DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	07/14/2014 - 07/28/2014 FEI NUMBER 3005331940

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William L. Swail, President/Owner

FIRM NAME	STREET ADDRESS
Peoples Pharmacy, Inc. #2	3801-B S Lamar Blvd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Austin, TX 78704-7943	Producer of Drug Products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, your firm does not have a stability program to justify the Beyond-Use-Dates (BUD) placed on all your drug products. Your firm's BUDs are usually from 14 days to 180 days depending on the drug product and dosage form. Examples include the following:

a) Lot #06-27-2014@14 of hydroxyzine pamoate 25mg/5mL suspension has a BUD of 90 days.
b) Lot #06-03-2014@25 of promethazine (strawberry dye-free) 25mg/5mL has a BUD of 30 days.
c) Lot #06-20-2014@14 of itraconazole/tobramycin/dexamethasone 0.5/0.3/0.13% ear cream has a BUD of 180 days.

OBSERVATION 2

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, your firm does not perform any testing on finished drug products you manufacture, including potency testing.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Margaret M. Annes, CSO Margaret M. Annes Patty P. Kaewussdangkul, CSO ~~Patty~~ P. Kaewussdangkul	07/28/2014