During an inspection of your firm (31) we observed:

Investigations are inadequate. Specifically, deviation-DE-U08-000277 was initiated on 22-June-2015 because none of the following (API) batches were submitted for stability:

(3) (4) (9) (4) (9) (4) (9)

The deviation record contains field, "Number of previous deviations in this product/system". This field requires previous deviations of the same product or deviation type to be reported. No previous deviations were reported in this field. Deviation-DE-U08-000277 was reported approximately 2 months previously for failing to submit batches of (9) (4) on stability.

This is a repeat observation from the 2014 inspection.