SICOR Pharmaceuticals, Inc.
A subsidiary of TEVA Pharmaceuticals USA
19 Hughes
Irvine, CA 92618-1902
Phone: 800.806.4226
Fax: 949.855.8210

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

July 24, 2006

RE: Request for Assessment of Safety and Effectiveness
Oxaliplatin for Injection
50 mg/vial and 100 mg/vial

CITIZEN PETITION

Dear Sir or Madam:

This petition is submitted in duplicate pursuant to 21 CFR 10.30 and in accordance with the regulation of 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons, as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Eloxatin™ (Oxaliplatin for Injection), 50 mg/vial and 100 mg/vial, NDA No. 21-492 held by Sanofi Aventis has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons. In addition, we request the Commissioner to confirm the eligibility of Eloxatin™ (Oxaliplatin for Injection) as a Reference Listed Drug such that it will be allowed to form the basis of an ANDA.

B. Statement of Grounds

The *Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluation* (Electronic Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act). The main criterion for the inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons.

In August 2002, the original Eloxatin™ for Injection was approved. In January 2005, Sanofi Aventis US received approval of an aqueous solution formulation of Eloxatin™

for treatment of the same indications that are claimed by the previously approved, lyophilized dosage form. In April 2006, both of Sanofi Aventis US's lyophilized and liquid drug products appeared in the FDA's Electronic Orange Book (see attached).

Based on package inserts obtained from the FDA's Drugs@FDA website, the safety information in the respective labeling of Sanofi Aventis US's Eloxatin™ for Injection is identical to Sanofi Aventis US's Eloxatin™ Injection. Attached is the patient information approved in March 2006 that includes both products. To date, no specific MedWatch notices or other labeling updates have been posted for Sanofi Avendtis' lyophilized product. In addition, based on available data from IMS, both liquid and lyophilized products were distributed in the US market during the fourth quarter of 2005.

Recently, Sanofi Aventis' Eloxatin™ (Oxaliplatin for Injection), 50 mg/vial and 100 mg/vial, was moved to the Discontinued Drug Products section of the Electronic Orange Book.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.0(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which petition relies, and that includes representative data and information known to the petitioner, which is unfavorable to the petition.

We trust you will find this citizen petition satisfactory for your review. If there are any questions concerning this request, please do not hesitate in contacting me at (949) 455-4728. I can also be contacted by facsimile at (949) 583-7351.

Sincerely,

Tania Hoffman

Tania Hoffman
Project Specialist, Regulatory Affairs
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Active Ingredient Search Results from "OB_Rx" table for query on "oxaliplatin."

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
021759		Yes	OXALIPLATIN	INJECTABLE; IV (INFUSION)	100MG/20ML (5MG/ML)	ELOXATIN	SANOFI SYNTHELABO
021492		Yes	OXALIPLATIN	INJECTABLE; IV (INFUSION)	100MG/VIAL	ELOXATIN	SANOFI SYNTHELABO
021759		Yes	OXALIPLATIN	INJECTABLE; IV (INFUSION)	50MG/10ML (5MG/ML)	ELOXATIN	SANOFI SYNTHELABO
021492		Yes	OXALIPLATIN	INJECTABLE; IV (INFUSION)	50MG/VIAL	ELOXATIN	SANOFI SYNTHELABO

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through December, 2005

Patent and Generic Drug Product Data Last Updated: February 16, 2006

PATIENT INFORMATION

ELOXATIN®
(OXALIplatin for injection)
and
ELOXATIN®
(OXALIplatin injection)
INJECTION

Read this information carefully as you start using ELOXATIN. It will help you learn more about ELOXATIN. This information does not take the place of talking to your doctor about your medical condition or your treatment. Ask your doctor about any questions you have.

What is ELOXATIN?

ELOXATIN (eh-LOX-ah-tin) is an anticancer (chemotherapy) medicine that is used:

- to treat adults with stage III colon cancer after surgery to remove the tumor.
- with other anti-cancer medicines called 5-fluorouracil (5-FU) and leucovorin (LV) to treat adults with advanced colon or rectal cancer (colo-rectal cancer).

ELOXATIN with infusional 5-FU and LV was shown to lower the chance of colon cancer returning when given to patients with stage III colon cancer after surgery to remove the tumor. It is not known if ELOXATIN increases survival in patients with stage III colon cancer. ELOXATIN with infusional 5-FU and LV was also shown to increase survival, shrink tumors and delay growth of tumors in some patients with advanced colorectal cancer."

The use of ELOXATIN in children has not been studied.

Who should not use ELOXATIN?

Do not use ELOXATIN if:

- You are allergic to platinum. The active ingredient in ELOXATIN is oxaliplatin, which is a platinum-containing drug. Cisplatin (Platinol®) and carboplatin (Paraplatin®) are other chemotherapy medicines that also contain platinum.
- You are pregnant. ELOXATIN may harm your unborn child. You should avoid becoming pregnant while taking ELOXATIN. Talk with your doctor about how to avoid pregnancy.

Tell your doctor:

- You are breast feeding. We do not know if ELOXATIN can pass through your milk and if it can harm your baby. You will need to decide whether to stop breast feeding or not to take ELOXATIN.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines and herbal supplements. ELOXATIN may affect how they work in your body.

How is ELOXATIN given to me?

ELOXATIN is given to you through your veins (blood vessels).

Your doctor will prescribe ELOXATIN in an amount that is appropriate for you. Your doctor will treat you with several medicines for your cancer. It is very important that you do exactly what your doctor and nurse have taught you to do. Some medicines may be given to you before ELOXATIN to help prevent nausea and vomiting.

ELOXATIN is given with 2 other chemotherapy drugs, leucovorin and 5-FU. Each treatment course is given to you over 2 days. You will receive ELOXATIN on the first day only. There are usually 14 days between each chemotherapy treatment course.

Treatment Day 1:

ELOXATIN and leucovorin are put into a vein through a thin plastic tube (intravenous infusion or I.V.) and given for 2 hours. You will be watched by a healthcare provider during this time.

Right after the ELOXATIN and leucovorin are finished, 2 doses of 5-FU will be given. The first dose is given right away into your I.V. tube. The second dose will be given into your I.V. tube over the next 22 hours, using a pump device.

Treatment Day 2:

You will not get ELOXATIN on Day 2. Leucovorin and 5-FU will be given the same way as on Day 1.

During your treatment with ELOXATIN:

- It is important for you to keep all appointments. Call your doctor if you must miss an appointment. There may be special instructions for you.
- Your doctor may change how often you get ELOXATIN, how much you get, or how long the infusion will take.
- You and your doctor will discuss how many times you will get ELOXATIN.

The 5-FU will be given through your I.V. with a pump. If you have any problems with the pump or the tube, call your doctor, your nurse, or the person who is responsible for your pump. You should never allow anyone other than a healthcare provider to touch your infusion pump or tubing.

What activities should I avoid while under treatment with ELOTAXIN?

- Avoid cold temperatures and cold objects. Cover your skin if you must go outside in cold temperatures.
- Do not drink cold drinks or use ice cubes in drinks.
- Do not put ice or ice packs on your body.

See the end of this leaflet, ("How I can help reduce the side effects caused by cold temperatures?")

You need to discuss your level of activity during treatment with your doctor and your nurse. You should follow their advice.

What are the possible side effects of ELOXATIN?

ELOXATIN can cause allergic reactions.

Get emergency help right away if:

- You suddenly have trouble breathing.
- Your throat feels like it is closing up.

Call your doctor right away if you have any of the following:

- Other signs of allergic reaction
  - Rash
  - Hives
  - Swelling of your lips or tongue
  - Sudden cough

Call your doctor if you get any of the following:

- Fever or signs of infection (redness and swelling at the intravenous site, pain on swallowing, cough that brings up mucous, sore throat, shivering, pain on urination)
- Vomiting that is persistent
- Diarrhea (frequent, loose, watery bowel movements)
- Signs of dehydration (too much water loss)
  - Tiredness
  - Thirst
  - Dry mouth
  - Lightheadedness (dizziness)
  - Decreased urination

Tell your doctor if you get a dry cough and have trouble breathing (shortness of breath) before your next treatment. These may be signs of a serious lung disease.

ELOXATIN can affect how your nerves work and make you feel (peripheral neuropathy). Tell your doctor right away, if you get any signs of nerve problems listed below:

- Very sensitive to cold temperatures and cold objects
- Trouble breathing, swallowing, or saying words, jaw tightness, odd feelings in your tongue, or chest pressure
- Pain, tingling, burning, (pins and needles, numb feeling) in your hands, feet, or around your mouth or throat, which may cause problems walking or performing activities of daily living

The first signs of nerve problems may occur with the initial treatment. The nerve problems can also start up to 2 days afterwards. If you develop nerve problems, the amount of ELOXATIN in your next treatment may be changed.

For information on ways to lessen or help with the nerve problems see the end of this leaflet, "How I can help reduce the side effects caused by cold temperatures?" Other common side effects from ELOXATIN include nausea, vomiting, diarrhea, constipation, mouth sores, stomach pain, fever, loss of appetite, and tiredness.

These are not all the possible side effects of ELOXATIN. For more information, ask your doctor or pharmacist.

How can I reduce the side effects caused by cold temperatures?

- Cover yourself with a blanket while you are getting your ELOXATIN infusion.
- Do not breathe deeply when exposed to cold air.
- Wear warm clothing in cold weather at all times. Cover your mouth and nose with a scarf or a pull-down cap (ski cap) to warm the air that goes to your lungs.
- Don't take things from the freezer or refrigerator without wearing gloves.
- Drink fluids warm or at room temperature.
- Always drink through a straw.
- **Do not** use ice chips if you have nausea or mouth sores. Ask your nurse about what you can use.
- Be aware that most metals are cold to touch especially in the winter. These include your car door and mailbox. Wear gloves to touch cold objects.
- Do not run the air conditioning at high levels in the house or in the car in hot weather.
- If your body gets cold, warm-up the affected part. If your hands get cold, wash them with warm water.
- Always let your nurse and doctor know **before** your next treatment how well you did since your last visit.

This list is not complete and your healthcare provider may have other useful tips for helping you with these side effects.

General Information about the safe and effective use of ELOXATIN.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets.

This leaflet summarizes the most important information about ELOXATIN. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about ELOXATIN that is written for health professionals.

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/s/

Robert Justice
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