THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Health and Social Services

Division of Public Health
Section of Epidemiology

3601 C Street, Suite 540
Anchorage, Alaska 99503-5932
Main: 907.269.8000
Fax: 907.562.7802

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Dear Public Health Nurse or Provider:

As of 6/30/2020, out of an abundance of caution, the Alaska TB Program issued a recommendation against initiating any new starts of the rifapentine-containing 3HP regimen for treatment of latent TB infection (LTBI) in response to CDC reports of a newly-detected impurity in Priftin© (rifapentine). Based on updated guidance from CDC, the Alaska TB program is now rescinding this recommendation.

From a letter distributed by the CDC's Division of Tuberculosis Elimination (DTBE) on 9/11/2020:

> "On August 26, 2020, FDA issued a statement related to mitigating shortages of rifampin and rifapentine and its interim guidance to continue using these drugs in the treatment of tuberculosis (TB) after nitrosamine-class impurities were detected through recently adopted regulatory standards to assay all medications for nitrosamines. FDA sets standard limits on the concentrations of the impurities and is allowing distribution of rifampin and rifapentine if the concentrations do not exceed interim limits while the impurities are investigated."
>
> "CDC's DTBE recommends that providers continue prescribing rifampin and rifapentine for all TB and latent TB infection (LTBI) treatment per existing guidelines."

The FDA statement is available here: https://www.fda.gov/drugs/drug-safety-and-availability/fda-works-mitigate-shortages-rifampin-and-rifapentine-after-manufacturers-find-nitrosamine

In alignment with this updated guidance from CDC and FDA, the Alaska TB Program is no longer restricting the drug therapy containing rifapentine (3HP) per CDC guidelines for the treatment of latent TB infection.

Please contact the Alaska TB Program at 269-8000 with any questions.

Sincerely,

Michelle Rothoff, MD
State of Alaska TB Controller