

exhibit #18

847/391-4406 Fax: 847/375-1114

1600 Feehanville Dr Mount Prospect, IL 60056 help@nabp.pharmacy

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Lemrey "Al" Carter, Executive Director/Secretary

DATE: December 16, 2021

RE: FDA Letter on Ivermectin

On December 13, 2021, the US Food and Drug Administration (FDA) issued a letter to NABP regarding drug products containing ivermectin, including compounded drug products, being offered for sale to treat or prevent Coronavirus Disease 2019 (COVID-19). The letter from FDA is attached.

Attachment

cc: NABP Executive Committee



December 13, 2021

Lemrey "Al" Carter, MS, PharmD, RPh Executive Director/Secretary National Association of Boards of Pharmacy 1600 Feehanville Dr Mount Prospect, IL 60056 acarter@NABP.pharmacy

Dear Dr. Carter:

The purpose of this letter is to bring to the attention of the National Association of Boards of Pharmacy information related to drug products containing ivermectin being offered for sale with claims that such products treat or prevent "Coronavirus Disease 2019" (COVID-19). Recently, FDA has received complaints about compounding pharmacies selling drug products containing ivermectin, claiming that they can treat or prevent COVID-19.

Ivermectin tablets are FDA-approved for humans at very specific doses to treat some parasitic worms, and there are FDA-approved topical (on the skin) formulations for head lice and skin conditions like rosacea. However, the FDA has neither authorized nor approved any ivermectin drug product for use in preventing or treating COVID-19. Although clinical trials assessing ivermectin tablets for the prevention or treatment of COVID-19 in people are ongoing, currently available data do not show that ivermectin is safe or effective for the prevention or treatment of COVID-19.

Additionally, as the agency has <u>previously explained</u>, there are many side effects associated with ivermectin, including skin rash, nausea, vomiting, diarrhea, stomach pain, facial or limb swelling, neurologic adverse events (dizziness, seizures, confusion), sudden drop in blood pressure, severe skin rash potentially requiring hospitalization and liver injury (hepatitis).

Using ivermectin products in preventing or treating COVID-19 may pose risks to patient health or lead to delays in getting effective treatment of COVID-19. Drug products that claim to treat or prevent COVID-19 but are not proven safe and effective for those purposes can place consumers at risk of serious harm.

We are also sending this letter to the Federation of State Medical Boards to facilitate communication among associations with shared goals regarding these matters.



We look forward to continuing to work with you on matters related to drug compounding. If you have questions, please contact the Office of Compounding Quality and Compliance at compounding@fda.hhs.gov.

Sincerely,

Shannon Glueck, PharmD Acting Branch Chief Branch 4 Division of Compounding II Office of Compounding Quality and Compliance Office of Compliance Center for Drug Evaluation and Research