

Key Differences for State and Local Planners

1. To be legally distributed or dispensed, SNS-supplied ciprofloxacin and doxycycline used as anthrax countermeasures, must be distributed or dispensed under an EUA; the written materials accompanying these medications are not part of FDA approved labeling.
2. EUA doxycycline and ciprofloxacin fact sheets will now be provided by the federal government. These fact sheets cannot be finalized until the EUA is authorized (at the time of an event).
3. To be legally distributed, fact sheets distributed to recipients and health care providers receiving SNS assets must be authorized under the EUA.
4. It will be the state or local's responsibility to provide copies of EUA-authorized fact sheets to health care providers and recipients receiving SNS assets.
5. CDC has proposed in its pre-EUA submission that doxycycline tablet crushing instructions provided to recipients be the FDA-supplied version, as found at http://www.fda.gov/cder/drug/infopage/penG_doxy/home_prep.htm. These instructions cannot legally accompany the drugs unless they are authorized under any EUA that might be issued.
6. Ciprofloxacin home preparations instructions are not provided in CDC's pre-EUA submission due to the unpalatable nature of this drug when dissolved and mixed with food.
7. CDC's pre-EUA submission covers the fact that SNS supplied unit of use bottles do not have all the required information on the label (such as patient name, prescriber, etc). CDC is not proposing that additional information be added to unit of use bottles of tablets.
8. CDC's pre-EUA submission proposes that a patient's name and dose (in ml) be added to dispensed bottles of oral suspension.
9. CDC's pre-EUA submission covers SNS assets that have been tested under the Shelf Life Extension Program (SLEP), under which expiration dates may be extended.
10. CDC's pre-EUA submission covers an initial 10-day supply which will be dispensed. This will be followed by an additional 50-day supply if deemed necessary. The 10-day supply is not referred to in FDA approved labeling for anthrax (which states 60-days of prophylaxis is recommended).
11. Legal dispensing of these SNS assets to patients may not occur until the EUA is authorized for these assets.
12. A pre-EUA for non-SNS assets is not currently being developed.
13. Non-SNS assets can be used before SNS assets arrive, but if they are not used under EUA or strictly in accordance with the drugs' approval, then PREP Act liability immunity protections may not be in effect.
14. Any EUA issued will likely impose some conditions at the time of the authorization that must be followed. These conditions will be outlined in FDA's EUA at the time of the event. Examples of conditions that could be imposed include:

- a. provide authorized health care provider and recipient fact sheets and doxycycline crushing instructions at the POD
- b. provide access to the package insert for each medication dispensed at the POD (could be one hard copy per location, or internet access etc)
- c. health care providers should reconstitute oral suspensions and write patient's name and dose on the label of oral suspensions
- d. provide written or graphic materials consistent with and not exceeding EUA materials (such as information provided on posters etc)
- e. follow established procedures for authorized changes to written information
- f. make records available to FDA upon request

These are examples of the potential conditions, but FDA could impose other conditions or different conditions.