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.

Mark W. Rivero
Compliance Officer, Compliance Branch
Office of Pharmaceutical Quality Operations
Division 2
Port Everglades Resident Post
U.S. Food and Drug Administration
Tel (954) 759-7718
mark.rivero@fda.hhs.gov

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

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

Hybrid Pharma,
1015 W. Newport Center Drive, Suite 106A
Deerfield Beach, Fl-33442
hp@hybridpharma.com
Ph: 954 708 2771
Fax: 954 708 2993