Exhibit 2. Doxycycline EUA Fact Sheet for Recipients

Doxycycline EUA Fact Sheet for Recipients

You are receiving doxycycline because you may have been exposed to the anthrax germ, which can be deadly. You do not have to take this drug, but taking doxycycline to treat anthrax will reduce your risk of getting sick and dying. If possible, you may want to discuss with a health care professional the benefits and risks described in this fact sheet, or any available alternatives.

The full course of treatment is usually 60 days. If you have received a partial supply, public officials will announce where you can get the rest of the medicine.

What is anthrax?

Anthrax is a serious disease caused by the germ *Bacillus* anthracis. People who breathe in (inhale) anthrax germs are at risk of serious illness, *including death*. However, you can't get anthrax from another person.

- First symptoms are cold-like or flu-like symptoms, e.g., a sore throat, mild fever, muscle aches.
- Later symptoms are cough, chest discomfort, shortness of breath, tiredness, muscle aches.

Symptoms usually occur within 7 days of inhaling anthrax germs, but can take up to 42 days to appear. See a doctor immediately if you have symptoms.

What is doxycycline?

Doxycycline is a prescription drug approved by the Food and Drug Administration (FDA) to prevent anthrax. Federal authorities have specially authorized certain uses of doxycycline,* including use **without** a prescription, for this emergency situation. If you take doxycycline as directed and begin to feel sick anyway, **get medical care right away**.

How do I take doxycycline?

- Adults and those 8 years and older and children 89 lbs (40 kg) or more take one pill (100 mg) in the morning and one pill in the evening on an empty stomach with a full glass of water.
- If you get an upset stomach or indigestion, take it with some food or milk. Be sure to drink lots of fluids.
- Children under 89 lbs (40 kg) and adults who can't swallow
 a pill follow the directions provided to you on crushing
 and mixing doxycycline.
- If you have received the liquid form, follow the directions on the bottle; you can store it at room temperature for up to 14 days.
- If you miss a dose, take only next scheduled dose Do not take two doses at one time.
- Doxycycline may not work as well when taken with some medicines. Take it 2 hours before or 2 hours after taking: antacids; multivitamins or supplements with calcium, iron, magnesium, or sodium bicarbonate; Sucralfate (Carafate); Colestipol (Colestid); cholestyramine; Didanosine; Bismuth subsalicylate (Helidac) (Pepto Bismol) (Kaopectate); or any other products to treat indigestion, nausea, or diarrhea.

- Doxycycline may affect dosing of certain blood thinners or seizure medicines; call your doctor if you are on these medications.
- Keep the pills dry; store them between 68–77°F (20–25°C).
- Keep containers out of the reach of children and pets; call the poison control center if accidental ingestion occurs (1-800-222-1222).

Who should NOT take doxycycline?

<u>STOP</u> taking the medicine if you get any of these serious, but rare, side effects; get medical help right away (go to the Emergency Room or call 911):

- swelling of the tongue, hands, or feet
- closing of the throat
- > trouble breathing
- severe itching or rash, especially hives and welts
- severe stomach cramps with high fever or bloody diarrhea
- yellowing of the eyes or skin or dark-colored urine
- pain when swallowing
- unusual bleeding or bruising
- severe headaches, dizziness, or double vision

Keep taking the medicine if you have:

- mild nausea or vomiting, upset stomach, loose stools
- vaginal yeast infection

Do not take doxycycline if you have had a severe allergic reaction to doxycycline or another tetracycline drug.

Are there other possible severe side effects?

- Serious liver problems (liver failure)
- Sensitivity to the sun
- Discolored teeth, poor tooth enamel in children under the age of 8 or when taken by their mothers during the last half of pregnancy or while nursing
- Slowed bone growth in children
- Birth control pills stop working. Use another form of birth control until you finish taking all of your doxycycline

What is unknown about the emergency use of doxycycline?

The benefit of providing you with emergency access to an initial supply of doxycycline is expected to outweigh the risks. However, it is unknown how well these emergency instructions will be used, how many individuals will receive the full, 60-day course of post-exposure prophylaxis (PEP), or what the impact of dispensing without an individual prescription will be.

How do I report side effects or errors?

Tell your doctor right away and report side effects or medication errors to MedWatch at www.fda.gov/medwatch (1-800-FDA-1088).

CONTACTS: If you have any questions, please contact XXXXX (placeholder for stakeholder's specific contact information).