California SB 486 Needle Disposal Plan for SIMPONI® (golimumab)

This describes the process in place for the end-of-life management of SIMPONI® self-injection devices. SIMPONI® (golimumab) is a drug for treatment of adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis, or active ankylosing spondylitis. The drug is provided in a prefilled syringe or a SmartJect® autoinjector. It is self-injected once-monthly. SIMPONI® is marketed in the U.S. by Janssen Biotech, Inc. (Note that as of June 22, 2011, Centocor Ortho Biotech, Inc. changed its name to Janssen Biotech, Inc.)

Janssen Biotech, Inc. is a Johnson & Johnson (J&J) company. J&J is committed to the health and well-being of families everywhere. Our commitment is shown in various sustainability and environmental initiatives and projects. More information about J&J's environmental progress can be found at:

http://www.jnj.com/connect/caring/environment-protection/

I. Description of Sharps Disposal Program:

When healthcare professionals prescribe SIMPONI®, they provide the patients with education materials such as the SIMPONI® Welcome Pack (Patient Starter Pack), which includes the SIMPONI® Welcome Guide and DVD (Patient Starter Brochure). Information about the end-of-life product management program, called SimponiOne® Safe Returns™, is presented in these patient education materials. People treating with SIMPONI® can also get information on SimponiOne® Safe Returns™ by calling 877-MY SIMPONI (877-697-4676), or by going on the website: www.SimponiOne.com.

The SimponiOne® Safe Returns™ program is available nationwide at no additional cost to the patients. Patients sign up for the program either by completing a business reply card in the registration pack available at their doctor's office, by calling the toll-free number, by completing a business reply card in the Welcome Guide, or by visiting the website (above). They will receive a Safe Returns™ pack in the mail, and will continue to receive a Safe Returns™ package each month until they request to opt out of Safe Returns™, and/or stop shipping back their used prefilled syringes or used SmartJect® autoinjectors after 90 days. Included in this pack are: the Safe Returns™ instructions, a postage-paid shipping box with liner, sharps container tube, plastic bag, shipping documents, and a SIMPONI® package insert. By following the Safe Returns™ instructions and giving the box to the mail carrier, dropping it at a US post office, or anywhere the US Postal Service arranges pickup, the used SmartJect® autoinjector or used prefilled syringe will be shipped to Stericycle, a licensed medical waste facility for disposal.

Attached is the SimponiOne® Safe Returns™ Instruction Guide (information for patients).

II. Patient Education about sharps disposal:

Information about proper disposal of used SmartJect® autoinjectors and prefilled syringes are provided to the patients through literature, website, and a toll-free phone number as described above. Also a DVD video that explains Safe Returns™ is provided in the SIMPONI® Welcome Pack (Patient Starter Pack) and is available on the SIMPONI® website.

III. Coordination with regional and state sharps management efforts:

The SimponiOne® Safe Returns™ program is available free to SIMPONI® patients nationwide. We believe that the program meets the intent and requirements of local, regional, and state-level sharps management efforts. We will consider other opportunities to engage with the state and regional authorities on sharps management patient education.

IV. Consumer Involvement:

The SimponiOne® Safe Returns™ program was developed using market research and feedback data from patients and healthcare professionals. We also involved stakeholders, such as representatives from the medical waste disposal companies and the US postal service, in the program development. Program activity, including new enrollments and total program participation, is tracked weekly and reviewed monthly. Since the program was launched in late 2009, Janssen Biotech, Inc. has continued to monitor the patient enrollment and participation to look for opportunities for improvement. Patients, caregivers, and healthcare professionals may inquire about the program, have questions answered, and concerns addressed by calling 877-MY SIMPONI (877-697-4676).

SAFE RETURNS™ INSTRUCTION GUIDE

SimponiOne® SAFE RETURNS™
Simple Safe Disposal. Only From SimponiOne.®

SimponiOne® Safe Returns™

Here's a unique monthly service exclusively for people being treated with once-a-month SIMPONI® that lets you:

- Properly and easily dispose of your used SmartJect® autoinjector or used prefilled syringe
- Get them out of your home and off your mind right after you use them
- Receive a new Safe Returns™ pack every month
- Sign up at no additional cost to you!

SIMPONI® is the first once-monthly self-injectable biologic treatment for adults with: moderate to severe rheumatoid arthritis (RA), with the medicine methotrexate; active psoriatic arthritis, alone or with the medicine methotrexate; or active ankylosing spondylitis. Methotrexate is used as directed. Once you and your doctor are comfortable with the self-injection process, you will inject SIMPONI® just once a month under the skin. Just one dose of SIMPONI® monthly works to relieve the signs and symptoms of RA, active psoriatic arthritis, and active ankylosing spondylitis. Results may not be the same for everyone.

Selected Important Safety Information

SIMPONI® (golimumab) can lower your ability to fight infections. Serious and sometimes fatal events may occur. There have been reports of serious infections including tuberculosis (TB) and infections caused by bacteria, fungi, or viruses that have spread throughout the body. Other possible serious side effects may include lymphoma or other cancers, hepatitis B, heart failure, nervous system problems, or allergic reactions. To learn more about these and other risks, please read the Important Safety Information included in this brochure and the enclosed Medication Guide, and talk with your doctor.

monthly Simponi® goli

To sign up for Safe Returns™, call 877-MY SIMPONI (877-697-4676) or visit SimponiOne.com

SimponiOne® Safe Returns™

MAIL-BACK INSTRUCTIONS

Your SimponiOne® Safe Returns™ pack has everything you need to properly and easily dispose of one SmartJect® autoinjector or one prefilled syringe after you've used it for your once-a-month dose of SIMPONI® (golimumab). When these instructions are properly followed, the mail-back box will meet all U.S. Postal Service regulations for mailing to a disposal site through the U.S. mail.

A Outer shipping box
B Postage-paid mail-back box with liner
C Container tube
D Plastic bag
E Shipping document

Appearance may vary slightly

Two ways to watch the Safe Returns™ Instructions online at SimponiOne.com:

- Click on Safe Returns™ under Services, for a step-by-step video demonstration.
- With RN Live Link™, watch online as a nurse walks you through the instructions while you talk on the phone.

1 When you receive your shipment:

Remove the SimponiOne® Safe Returns™ pack (B) from the outer shipping box (A). The outer shipping box can then be thrown away. **Don't discard your postage-paid mail-back box or anything inside it.** Store it in a dry area.

2 How to use your SimponiOne® Safe Returns™ pack

- You're ready to dispose of a SmartJect® autoinjector or prefilled syringe after your once-a-month dose of SIMPONI®. Open the mail-back box and take out the plastic container tube (C) and the plastic bag (D).
- Place the used SmartJect® autoinjector or used prefilled syringe in the container tube, with the injection end pointed away from you, and close the tube by screwing the cap on firmly. Make sure it is tight and secure.

SimponiOne® SAFE RETURNS™
Simple Safe Disposal. Only From SimponiOne.®

SAFE RETURNS™ INSTRUCTION GUIDE

3 Now you're ready to send in your postage-paid mail-back box

- Place the filled container tube into the plastic bag and close the bag securely by zipping it closed. Put the plastic bag into the postage-paid mail-back box.
- Take out the 4-part shipping document (E) from the plastic pouch on the outside of the mail-back box. **Don't damage the pouch** — the completed forms must be reinserted.
- Seal the box by peeling off the strip covering the tape on the inside flap. Close the lid and press firmly to seal the adhesive.
- **Shipping Documents:** Confirm the information in Section 1 and make changes as needed. Sign where it says Generator Certificate. Remove the last copy of the document and keep it for your records (NJ residents keep first copy only). Then put the 3 remaining copies back into the pouch and close it.
- Mail the properly sealed Safe Returns™ box in a U.S. post office, or anywhere the U.S. Postal Service arranges pickups. You may also give it to your mail carrier for pickup.
- **Important:** You must send in your Safe Returns™ box in order to receive a new box each month.

PLEASE NOTE

- Don't put anything in your SimponiOne® Safe Returns™ mail-back box other than one used SmartJect® autoinjector or one used prefilled syringe, following the instructions above.
- Janssen Biotech, Inc., the manufacturer of SIMPONI® (golimumab), is not liable for anything shipped via Safe Returns™.
- The total residual fluid is limited to 50 mL.
- Total weight of the container is limited to 1 lb.

Remember to send in your Safe Returns™ pack in order to receive a new pack each month.

If you need to change your mailing information, or if you damage or misplace your pack and need to order a new one — or to learn more about SimponiOne® Support services,

call 877-MY SIMPONI (877-697-4676) or visit SimponiOne.com.

REGULATORY NOTICE TO PATIENT REGARDING MAILING OF PACK: All patients must be aware that they are responsible for preparing the pack for mailing in accordance with the directions provided. No other materials may be placed in the pack for mailing. All original packaging materials provided must be utilized. Improper packaging or mailing of any other materials is in violation of Federal Postal Service Regulations and could be subject to action up to and including full prosecution of the laws of the Federal U.S. Postal Service. Should you have any questions or have any problems with the pack call **877-MY SIMPONI (877-697-4676)**.

SimponiOne®
SAFE RETURNS™
Simple Safe Disposal. Only From SimponiOne.®

IMPORTANT SAFETY INFORMATION

SIMPONI® (golimumab) is a prescription medicine. SIMPONI® can lower your ability to fight infections. There are reports of serious infections caused by bacteria, fungi, or viruses that have spread throughout the body, including tuberculosis (TB) and histoplasmosis. Some of these infections have been fatal. Your doctor will test you for TB before starting SIMPONI® and will monitor you for signs of TB during treatment. Tell your doctor if you have been in close contact with people with TB. Tell your doctor if you have been in a region (such as the Ohio and Mississippi River Valleys and the Southwest) where certain fungal infections like histoplasmosis or coccidioidomycosis are common.

You should not start SIMPONI® if you have any kind of infection. Tell your doctor if you are prone to or have a history of infections or have diabetes, HIV or a weak immune system. You should also tell your doctor if you are currently being treated for an infection or if you have or develop any signs of an infection such as:

- fever, sweat, or chills
- muscle aches
- cough
- shortness of breath
- blood in phlegm
- weight loss
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- burning when you urinate or urinate more than normal
- feel very tired

Unusual cancers have been reported in children and teenage patients taking TNF-blocker medicines. For children and adults taking TNF blockers, including SIMPONI®, the chances for getting lymphoma or other cancers may increase. You should tell your doctor if you have had or develop lymphoma or other cancers.

Tell your doctor about all the medications you take including ORENCIA (abatacept), KINERET (anakinra), ACTEMRA (tocilizumab), RITUXAN (rituximab), or another TNF blocker, or if you are scheduled to or recently received a vaccine. People taking SIMPONI® should not receive live vaccines.

Reactivation of hepatitis B virus has been reported in patients who are carriers of this virus and are taking TNF-blocker medicines, such as SIMPONI®. Some of these cases have been fatal. Your doctor should do blood tests before and after you start treatment with SIMPONI®. Tell your doctor if you know or think you may be a carrier of hepatitis B virus or if you experience signs of hepatitis B infection, such as:

- feel very tired
- dark urine
- skin or eyes look yellow
- little or no appetite
- vomiting
- muscle aches
- clay-colored bowel movements
- fevers
- chills
- stomach discomfort
- skin rash

Heart failure can occur or get worse in people who use TNF blockers, including SIMPONI®. Your doctor will closely monitor you if you have heart failure. Tell your doctor right away if you get new or worsening symptoms of heart failure like shortness of breath or swelling of your lower legs or feet.

Rarely, people using TNF blockers, including SIMPONI®, can have nervous system problems such as multiple sclerosis or Guillain-Barré syndrome. Tell your doctor right away if you have symptoms like vision changes, weakness in your arms or legs, or numbness or tingling in any part of your body.

Serious liver problems can happen in people using TNF blockers, including SIMPONI®. Contact your doctor immediately if you develop symptoms such as feeling very tired, skin or eyes look yellow, poor appetite or vomiting, or pain on the right side of your stomach.

Low blood counts have been seen with people using TNF blockers, including SIMPONI®. If this occurs, your body may not make enough blood cells to help fight infections or help stop bleeding. Your doctor will check your blood counts before and during treatment. Tell your doctor if you have signs such as fever, bruising, bleeding easily, or paleness.

Rarely, people using TNF blockers have developed lupus-like symptoms. Tell your doctor if you have any symptoms such as a rash on your cheeks or other parts of the body, sensitivity to the sun, new joint or muscle pain, becoming very tired, chest pain or shortness of breath, swelling of the feet, ankles, and/or legs.

New or worse psoriasis symptoms may occur. Tell your doctor if you develop red scaly patches or raised bumps that are filled with pus.

Tell your doctor if you are pregnant, planning to become pregnant or are breastfeeding or have a baby and were using SIMPONI® during pregnancy. Tell your baby's doctor before your baby receives any vaccine because of an increased risk of infection for up to 6 months after birth.

Tell your doctor if you are allergic to rubber or latex. The needle cover contains dry natural rubber.

Tell your doctor if you have any symptoms of an allergic reaction while taking SIMPONI® such as hives, swollen face, breathing trouble, chest pain. Some reactions can be serious and life-threatening.

Common side effects of SIMPONI® include: upper respiratory tract infection, reaction at site of injection, and viral infections.

Please read the Medication Guide for SIMPONI® and discuss any questions you have with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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