

Exhibit 18



December 13, 2021

Humayun J. Chaudhry, DO, MS, FACP, FACOI
President and Chief Executive Officer
Federation of State Medical Boards
400 Fuller Wiser Road, Suite 300
Euless, TX 76309
hchaudhry@fsmb.org

Dear Dr. Chaudhry:

The purpose of this letter is to bring to the attention of the Federation of State Medical Boards 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 [previously explained](#), 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 National Association of Boards of Pharmacy 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 N.
Glueck -S

Digitally signed by Shannon N. Glueck -S
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ou=People, o.9.2342.19200300.100.1.1=2002034167,
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Shannon Glueck, PharmD
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