



The Honorable Michael C. Burgess, M.D.  
Chairman  
Subcommittee on Health  
Committee on Energy and Commerce  
U.S. House of Representatives  
Washington, D.C. 20515

JUL 27 2018

Dear Chairman Burgess:

Thank you for providing the Food and Drug Administration (FDA or the Agency) with the opportunity to testify at the March 21, 2018, hearing before the Committee on Energy and Commerce, Subcommittee on Health, entitled "Combatting the Opioid Crisis: Prevention and Public Health Solutions." This letter is a response for the record to questions posed by the committee.

If you have further questions, please let us know.

Sincerely,

John Martin  
Principal Associate Commissioner  
for Legislative Affairs

Your questions are restated below in bold, followed by FDA’s response.

**The Honorable Michael C. Burgess, M.D.**

- 1) **Dr. Gottlieb, my discussion draft being considered at today’s hearing directs the Food and Drug Administration to issue guidance on how the agency will specifically provide accelerated approval and breakthrough therapy status for medicines developed to treat pain and addiction.**
  - a) **Should this bill pass Congress and be signed into law, would FDA be better equipped to facilitate the accelerated approval process for these therapies while engaging with the necessary stakeholders?**

The Administration has not taken a position on this legislation. We believe further consideration is needed on whether legislation is needed to accelerate the development of non-opioid therapies to treat pain and addiction. As a part of our commitment to the expedited programs authorized by FD&C Act section 506, FDA has already published detailed process guidance providing key information for a developer who might be interested taking advantage of breakthrough therapy designation, fast track designation and accelerated approval (as well as priority review, a related tool authorized in PDUFA). While this guidance is not product area-specific, it provides the needed information for a developer who might be interested in making use of designations and pathways for novel pain and addiction treatment therapies.

Typically, FDA refrains from issuing product area-specific guidance documents unless there is a need to address scientific or clinical issues specific to those products. It is not clear what scientific or clinical issues specific to application of our expedited programs to non-opioid or non-addictive medical products to treat pain or addiction would benefit from FDA guidance. To the extent sponsors have questions about how FDA’s expedited programs apply to their specific products, such questions are addressed in our existing guidance on the use of expedited programs in general and in meetings or other communications between FDA and individual sponsors. These latter interactions with FDA permit targeted, product-specific discussion of a type that is typically not possible in guidance – even product area-specific guidance.

- b) Do you have any additional thoughts about the draft legislation that you would like to share?**

FDA is committed to re-evaluating whether it would be beneficial to issue additional guidance on the applicability of the expedited programs to non-opioid and non-addictive medical products to treat pain or addiction. Such additional guidance, if needed, could be provided either by updating our existing guidance on expedited programs or issuing product area-specific guidance, if appropriate.

We recognize the importance of ensuring that sponsors (and other stakeholders) are aware that non-opioid and non-addictive medical products to treat pain or addiction may be eligible for one or more expedited programs. We believe, however, that the sponsors and potential sponsors of such products are already aware of these programs, and have been taking

advantage of them. We also believe that to the extent there is a need for additional outreach on application of the expedited programs to these products, FDA has, and is committed to using, other means to accomplish this, such as public meetings and discussion with individual sponsors.