

July 28, 2010

Integrated Waste Management Specialist Attention: Mr. Burke Lucy Department of Resources Recycling and Recovery (CalRecycle) 1001 I Street, PO Box 4025 Sacramento, CA 95812

Re: Senate Bill 486—Ferring Plan

Products: Repronex, Menopur, Bravelle, and Novarel

Dear Mr. Burke Lucy:

In response to California Senate Bill 486, Ferring submits the following plan describing our proposed action to support the safe collection and proper disposal of home-generated sharps waste:

Ferring supports the safe collection and proper disposal of home-generated sharps waste through educating patients who use our injectible products about safe sharps management. This information will be offered in the product labeling and online.

1) The following wording will be proposed to FDA for approval to included under the directions for use in the product labeling (package insert and patient package insert) for products usually intended to be self-injected at home:

Disposing of needles and syringes:

To safely dispose of medical sharps, place used needles and syringes in a closeable, puncture-resistant container, such as a red biohazard sharps container. Sharps containers should then be taken to a collection center for proper disposal. Ask your physician or pharmacist or reference our website for more information about safely disposing used sharps.

State Laws:

In some states, it is illegal to throw away medical sharps in household garbage, recycling, and compost bins. Needles and other sharps must be placed in an approved sharps container and disposed of at an approved drop-off site.

More information and options for sharps disposal can be found at our website www.ferringusa.com/sharps

2) The following information will be available for patients on the Ferring internet site:

Medical Sharps Disposal Information

Improper disposal of medical sharps (including needles, syringes, and lancets) can cause needle-stick injuries and spread infectious diseases. It is important to dispose of needles properly in order to avoid needle sticks at home and protect garbage and recycling workers.

How to Safely Dispose of Sharps

Place needles and other medical sharps in a closeable, puncture-resistant container, such as a red biohazard sharps container. When the container is three quarters full, seal and take the container to a collection center for proper disposal.

Where to Dispose of Sharps:

The Coalition for Safe Community Needle Disposal provides an online database to help you find a nearby disposal center: http://www.safeneedledisposal.org/dispcenters.html

State Laws:

In some states, it is illegal to throw away medical sharps in household garbage, recycling, and compost bins. Needles and other sharps must be placed in an approved sharps container and disposed of at an approved drop-off site.

More information on sharps disposal and hazardous waste management in California can be found at the California Department of Resources Recycling and Recovery website.

- General Information: http://www.calrecycle.ca.gov/HomeHazWaste/Sharps/Household.htm
- Find a Collection Facility: http://www.calrecycle.ca.gov/HomeHazWaste/Healthcare/Collection/
- A Guide to Syringe Disposal: http://www.calrecycle.ca.gov/HomeHazWaste/sharps/Brochure.pdf

Senate Bill 486—Ferring Plan Products: Repronex, Menopur, Bravelle, and Novarel Page 3

Should you have any questions or require further information, please call (973) 796-1730 or email john.kim@ferring.com .

Sincerely,

John Kim, R.Ph., J.D.

Senior Director, Regulatory Affairs