FDA notification regarding unapproved drugs included in kits

Stop distributing unapproved drugs included in kits

On September 20, 2024, FDA requested (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/azurity-pharmaceuticals-inc-656489-09202024) Azurity Pharmaceuticals Inc. stop distributing unapproved drugs marketed as "Unit-of-Use Prescription Compounding Kits," including:

- FIRST Lansoprazole
- FIRST Pantoprazole
- FIRST Metronidazole
- FIRST Mouthwash BLM

These kits have not been proven safe and effective and do not qualify for exemptions under the compounding provisions in sections 503A (/drugs/human-drug-compounding/section-503a-federal-food-drug-and-cosmetic-act) and 503B (/drugs/human-drug-compounding/text-compounding-quality-act) of the Federal Food, Drug and Cosmetic Act.

FDA encourages companies marketing unapproved drugs to seek FDA approval. The NDC Directory (https://dps.fda.gov/ndc) identifies FDA approval status of all prescription drug marketed in the United States.