Obtained via FOIA by Judicial Watch, Inc.

From: Gruber, Marion
To: Fink, Doran; Krause, Philip; Finn, Theresa; McVittie, Loris
Subject: RE: **UPDATE TO MANAGEMENT_ Moderna IND 19745 -- Request for TC re: EUA boost; Response to Feedback and additional questions**
Date: Friday, August 20, 2021 1:01:00 PM
Attachments: image001.png
image002.png
image003.jpg
image004.jpg
image005.jpg
image006.jpg
image007.jpg
image008.jpg

He keeps on telling me that following this approval, he will sit down with us to hammer out a plan to get on top of the workload because "while I was gone he actually did an inventory and determined that our workload is no longer manageable"……at the same time he encourages sponsors to send in submissions and I am sure promises fast turn-around.

From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Friday, August 20, 2021 12:46 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
Subject: RE: **UPDATE TO MANAGEMENT_ Moderna IND 19745 -- Request for TC re: EUA boost; Response to Feedback and additional questions**

I had to bite my tongue when Peter mentioned this morning we wouldn't be doing rushed reviews anymore so as not to ask about the booster doses that the administration promised to everyone by Sept 20!

FYI, the ACIP WG is thinking there is some merit to targeted booster doses for certain populations (e.g., HCW to avoid loss of workforce to illness, and elderly who are most at risk for hospitalization/death due to diminished response to primary series, subsequent waning, and dependence on neutralizing antibodies because of immunosenescence). However, that would be a complicated set of recommendations, and because those populations were targeted for primary series first, a broader recommendation based on time since primary series (e.g., at least 8 months) may accomplish the same thing.

And then there is the question of the data that will support these booster doses – maybe I'm wrong, but my understanding is that Pfizer is proposing that their sBLA include the Phase 1 booster data from a grand total of 23 subjects. I'm not sure what Moderna will have, but the data Fauci presented in the press conference was from NIAID studies, which was ~25 subjects per treatment arm.

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Friday, August 20, 2021 12:40 PM
To: Krause, Philip <Philip.Krause@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>; McVittie, Loris <Loris.McVittie@fda.hhs.gov>
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