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 MOTION TO COMPEL PRODUCTION OF DOCUMENTS AND FOR LEAVE TO CONDUCT LIMITED DISCOVERY

Plaintiff, Hybrid Pharma LLC ("Plaintiff"), by and through undersigned counsel and pursuant to Fed. R. Civ. P. 37 and Local Rule 26.1, moves for the entry of an order compelling defendant Food and Drug Administration ("Defendant") to produce documents in response to Plaintiff's First Request for Production of Documents and for leave to conduct limited discovery.

BACKGROUND

Plaintiff initiated this action pursuant to the Administrative Procedures Act ("APA") seeking to challenge two warning letters issued by Defendant. On June 3, 2025, Plaintiff served its First Request for Production of Documents to Defendant. A copy is attached hereto as Exhibit A. Subsequently, Plaintiff filed a Motion to Compel which was opposed by Defendant. ECF Nos. 21, 24. On October 21, 2025, Plaintiff's motion was denied without prejudice by Magistrate Valle directing the parties to await the decision of this Court on Defendant's Motion to Dismiss. ECF No. 27. On January 29, 2026, the Court entered an order denying Defendant's Motion to Dismiss and set a briefing schedule. ECF Nos. 29, 31.

On March 23, 2026, Defendant produced a Certified Administrative Record and filed notice of same. ECF No. 33. This production consisted of over 7,700 pages of documents and numerous videos. As set forth in further detail below, upon review to date, Plaintiff has obtained evidence reflecting bad faith and/or improper behavior in the decision-making process beginning prior to the issuance of the first warning letter. This type of showing, at a minimum, permits Plaintiff to seek further limited discovery, including but not limited to, the production of internal agency communications regarding the warning letters and conducting a deposition of the employee that issued both letters (which was the same person) and the compliance officers assigned for servicing of each warning letter.

On April 13, 2026, counsel sent an email to Defendant's counsel renewing requests made in its initial first request to produce; specifically, for the production of internal communications amongst agency personnel regarding the warning letters. In response, Defendant objected to the request relying on the deliberative process privilege. Plaintiff's counsel also sent notice via email to Defendant's counsel prior to filing this motion in which Defendant confirmed the same objection. Thus, Plaintiff has filed the instant motion seeking an order compelling production of additional documents and for leave to conduct limited depositions of the letters' author and each letter's compliance officer based on the conduct outlined below. As such, Plaintiff respectfully seeks relief from the Court as the need for accurate fact-finding overrides the government's interest in nondisclosure.

MEMORANDUM OF LAW

I. EVENTS PRIOR TO ISSUANCE OF THE FIRST WARNING LETTER

Plaintiff is registered with Defendant as a 503B outsourcing facility. Ex. B, Declaration of Ponswamy Rajalingam ("Raja Declaration"), ¶ 2. In addition, Plaintiff holds a Special Sterile

Compounding Permit, Community Pharmacy Permit, and Pharmacy Technician Training Program Permit with the Florida Board of Pharmacy ("FBOP"), a Retail Pharmacy Drug Wholesale Distributor License with the Florida Department of Business and Professional Regulation ("DBPR"), and a Schedule 1 Manufacturer License with the Drug Enforcement Agency ("DEA"). *Id.* ¶ 3. As a registered outsourcing facility, Plaintiff specializes in compounding and dispensing vital pharmaceuticals to mitigate drug shortages and fill specific needs for hospitals, physician clinics and clinical trials. *Id.* ¶ 4.

From July 18, 2016, through July 28, 2016, Defendant conducted its first inspection of Plaintiff. *Id.* ¶ 6. At the conclusion of the 2016 inspection, Defendant issued a Form 483 ("2016 Form 483") to Plaintiff which alleged specific and non-specific inspection observations. *Id.* ¶ 7. A Form 483 is a standard form of Defendant that is utilized at the conclusion of an inspection when inspectors identify conditions that *may* violate a law with the purpose of encouraging prompt corrective action *to avoid further action*. *Id.* ¶ 8.

On August 17, 2016, Plaintiff timely provided a written response to Defendant addressing the alleged deficiencies in the 2016 Form 483 that either identified immediate corrective action taken by Plaintiff or the basis and supporting documentation as to why it disagreed with the observation to continue discussion. *Id.* ¶ 9. In response, on May 17, 2017, Salvatore Randazzo, a compliance officer for Defendant, sent Plaintiff a letter ("Randazzo Letter") indicating that Defendant needed additional information regarding only *three* remaining items from the 2016 inspection to fully determine whether any concerns remained – i.e., a copy of a cleanroom certification report, a copy of a revised cleaning procedure referenced in response to observation three in the 2016 Form 483, and the status of the flooring tiles located in the cleanroom. *Id.* ¶ 10. Notably, the Randazzo Letter also made the admission that Plaintiff's labels were "adequate." *Id.*

On June 9, 2017, Plaintiff responded to the Randazzo Letter providing a copy of the complete cleanroom certification report conducted by an independent third-party, providing a copy of Plaintiff's revised cleaning procedure crafted by Lynne Stirling Broderick Ph.D., an independent consultant specializing in biochemistry and microbiology, and confirming that the tiles are not laminate and are covered in a special epoxy coating making the floor seamless (i.e., preventing a risk of contamination). *Id.* ¶ 11.

Despite Plaintiff's prompt responses, cooperation and noted corrective actions, Defendant issued a Warning Letter on November 30, 2018 ("2016 WL"). *Id.* ¶ 12. Warning letters issued by Defendant are published on its website for anyone with access to the internet to review whether the determinations made in such notices are warranted or not. *Id.* ¶ 13. If there is a reasonable expectation of prompt action or actual action and alleged violations are not of regulatory significance, *warning letters are not warranted pursuant to Defendant's policies and procedures*. *Id.*.

The 2016 WL was issued over one year later (i.e., following the Randazzo Letter) with no further correspondence from Defendant prior to such issuance. *Id.* ¶ 14. The 2016 WL alleged the following four observations in support of its issuance: (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. *Id.* ¶ 15. *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). *Id.* ¶ 16.

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. *Id.* ¶ 17. 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). *Id.* ¶ 18. At the time of the 2016 inspection, the statutory bulks list *had not been finalized* by Defendant and was conceptually being created via nominations that would take years. *Id.* ¶ 19. Moreover, in a footnote on the 2016 WL, Defendant relied on "interim" non-binding "guidance" just issued approximately thirty days prior to the inspection to penalize Plaintiff for production already completed at that time. *Id.* ¶ 20. Of the three substances identified by Defendant, testosterone cypionate was already nominated for the bulks list and as for the two other substances, Plaintiff was advised by customers that such substances were in the process of being nominated. *Id.* ¶ 21.

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*. *Id.* ¶ 22. The Randazzo Letter, issued over one year prior to the 2016 WL, similarly states that the labels were found to be "adequate." *Id.* ¶ 23. Yet again, Defendant chose to run with this determination anyway.

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. *Id.* ¶ 24. Importantly, the Randazzo Letter does not identify this issue either

nor does the 2016 Form 483, but the agency determined to move forward with it anyway (i.e, a common theme throughout this summary). *Id*.

To the contrary, Defendant sent Plaintiff an email on June 1, 2015, directing Plaintiff to submit its initial report via email utilizing an excel spreadsheet format due to continuing technical problems with Defendant's product reporting portal. *Id.* ¶ 25. As required, on June 30, 2015, Plaintiff sent Defendant its initial product report in excel spreadsheet format. *Id.* ¶ 26. Thus, such report was submitted by Plaintiff. In the 2016 WL, the alleged other substances not reported are not identified.

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. *Id.* ¶ 27. Again, this item was not raised in the Randazzo Letter. *Id.* To the contrary, prior to and at the time of the 2016 inspection, Plaintiff had already developed and implemented a standard operation procedure entitled "Hybrid Pharma GMP SOP Complaints and Recalls" ("Complaint SOP") that addressed procedures for complaints, recalls, adverse events, and quality control related events. *Id.* ¶ 28. Here, Defendant's claim is that Plaintiff lacked a written process altogether, not that Defendant believed the process was deficient or needed additional revisions. Again, the Complaint SOP already existed at the time, and Defendant's contention is demonstrably false.

Defendant issued a second warning letter on June 7, 2022, relying upon many of the same issues as the first, including inadequate labels and missing product reports. *Id.* ¶ 30. And notably, despite advisement by its own inspector following a 2021 inspection that Plaintiff resolved all previous alleged observations from a previous 2019 inspection except for one that was being

actively debated on science principles and another that was partially corrected, Defendant elevated its regulatory action against Plaintiff and issued the second letter anyway. *Id.* ¶ 31.

From the start, we have situation of a government regulator issuing a determination ignoring material facts and disregarding previous agency correspondence inconvenient for its conclusion. Given the foregoing, Plaintiff should be permitted to examine the full decision-making process in order to determine if all technical procedures were followed for approving and issuing the warning letters and how the agency reached such conclusions despite the documents and findings to the contrary.

II. PLAINTIFF HAS MADE THE REQUISITE SHOWING OF BAD FAITH AND/OR IMPROPER BEHAVIOR TO SUPPORT ADDITIONAL DISCOVERY

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 above, 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.

The deliberative process privilege "covers documents reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated by protecting open and frank discussion among those who make them within the Government." *Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 8-9 (2001). However, an inquiry into the mental processes of an administrative decision maker may be made upon a "showing of bad faith or improper behavior." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420 (1971).

Pursuant to Chapter 4 of Defendant's Regulatory Procedures Manual ("Manual"), in determining whether to issue a warning letter, Defendant considers:

> (i) Evidence shows that a firm, product, and/or individual is in violation of the law or regulations and that failure to achieve adequate and prompt correction may result in agency consideration of an enforcement action;
>
> (ii) The violation(s) are determined to be of regulatory significance, and the issuance of a Warning Letter is appropriate and consistent with agency policy, as described in Compliance Policy Guides or elsewhere; and
>
> (iii) There is a reasonable expectation that the responsible firm and persons will take prompt corrective action.

In this case, Defendant issued the 2016 WL based on four specific items or issues. In utilizing Defendant's own factors above, the 2016 WL was not warranted given the clear contradicting circumstances. First, there were no clear violations of law. Defendant either relied upon interim, non-binding guidance or findings contradicted by its own documents. Second, these were not issues of regulatory significance. None of these issues were named in the Randazzo Letter issued over one year. Finally, there was a clear reasonable expectation that Plaintiff would take prompt corrective action. The record reflects Plaintiff immediately responded to the Form 483 and Randazzo Letter with supporting documents. Any notion or speculation that Plaintiff was an out-of-control registrant needing to be stopped is absurd. Furthermore, the Manual states in the same section: "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**." (Emphasis added). Separate and independent from an analysis of the factors above, Defendant's own Manual directs personnel to not issue a warning letter if corrective action is deemed adequate and has already been taken. Here, Defendant disregarded this provision and relied upon alleged inadequate labels as an independent basis despite conceding in the Randazzo Letter and in the 2016 WL itself that such labels were already corrected and deemed adequate.

There is no reasonable explanation for ignoring this material fact and the Manual's directive. Thus, Defendant by somehow choosing to jump to the extreme extent of issuing a warning letter despite the circumstances to the contrary clearly shows a decision made in bad faith and/or via improper behavior.

Second, Plaintiff seeks leave to conduct a deposition of Monica Maxwell, Shawn Larson, and John Diehl. Ms. Maxwell was the agency employee that issued both warning letters. Ex. A, Raja Declaration, ¶ 32. John Diehl and Shawn Larson were the compliance officers assigned to the first and second warning letters, respectively. *Id.* ¶ 33. In this district, "[c]ourts have permitted discovery [in APA cases] under the following sets of circumstances: 1) where the administrative record does not adequately explain the agency's action or grounds of decision so as to frustrate effective judicial review; 2) where it appears the agency relied on documents, materials or other information not included in the administrative record, 3) where technical terms or complex subject matter requires explanation; or 4) where there is a strong showing of agency bad faith or improper behavior." *Miccosukee Tribe of Indians of Florida v. United States*, Case No. 05-CIV-23045 at *5-6, 2007 U.S. Dist. LEXIS 32612 (S.D. Fla. May 3, 2007).

Given the evidence presented above, a limited deposition as to the circumstances surrounding the issuance of both warning letters is warranted under all circumstances set forth in *Miccosukee*. In considering the first circumstance, for the first warning letter alone, the agency issued the letter based on claims contradicted by the evidence and circumstances not supported by Defendant's own Manual. The egregious circumstances surrounding the issuance of the 2016 WL should be enough but in support, it should also be noted that Defendant's own inspector following the 2021 inspection noted that all previous observations were resolved except for two which were either being debated or partially resolved. Thus, the record does not adequately explain the

agency's actions. Under the second circumstance, given the disregard of material facts, Defendant personnel must have been relying upon documents not in the record; thus, we need to determine what was being considered. For example, what was the reasoning behind relying upon alleged "inadequate labels" when the agency had already deemed them adequate. There is no reasonable explanation for this decision based on what has been produced. Under the third circumstance, the items at issue are scientific and technical in nature. Under Defendant's Manual, a warning letter must go through a multi-tiered approval process. It would be beneficial for all to determine what technical steps the warning letters went through before approval and publication. Finally, under the fourth circumstance, Plaintiff has set forth evidence of bad faith and/or improper behavior as outlined herein. Given this situation, Plaintiff should be permitted to conduct a limited examination into the process of issuing both letters from the author and compliance officers themselves.

LOCAL RULE 7.1 CERTIFICATION

On May 15, 2026, Plaintiff's counsel conferred with counsel for Defendant in a good faith effort to resolve the issues raised in this motion and has been unable to do so. Defendant opposes the relief sought herein.

CERTIFICATE OF SERVICE

I hereby certify that on May 15, 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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