FDA ad watchdog slaps 2 pharmas with warning letters for promo emails, Google link

FDA's promotions enforcement arm sent warning letters to two pharma companies recently for improper communications, raising the total to four for the year. (FDA)

The FDA has fired off warning letters to Nephron Pharmaceuticals and obesity med Contrave's owner, Nalpropion Pharmaceuticals.

The Office of Prescription Drug Promotions (OPDP) reprimanded Nephron for emails promoting budesonide, while Nalpropion's warning centered on a Google link promoting Contrave. Warning letters are OPDP's strongest rebuke for improper pharma promotions.

Nephron's letter concerned emails sent in July by CEO Lou Kennedy and a sales rep, touting its budesonide generic asthma drug as a treatment for symptoms of COVID-19.

The FDA pointed to a list of overly enthusiastic claims made in the email from Kennedy, beginning with the "prominent headline claim," in all caps, "BUDESONIDE RELIEVES RESPIRATORY SYMPTOMS ASSOCIATED WITH COVID-19."

In the email, Nephron wrote that "doctors and researchers" tout the asthma drug as a treatment for symptoms of the novel coronavirus. The hyperbole continued with the stated claim: "One physician, who went viral this month, called budesonide a 'silver bullet.' "

A second email from a Nephron sales rep included a link to a YouTube video supposedly featuring a physician talking about using budesonide with an antibiotic. The sales rep added to its email recipients: "You may want to share this with your respiratory team and pulmonary docs. Cost-effective way to treat Coronavirus!"

Kennedy confirmed receiving the FDA warning letter in an emailed statement, adding, "We are working diligently with FDA to resolve the matter."

Kennedy and Nephron made national news in July when they announced plans to spend $216 million to pitch in on COVID-19 manufacturing efforts. Kennedy said the South Carolina-based generics maker would expand its vaccine fill-finish capacity and warehousing space as part of an expansion effort in the state.

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Nephron said at the time it was talking to two "large pharmas" to use the drugmaker's new vaccine space, which Kennedy said could be online as soon as the first quarter of 2021.

In May, Nephron hosted GOP Sen. Lindsey Graham of South Carolina, who touted the drugmaker's role in producing American-made drugs. Kennedy told FiercePharma in the July interview that her company's mission has been to produce affordable medicines of the highest quality for U.S. patients.

The second warning letter from OPDP went to Nalpropion Pharmaceuticals for a sponsored link on Google search. The link made "false or misleading claims" about the risks associated with Contrave, the letter said. The drug, which carries a black box warning, is an obesity drug indicated for use along with diet and exercise.

OPDP noted the link promoted "lose 2-4x more weight on average than with diet and exercise alone!" but did not include any risk information. While the link did include a statement that readers should view safety information and a boxed warning, that's not enough to mitigate the risk omission, OPDP said. OPDP included the offending search page in its filing.

RELATED: FDA ad police smack Orexigen for leaving black-box risk out of Contrave TV ad

OPDP also noted that it had warned Contrave's previous owner, Orexigen Therapeutics, in 2017 over a TV ad that omitted risks. It wrote "we are concerned that Nalpropion is continuing promotion of Contrave in a manner that similarly fails to adequately convey risk information."

Nalpropion, which is owned by Currax Pharmaceuticals, bought the worldwide rights to Contrave and other assets from Orexigen in 2018 for $75 million in cash.

Both warning letters were based on reports filed to OPDP's Bad Ad program which allows people to anonymously disclose potential violations. They are the third and fourth warning letters issued so far in 2020.