

Outlook

RE: [EXTERNAL] FMD_483_EIR

From Rivero, Mark <Mark.Rivero@fda.hhs.gov>
Date Thu 8/17/2023 8:14 AM
To hp hybridpharma.com <hp@hybridpharma.com>
Cc Loyd-Jones, Ronda R <Ronda.Loyd-Jones@fda.hhs.gov>

Dear Dr. Rajalingam,

This email is to acknowledge receipt of your email, dated August 11, 2023. **FDA's FOIA Office reports the Agency no longer post FMD 145 letters because of a lack of resources.** Please refer to recent correspondence, dated August 8, 2023, from OCC Attorney, Margo Badawy, regarding the closure of Warning Letters and the subsequent issuance of FMD 145 copies of EIRs.

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U.S. FOOD & DRUG ADMINISTRATION

Handwritten note:

After this e-mail FDA posted more than one hundred (100) FMD 145 and not for Hybrid.

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From: hp hybridpharma.com <hp@hybridpharma.com>
Sent: Friday, August 11, 2023 7:10 PM
To: Rivero, Mark <Mark.Rivero@fda.hhs.gov>
Cc: Loyd-Jones, Ronda R <Ronda.Loyd-Jones@fda.hhs.gov>
Subject: [EXTERNAL] FMD_483_EIR

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Dear Mr. Rivero,

Thank for your responses so far.

- I appreciate if you look into the details what we requested. We like to have FMD-145, EIR for the 483s also.
- In a quick search, we came across few FMDs issued to 503B facilities for their 483s in the public domain.
The example is attached - which is extracted from FDA database in the public domain.
- There may not be a policy specifically written. But we would also like to have our EIRs released with FMD for the 483s.
- We sincerely expect the agency will close Hybrid Pharma's 483s and WL. All the 483s were properly and timely explained, corrected in detail over the years.

Expecting your reply.

Thank you,

Raja

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