

Message

From: StClair, Christie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=06618C5ED0E744A3BFE8443360018C26-STCLAIR, CH]
Sent: 10/16/2017 8:49:23 PM
To: Ed Maixner [Ex. 6] Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b293283291dc44e0b5d1c36be9281d8a-Press]
Subject: RE: News media inquiry on administrator's goals on promoting extra-label medication uses

Hi Ed,

I believe you meant to send this to the FDA, not EPA.

Christie

From: Ed Maixner [mailto:Ex. 6]
Sent: Monday, October 16, 2017 3:25 PM
To: Press <Press@epa.gov>
Subject: News media inquiry on administrator's goals on promoting extra-label medication uses

I want to ask Administrator Scott Gottlieb about his goals, in general, about easing restrictions on manufacturers promoting extra-label uses of FDA-approved drugs for animals and people. Please forward this to the appropriate FDA media contact with a request for meeting my late-Tuesday copy deadline.

FDA has, for example, proposed a guidance allowing for drug makers to freely send doctors results of research and other scientific information regarding extra-label uses of approved medications

[SEE <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm387652.pdf>],

and has proposed a draft guidance to simplify off-label uses of animal drugs by "Indexing of Legally Marketed Unapproved New Animal Drugs for Minor Species"

[SEE <https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm576037.htm>].

Mr. Gottlieb has written in the past about the benefits to health if the flow of information on off-label uses was less encumbered. So I want to learn if he wants to pursue some further in that direction as the head of FDA.

My copy deadline is COB Tuesday. Thank you in advance for your response.

Ed Maixner, Contributing Editor
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