

The FDA is reminding patients and health care professionals not to use drug products intended to be sterile made by Pacifico National Inc., an outsourcing facility doing business as AmEx Pharmacy, in Melbourne, Florida. The drugs—which include compounded ophthalmic products among other drug products — pose unnecessary risks due to significant quality and sterility concerns.

An FDA inspection of AmEx Pharmacy’s facility found conditions that could cause the company’s drugs to become contaminated or otherwise pose risks to patients. As a result, the agency recommended on June 25th that AmEx Pharmacy voluntarily recall all unexpired drugs intended to be sterile and cease sterile operations until the company takes adequate corrective actions. However, AmEx Pharmacy declined to initiate a recall of all unexpired drugs intended to be sterile and has not provided adequate assurances regarding the sterility and quality of its remaining and newly manufactured products.

Because of this, the agency today issued a formal request to the outsourcing facility to recall all non-expired lots of drugs intended to be sterile. The FDA is also urging consumers to stop using these drugs and dispose of them immediately. Additionally, the agency is requesting the outsourcing facility cease production of drugs intended to be sterile until adequate remediation actions have been taken.

Find details at: [FDA requests recall of sterile compounded drug products produced by Pacifico National Inc., dba AmEx Pharmacy](#)

For more information, please visit FDA's [Human Drug Compounding](#) web site.