

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

CASE NO. 24-CV-62413-DAMIAN/VALLE

HYBRID PHARMA LLC,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,

Defendant.

**PLAINTIFF’S REPLY TO DEFENDANT’S OPPOSITION TO
PLAINTIFF’S MOTION TO COMPEL PRODUCTION OF DOCUMENTS
AND FOR LEAVE TO CONDUCT LIMITED DISCOVERY**

Plaintiff, Hybrid Pharma LLC (“Plaintiff”), by and through undersigned counsel, hereby replies to Defendant Food and Drug Administration’s (“Defendant”) Opposition to Plaintiff’s Motion to Compel Production of Documents and For Leave to Conduct Discovery [ECF 43].

BACKGROUND

In its opposition, Defendant couches this action as a mere disagreement on the records. This could not be further from the truth. Since registering with Defendant as an outsourcing facility, Plaintiff has nothing but diligently worked with the agency on addressing any concerns they may have following inspections. Despite Plaintiff’s efforts and even Defendant acknowledging satisfaction with such efforts in certain instances, Defendant continues to go to extreme measures beyond what is required by its own regulatory procedures contrary to its own records reflecting unlawful conduct requiring judicial review.

For decades, agencies, such as Defendant, are able to go to such extremes without recourse while hiding behind the tenuous legal shield of “final agency action.” In other words, many courts would refuse to permit a damaged business from seeking review from actions of an agency unless

the action challenged was “final agency action.” However, as reflected in this Court’s Order in response to Defendant’s Motion to Dismiss [ECF 29] and the parties’ previous case resolved just prior to this action [0:24-cv-61043] (i.e., forcing Defendant to comply with its own Code of Federal Regulations), Defendant cannot rely on such a shield any longer.

As a recap, the agency action at issue here is the issuance of a warning letter. A warning letter is a severe action and document of last resort issued to firms with a record of non-compliance who are unlikely to resolve same with violations of regulatory significance. Such letters are published on the internet for the public to observe which are devastating to any business that receives one whether the warning letter is warranted or not. Pursuant to Defendant’s own Regulatory Procedures Manual, the use of a warning letter **should not be issued** if the agency concludes that a firm’s corrective actions are **adequate** and that the violations that would have supported the letter **have been corrected**.

To try to mitigate the conduct brought to the attention of this Court, Defendant first downplays this action as a mere single count lawsuit brought pursuant to the Administrative Procedures Act (“APA”). This reflects that Defendant fundamentally misunderstands the legal framework open to an aggrieved party in this situation. For example, other parties in the same position as Plaintiff have already attempted to sue for damages under other theories but such theories do not prevail. *See e.g., Holistic Candlers v. U.S. Food Drug Admin*, 770 F. Supp. 2d 156, 161 (D.D.C. 2011) (Dismissing counts for violations of the plaintiff’s first, ninth, tenth, and fourteenth amendment rights related to the issuance of a warning letter). Thus, bringing an APA claim is nothing out of the ordinary. Next, Defendant claims Plaintiff’s efforts to seek additional discovery is a “sideshow” and was “long desired.” Given the allegations made by Plaintiff in its Complaint and First Amended Complaint (i.e., waiting years without any response to proposed

responses to inspection observations and Defendant's refusal to properly respond without obfuscation to its Citizen Petition), it is no secret that Plaintiff not only wants to get to the bottom of Defendant's conduct but has properly sought such review pursuant to an APA action. As discussed in Plaintiff's motion at issue which is not disputed by Defendant, in the event of bad faith or impropriety, additional discovery can be obtained. Again, there is nothing out of the ordinary with seeking same. Defendant even tries to paint undersigned counsel's request for more time to review over seven thousand pages within a thirty-day period as puzzling or part of some scheme which is absurd given undersigned is a solo practitioner. Finally, Defendant only addresses three of the four points raised by Plaintiff as to the 2016 Warning Letter ("2016 WL") and fails to acknowledge its own positions in such letter which are contrary to the evidence at issue. In summary, this is the agency's continued resistance to having to address an aggrieved party's complaints. The agency demands action within a 15 day period following the issuance of a warning letter but routinely takes years to respond in kind. Thus, dealing with government agencies should not be a one way street in which the agency does not interact by its own standards. As set forth in more detail below and in Plaintiff's initial motion, additional discovery should be permitted.

MEMORANDUM OF LAW

I. DEFENDANT'S EVASIVE AND FACTUALLY INCORRECT POSITIONS INDEPENDENTLY SUPPORT A FINDING OF BAD FAITH AND/OR IMPROPER BEHAVIOR

First, Plaintiff seeks the production of all internal agency communications discussing Plaintiff's warning letters and opinions and recommendations leading up to issuance of same. Defendant has raised the deliberative process privilege. However, given the bad faith and/or improper behavior established, Plaintiff should be permitted to examine the full decision-making

process, including the mental processes of the decision makers, in light of Defendant's decision to proceed in clear contradiction to the evidence presented.

To recap, the 2016 WL was issued over *one year later* following the Randazzo Letter with no further correspondence from Defendant prior to such issuance. The 2016 WL specifically alleged the following four observations: (1) Plaintiff compounded a product not listed on the agency's bulks or shortage list; (2) an unspecified "some" of Plaintiff's labels were "inadequate"; (3) Plaintiff did not upload a report listing drugs compounded upon registration; and (4) Plaintiff had not developed and implemented written processes for evaluating and reporting adverse events at the time of inspection. Again, *none of these alleged issues were mentioned in the Randazzo Letter, nor were all even mentioned in the 2016 Form 483 by Defendant's own inspector* (but were somehow immediately elevated to support the 2016 WL).

In support of item 1 of the 2016 WL, Defendant contended that investigators noted three substances – sildenafil, human chorionic gonadotropin, and testosterone cypionate – were not part of a drug listed on the 503B bulks list or shortage list. To the contrary, such basis was *not* an observation previously identified by the inspector during Defendant's 2016 inspection nor was it listed on the 2016 Form 483 (or to go even further, was not raised in the Randazzo Letter). Defendant did not even address this in its opposition which is telling as it was of no regulatory significance.

In support of item 2 of the 2016 WL, Defendant based this item on "some" unspecified labels reviewed during the 2016 inspection but later conceded in the 2016 WL itself that the corrective action set forth in Plaintiff's response to the 2016 Form 483 in August 2016 was "adequate" but *utilized this as a basis anyway*. The Randazzo Letter, issued over one year prior to the 2016 WL, similarly states that the labels were found to be "adequate." Yet again, Defendant

chose to run with this determination in direct contradiction to its own finding. Defendant concedes this in its opposition and provides no explanation whatsoever.

In support of item 3 of the 2016 WL, Defendant stated that Plaintiff did not submit a product report upon initially registering as an outsourcing facility *and* failed to list all products on subsequent reports. Again, neither the Randazzo Letter nor the inspector's Form 483 identify this as an issue. In its opposition, Defendant still contends an initial list was not provided despite email communications from Defendant itself directing Plaintiff to submit via email at the time of its registration. This further reflects the common theme in the case of Plaintiff...despite documents to the contrary Defendant decided to take a different position anyway.

Finally, in support of item 4 of the 2016 WL, Defendant stated that Plaintiff had not developed and implemented written processes for the surveillance, receipt, evaluation, and reporting of adverse events of drug products. Again, this item was not raised in the Randazzo Letter. In its opposition, Defendant contends that this is a simple debate over whether the operating procedure was deficient; however, this is incorrect framing. Here, Defendant's claim in the 2016 WL is that Plaintiff *lacked* a written process altogether, not that Defendant believed the process was deficient or needed additional revisions. Again, the Complaint standard operating procedure already existed at the time, and Defendant's contention is demonstrably false or Defendant fundamentally misunderstands its own actions.

Far from supplying a rationale that forecloses further inquiry, the record affirmatively documents a pattern of departures from Defendant's own procedural requirements without offering any basis for them. That is not a record that explains agency actions – **it is a record that demands explanation.**

The strength of this showing is confirmed by comparison to *Neighborhood Assistance Corp. of America v. U.S. Department of Housing and Urban Development*, No. 11-cv-1312 (RLW), 2011 U.S. Dist. LEXIS 91571 (D.D.C. 2011), where the court granted a motion for limited expedited discovery – including deposition of four agency officials – upon finding that the plaintiff had made “a strong preliminary showing that the agency acted improperly or in bad faith” through specific sworn affidavit testimony establishing that the agency had been targeting the plaintiff for two years leading up to the challenged regulatory action. The court found “good cause to allow limited discovery” based on that showing, without requiring conclusive proof of the very impropriety the depositions were designed to uncover. *Id.* at *3 - 4. Plaintiff’s showing is structurally identical and factually stronger: rather than sworn affidavit testimony about what agency officials said, Plaintiff points to what Defendant’s own administrative record shows – a warning letter that expressly relied on grounds the Defendant had either already conceded an issue was resolved, were identified as not of regulatory significance (i.e., not mentioned by a prior Form 483 or correspondence from agency officials), or reached a conclusion clearly contradicted by its own records.

Additionally, in *Jupiter Wreck, Inc. v. United States Army Corp of Engineers*, No. 24-80906-CIV-CANNON/McCabe, 2025 U.S. Dist. LEXIS 263264, at *12 (S.D. Fla. 2025), the Court applied the “requisite showing of improper behavior . . . sufficient to overcome defendant’s deliberative-process assertion . . . thus to enable the court to consider matters outside the administrative record” The Court’s bad faith finding rested in substantial part on the fact that when the agency’s decision maker was confronted with a conflict in his conduct, he responded with an inaccurate denial rather than genuinely engaging with it – and the court treated that evasive and factually incorrect response as independently supporting the improper behavior finding. *Id.*

The parallel here is direct: Defendant's administrative record reflected a documented and inexplicable departure from Defendant's own contemporaneous findings, of precisely the kind that *Jupiter Wreck* held sufficient to look beyond the administrative record.

However, an example of where the court has denied extra-record discovery due to insufficient bad faith claims is in *Afianian v. Duke*, No. CV 17-07643, 2018 U.S. Dist. LEXIS 230230, at *14-15 (C.D. Cal. 2018), where the court found that the plaintiff's bad faith argument amounted to nothing more than a "disagreement with [the] defendant's purported policy . . . and not a showing of bad faith or improper behavior." "[D]iscovery regarding this purportedly improper behavior is not necessary because the allegedly improper reason is set forth in the record." *Id.*

Neither of these conditions that *Afianian* lays out are present here as Plaintiff's bad faith arguments do not rest on disagreement with Defendant's authority to issue warning letters or with its general regulatory approach. It rests on specific, documented instances where Defendant departed from its own stated procedures and prior findings in ways the record cannot explain. And unlike in *Afianian*, where the allegedly improper reason was already expressly stated in the record, Defendant's administrative record here contains no explanation for its conduct whatsoever. The record documents what Defendant did; *it does not explain why*. That is the precise gap that *Afianian* left open, and that makes extra-record discovery not only available but necessary here.

II. GIVEN THE SUFFICIENCY OF PLAINTIFF'S BAD FAITH AND IMPROPER BEHAVIOR CLAIM, PLAINTIFF IS ENTITLED TO CONDUCT LIMITED DEPOSITIONS

Second, Plaintiff has sought leave to conduct limited depositions of Monica Maxwell, the Defendant employee who authorized both warning letters, and compliance officers John Diehl and Shawn Larson, who were assigned to monitor Plaintiff. The administrative record produced by

Defendant does not merely fail to justify the agency's conduct – it affirmatively contradicts it. No neutral application of Defendant's governing criteria can account for the departures documented in the that record, and the administrative record alone cannot provide this Court with a complete and accurate picture of the decision-making process that produced them. The depositions of the three individuals most directly responsible for that process are therefore necessary to determine whether Defendant's procedural requirements were followed, what factual and legal basis actually drove the issuance of both letters, and whether the agency acted in bad faith or through improper behavior in reaching conclusions to its own record contradictions.

The specific authorization of agency personnel in APA bad faith cases is directly supported by *Neighborhood Assistance Corp*, where the court found “good cause to allow limited discovery” and authorized the plaintiff to “depone four individuals who had dealings with the agency during or after the relevant audit or who were involved with the adoption” of the challenged regulation – including “a 30(b)(b) deposition of the HUD official most familiar with” the rulemaking. *Id.* at 2 - 4. The court found that the plaintiff made “a strong preliminary showing of that the agency acted improperly or in bad faith” due to the sworn affidavit testimony that showed that the defendant had targeted the plaintiff. *Id.*

The same logic applies equally here: Maxwell authored both warning letters, and Diehl and Larson served as the compliance officers assigned. No other individuals possessed more direct personal knowledge of why Defendant proceeded on grounds its own record contradict, why issues never raised during the inspection process were elevated to warning letter status, and how the agency's multi-tiered approval process operated in connection with both letters, just as the HUD official in *Neighborhood Assistance Corp* who was most familiar with the contentious rulemaking.

In its opposition to the request for depositions, Defendant solely relies on debating what exceptions apply in APA discovery request instances but concedes that bad faith and/or improper behavior apply anyway. Such discussion is futile given the claim under that exact basis by Plaintiff. Based on the foregoing, Plaintiff's motion should be granted.

CERTIFICATE OF SERVICE

I hereby certify that on June 22, 2026, a copy of the foregoing was electronically filed with the Clerk of Court via the CM/ECF system, which will transmit a notice of electronic filing to all parties of record.

Respectfully Submitted,

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