

From: Christopher Hickman <chris.hickman@buzzfeed.com>
Sent: Monday, October 07, 2019 4:18 PM
To: Simpson, Cheree <Cheree.Simpson@fda.hhs.gov>; FDA FOIA <FDAFOIA@fda.hhs.gov>
Cc: Scott Pham <scott.pham@buzzfeed.com>
Subject: FOIA Request ID # 1955908 from BuzzFeed

To Whom It May Concern,

My name is Christopher Hickman and I am counsel to BuzzFeed News and its reporter Scott Pham.

As you know, Mr. Pham's request (FDA 1955908) seeking 1) all records associated with the FDA's inquiry into the misuse and abuse of gabapentinoids; 2) all records associated with the FDA's inquiry into the possible misuse and abuse of generic pregabalin; and 3) all talking points and draft talking points composed for Commissioner Scott Gottlieb's February 15, 2018 remarks at the Public Workshop on Strategies for Promoting Use and Appropriate Prescribing of Prescription Opioids, is currently being processed by your office. You received that request on July 25, and later acknowledged that request on August 1. Further, in a telephone conversation with Mr. Pham on September 12, during which he asked for an update on the status of his request, you purported to place it in the "complex" queue and estimated a 18-24 months' time for completion.

We contest that Mr. Pham's request is "complex" in nature. As FDA guidance explains, "complex" track classifications typically refer to 510k, De Novo, and PMA records. Mr. Pham's request entails only those records that refer to use and/or misuse of gabapentinoids and generic pregabalin, both of which have been approved for use by the FDA and, therefore, appear to be inconsistent with the complex track designation. Moreover, these documents refer to issues publicly discussed and described by the Commissioner as pressing and time sensitive. He

Exhibit D

described the agency's "swift attention" to the matter and the need to "get ahead of these problems." Therefore, we request that you place the request in the "simple" track consistent with this guidance.

We further request, pursuant to FOIA, an estimated date of completion for this request. As the request was received by the agency on August 1, 2019, we were expecting a response date of August 29, 2019 as described in the statutory time limits set forth in FOIA. We take our commitment to FOIA seriously, and require that government agencies follow the letter of the law as enacted by Congress.

Best,

Christopher Hickman

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Christopher Hickman | **BuzzFeed** | Senior Counsel, Media and Intellectual Property | 917.721.9534
[111 E. 18th Street, New York NY 10003](#)