins, and never flush them down the toilet. This puts trash and sewage workers, janitors, housekeepers, household members, and children at risk of being harmed.

What to Do If You Are Accidently Stuck By a Used Needle or Other Sharp

If you are accidently stuck by another person's used needle or other sharp:

1. Wash the exposed area right away with water and soap or use a skin disinfectant (antiseptic) such as rubbing alcohol or hand sanitizer
2. Seek immediate medical attention by calling your physician or local hospital

Follow these same instructions if you get blood or other bodily fluids in your eyes, nose, mouth, or on your skin. For more information on viruses and needle-stick prevention, visit the Occupational Safety and Health Administration's website at http://www.osha.gov/SLTC/bloodbornepathogens/index.html.

Appendix B

Bristol Myers Squibb Company Products Website Link

ORENCIA® (abatacept) website:

http://www.orencia.com/

ORENCIA® (abatacept): Optional Used Sharps Disposal Program:

https://www.orencia.com/starting-orencia#faq

ORENCIA® (abatacept): Instructions For Use for patients:

http://packageinserts.bms.com/ifu/ifu_orencia.pdf

Appendix C

Additional Guidance Links for Sharps Management

http://www.fda.gov/medicaldevices/productsandmedicalprocedures/homehealthandconsumer/consumerproducts/sharps/

ORENCIA® Injection & Infusion Administration Guide | ORENCIA® (abatacept)

Appendix D

California and Minnesota Links on Sharps Disposal

The State of California has published information on Sharps management and disposal at the following webpages:

Pharmaceutical and Sharps Waste Stewardship - CalRecycle Home Page

The State of Minnesota has published guidance documents on sharps management and disposal at the following webpage:

Managing household needles and syringes