UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

NOT FOR PUBLICATION

UNITED STATES OF AMERICA

Plaintiff,

– against –

MEMORANDUM & ORDER

CONFIDENCE, U.S.A., INC., HELEN CHIAN, AND JIM CHAO

19–CV–3073 (ERK) (SIL)

Defendants.

KORMAN, *J.*:

Plaintiff United States of America ("plaintiff") moves for summary judgment on its complaint seeking a permanent injunction against defendants Confidence, U.S.A., Inc. ("Confidence"), Helen Chian, and Jim Chao for continuing violations under the Food Drug and Cosmetic Act ("FDCA"). Specifically, plaintiff argues that defendants violate the FDCA by distributing adulterated dietary supplements in interstate commerce and by causing their dietary supplements to become adulterated while holding them for sale after shipment of one or more of their components in interstate commerce. *See* 21 U.SC. §§ 331(a), (k).

Plaintiff argues that defendants' products are adulterated as a matter of law because defendants violate current good manufacturing practice ("cGMP") regulations that govern the production and distribution of dietary supplements. In

particular, plaintiff claims that numerous FDA inspections over the past decade have revealed that defendants fail to properly establish criteria for determining the identity and purity of the ingredients in their products. Plaintiff also claims that the testing methods that defendants use are inadequate to verify that the ingredients in defendants' supplements are what they purport to be. Given the long history of defendants' compliance failures, plaintiff seeks a permanent injunction barring defendants from manufacturing and distributing dietary supplements in interstate commerce until they can demonstrate that their practices are in compliance with the law. I have carefully reviewed the language of the proposed injunction that plaintiff requests and, subject to the caveat discussed in the conclusion of this order, I grant plaintiff's motion.

BACKGROUND

Confidence is a New York corporation, founded and operated by Chian and Chao, which manufactures and distributes dietary supplements out of Port Washington. ECF No. 25 ¶¶ A1–2, 7. Chao also owns the Herbal Store, which is a Flushing-based retail vitamin and dietary supplement store that sells products manufactured by Confidence. *Id.* ¶¶ A17, B6. Defendants distribute Confidence's products throughout the United States and internationally, primarily to Chinese-speaking communities. *Id.* ¶ A24, B7.

For the past decade, the Food and Drug Administration ("FDA") has issued multiple warnings to defendants that their manufacturing and distribution practices violate the FDCA. Plaintiff argues that "despite multiple inspections, an agency Warning Letter, and a civil *in rem* seizure," defendants have failed to make the necessary corrections and that this history of failed compliance requires a permanent injunction to ensure that violations of the FDCA do not continue. ECF No. 21 at 7. Defendants respond that the FDA's last inspection of Confidence's facilities was over two years ago and that Confidence has since implemented voluntary measures to verify that it is in compliance with FDA regulations. ECF No. 24 at 5–6. They argue that because plaintiff is "relying on stale and erroneous FDA inspectional observations, ignoring significant improvements implemented by Confidence which show that any alleged violations will not recur, summary judgment must be denied and a permanent injunction is inappropriate." *Id.* at 7. Before describing defendants' alleged history of noncompliance and the purported remedial measures they have taken, an explanation of the regulatory background in which they operate is necessary.

A. Statutory and Regulatory Background

The manufacture and distribution of dietary supplements in interstate commerce is regulated by the FDCA, 21 U.S.C. § 301 *et seq*. The FDCA defines a dietary supplement as "a product . . . intended to supplement the diet" that contains,

inter alia, "a vitamin; a mineral; an herb or other botanical; an amino acid; [or] a dietary substance for use by man to supplement the diet by increasing the total dietary intake." *Id.* § 321(ff). A dietary supplement is also "not represented for use as a conventional food or as a sole item of a meal or the diet" and is "labeled as a dietary supplement." *Id.* With exceptions not applicable here, "a dietary supplement shall be deemed a food within the meaning of" the FDCA. *Id.*

The FDCA prohibits the distribution in interstate commerce of articles of food—including dietary supplements—that are adulterated, as well as the commission of any act that results in articles of food becoming adulterated while being held for sale after shipment of their components in interstate commerce. *Id.* §§ 331(a), (k). A dietary supplement is deemed to be adulterated if it has been "prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations." *Id.* § 342(g)(1). Congress has delegated the authority to promulgate cGMP regulations to the Secretary of Health and Human Services, who oversees the FDA. *Id.* § 342(g)(2); *Nutritional Health All. v. FDA*, 318 F.3d 92, 99 n.8 (2d Cir. 2003). The cGMP regulations for dietary supplements are set forth in 21 C.F.R. Part 111. These regulations "aim to ensure that a dietary supplement is what it says it is—that it has the identity, purity, strength, and composition it is represented to have." *United States v. Cole*, 84 F. Supp. 3d 1159, 1167 (D. Or. 2015).

To guarantee that a dietary supplement is what it says it is, manufacturers must establish identity, strength, purity, and composition specifications for each component used in the dietary supplement and ensure that every shipment of the component meets the specifications before using it in the manufacturing process. 21 C.F.R. §§ 111.70(b); 111.75(a). The manufacturer of a supplement must verify the identity of dietary ingredients (such as a vitamin or mineral) by appropriate testing before using the ingredient unless it receives an exemption from the FDA. *Id.* § 111.75(a)(1). The manufacturer can verify the identity of non-dietary ingredients (*e.g.*, flavoring and coloring), as well as specifications of dietary ingredients other than identity, by appropriate testing or by relying on a certificate of analysis of a properly qualified supplier. 21 § C.F.R. 111.75(a)(2); *see also* Final Rule, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34,752, 34,835 (June 25, 2007).

In addition to establishing and verifying identity, purity, strength, and composition specifications with respect to the *components* of a dietary supplement, a manufacturer must establish and verify such specifications in finished products as well. 21 C.F.R. §§ 111.70(e), 111.75(c). If there is no scientifically valid method for verifying a certain specification in a finished product, the manufacturer may exempt the specification from being tested. 21 C.F.R. § 111.75(d)(1). For a finished product to qualify for this verification exemption, a company's quality control

personnel must adequately document that there is no scientifically valid method for verifying the exempted specification in the finished product. *Id.* They must also document how the manufacturer will ensure that the product specification is met absent testing in the finished product. *Id.*

When a manufacturer's product fails to meet a specification, quality control personnel must conduct a review of the finished product and decide whether the product can be remedied or must be rejected. 21 C.F.R. § 111.113. Quality control personnel must establish and follow written procedures for their product review and disposition decisions, and they must document their work to ensure effective review. *Id.* §§ 111.103, 111.105.

B. Confidence's History of cGMP Violations

Since 2010, the FDA has inspected Confidence six times, with the most recent inspection concluding on August 10, 2018. ECF No. 23-4; ECF No. 25 at ¶ A45. At the close of each inspection, the FDA observed violations of the cGMP regulations and notified defendants about Confidence's compliance shortfalls. ECF Nos. 23-13; 23-27; 23-34; 23-43; 23-46; 23-50. The FDA has repeatedly warned defendants of the consequences of failing to comply with the cGMP regulations. On July 7, 2011, the FDA sent a Warning Letter to Confidence, stating that failure to promptly correct violations could result in enforcement action, including product seizure or an injunction. ECF No. 23-48. In 2012, the FDA instituted a civil

forfeiture action against Confidence based on its failure to remediate previously observed violations, specifically the failure to:

- ensure that its finished batches met product specifications (21 C.F.R. § 111.75(c));
- conduct appropriate tests to verify the identity of any product ingredient (*Id.* § 111.75(a)(1)(i));
- establish component specifications for the capsules used with the dietary supplements (*Id.* § 111.70(b));
- establish specifications for product labels or packaging (*Id.*§ 111.70(d)); and
- maintain documentation for how suppliers of component ingredients are qualified and establish that the suppliers' certificates of analysis were reliable. (*Id.*§ 111.75(a)(2))

ECF No. 23-41 ¶¶ 17–18. Pursuant to the forfeiture action, the U.S. Marshals Service seized products with an estimated value of $60,000 from Confidence. ECF No. 25 ¶ A80. After Confidence defaulted, Judge Spatt ordered the forfeiture of five dietary supplements that were the subject of the FDA's complaint on the ground that those supplements were adulterated within the meaning of the FDCA. ECF No. 23-35.

Even after the forfeiture action concluded, the FDA continued to find cGMP violations at Confidence's facilities. Specifically, the FDA conducted an inspection from December 2016 to January 2017 (the "2017 Inspection") and a follow-up inspection in August 2018 (the "2018 Inspection"). At the conclusion of each of

these inspections, FDA investigators issued a List of Inspectional Observations, which identified cGMP regulation violations. ECF Nos. 23-13, 23-27. Plaintiff argues that violations of the following regulations justify the imposition of an injunction.

1. Failure to Establish Finished Product Specifications

The FDA concluded that defendants failed to establish specifications for the identity, purity, strength, and composition of their finished dietary supplements as required by 21 C.F.R. § 111.70(e). In particular, during the 2017 Inspection, investigators found that four products located at the Herbal Store—Vit-Prostate, Vit-Milk Cal, Vit-CalCitrate, and Zinc Balance—lacked any product specifications at all and received no testing. ECF Nos. 23-18 at 15-16, 23-32 at ¶ 30. Chao told investigators that these four products were "prototypes and only manufactured in small batches (6-12 bottles) for advertisement purposes only." ECF No. 23-18 at 16. Indeed, defendants still maintain that these four products were found by FDA inspectors in a box mixed with Christmas decorations outside the retail area of the store and were only to be used for photo shoots and not intended for human consumption. ECF Nos. 26 ¶ 60, 27 ¶ 28. Yet, in its inspection report, the FDA explained that it was able to obtain an archive of Confidence's website, which showed that three of these untested products were offered for sale from 2015–2016

and that pictures from a previous inspection showed one of the products offered for sale at the Herbal Store. ECF No. 23-18 at 16.

The FDA also observed during the 2017 Inspection that Confidence failed to create reference standards for the products Colon Cleanse, Liver Defense, Herbal Slim I, and Libido Boost. ECF No. 23-2 ¶ 18A. A reference standard is used as a point of comparison to verify the identity and purity of the product. Rather than provide the FDA with the reference standards that Confidence used to ensure that its products were what they purported to be, the documentation for these products simply stated that they "conform[ed] to library spectra." *See* ECF Nos. 23-19 at 15, 23-20 at 14, 23-21 at 15, 23-22 at 15. Accordingly, plaintiff argues that defendants failed to establish adequate specifications for these four products. ECF No. 21 at 17. Confidence claims that it has since discontinued production of these supplements. ECF No. 25 ¶ B50.

2. <u>Failure to Properly Test Dietary Ingredients</u>

Plaintiff also argues that defendants failed to conduct appropriate testing to verify the identity of dietary ingredients as required by 21 C.F.R. § 111.75(a)(1). ECF No. 21 at 17. Specifically, Confidence documented that it used three types of tests to verify the ingredients it used to manufacture its dietary supplements: (i) Fourier-Transform Infrared Spectroscopy ("FTIR"); (ii) organoleptic analysis; and (iii) turbidity testing. ECF Nos. 23-2 ¶18, 23-32 ¶ 33. According to the FDA,

Confidence did not carry out these tests in an appropriate fashion, which resulted in it not being able to determine the identity or purity of the ingredients that it put into its products for distribution to consumers. ECF No. 21 at 18. A description of each of these three tests and how they were employed by Confidence follows.

FTIR

FTIR measures absorption of infrared radiation in a tested material and produces a "spectrum," which is the equivalent of a molecular "fingerprint." ECF No. 23-32 ¶ 33a. If used correctly, FTIR can verify the identity of a dietary ingredient by comparing the spectrum of the ingredient with the spectrum of a reference standard. *Id.* If there is a match between tested ingredient and the reference standard, then a manufacturer can verify that the ingredient is what it purports to be. *Id.* In order to carry out such a verification, a manufacturer must either develop its own reference standard from a dietary ingredient of known purity or obtain a reference identity standard from a recognized standards library. *Id.* That was not what defendants did. Instead, defendants compared their ingredients against reference standards provided by the same third-party Chinese supplier that sold them the ingredients they were testing. *Id.* ¶ 35; ECF No. 23-18 at 17–18. The FDA concluded that defendants did not confirm the accuracy of the Chinese-supplied reference standard and thus could not verify that the ingredients received from the supplier were what they purported to be. *Id.*

In their response to the 2017 Inspection, defendants explained that materials used in the Traditional Chinese Medicine products it manufactured could not be identified accurately using a commercially available reference standard. ECF No. 23-31 at 9. Consequently, defendants admitted that they used the samples provided by their supplier as a reference standard and argued that they were permitted to do so because they qualified the supplier by confirming the reliability of the supplier's testing of its ingredients, and they relied on the supplier's certificate of analysis of those ingredients. *Id.* at 6–9. But to support this position, defendants cited the inapposite 21 § C.F.R. 111.75(a)(2), which only permits a dietary supplement manufacturer to rely on the certificate of analysis of a qualified supplier to verify the identity of a *non*-dietary component.[1]

Despite its warning that Confidence was using FTIR incorrectly to verify the identity of dietary ingredients in its supplements, the FDA discovered similar issues in its follow-up 2018 Inspection. The inspection revealed that Confidence used FTIR to verify the ingredient hyaluronic acid by comparing the incoming lot of

[1] *See also* Final Rule, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements, 72 Fed. Reg. 34,752, 34,835 (June 25, 2007) ("(1) Each manufacturer must confirm the identity of each component prior to use (*you must test or examine dietary ingredients to verify the identity, but may rely on a certificate of analysis to confirm the identity of components other than dietary ingredients*) and (2) each company must confirm other required specifications for components prior to use, either by relying upon a certificate of analysis or by testing or examining the component.") (emphasis added).

hyaluronic acid to a prior lot of the same ingredient. ECF No. 25 ¶ A58. The FDA found that, because Confidence did not develop its own reference standard for hyaluronic acid or obtain a reference standard from a recognized standards library, it could only verify that the ingredient it was testing was the same as the ingredient in the prior lot and not that it was actually hyaluronic acid. ECF No. 23-32 ¶ 33. Indeed, Confidence admitted to the FDA, in response to the 2018 Inspection findings, that it "used its earlier lot of Hyaluronic Acid as a reference standard . . . because until earlier this year, there was no commercially available primary or secondary reference standard" for the ingredient. ECF No. 23-16 at 5. Yet at the same time, Confidence represented to the FDA that it was able to obtain an acceptable reference standard on August 16, 2018—only six days after the FDA's inspection concluded—which indicates that it would have been able to obtain that reference standard before the 2018 Inspection. *Id.* Moreover, Confidence admitted that tests conducted by an outside laboratory found "inflated levels of Hyaluronic Acid" in its dietary supplement "due to interference with other substances in the product." *Id.* Confidence represents that it has discontinued production of the supplement that contained hyaluronic acid. ECF No. 25 ¶ B51.

Organoleptic Testing

In addition to FTIR, Confidence engaged in organoleptic analysis to verify certain ingredients. Organoleptic testing is an examination of an ingredient based

on sight, taste, touch and smell. ECF No. 23-32 ¶ 33b. With adequate training and experience, organoleptic testing may be appropriate to verify some substances that can be easily identified by sensory means—such as whole or coarsely cut botanical parts. *Id.* The FDA contends that it is much more difficult to use organoleptic testing to differentiate between extracts of a dietary ingredient at different concentrations, which is how such testing was employed by Confidence. *Id.* Confidence admits that it relied on organoleptic testing to verify two ingredients, Poria Mushroom Extract 10:1 and Codonopsis Root Extract 5:1. ECF No. 25 ¶ A71. The FDA found that, because of the nature of these extracts, Confidence could not confirm their identity by using the organoleptic testing method. ECF No. 23-32 ¶ 33b.

Defendants respond by arguing that organoleptic testing was appropriately used at Confidence and was undertaken by a qualified analyst. ECF No. 27 ¶ 16. To support this position, defendants submit their analyst's resume as part of the record. ECF No. 27-1. But the analyst's resume does not state that he is trained or qualified in conducting organoleptic testing of herb or botanical extracts. *Id.* Defendants also represent that organoleptic testing is no longer used at Confidence to identify ingredients and is now used only in a limited capacity to test the visual appearance of a finished product. ECF No. 25 ¶ B32.

Turbidity Testing

Finally, Confidence used turbidity testing to identify the ingredient Ginger Root 10:1. ECF No. 25 ¶ A72. Turbidity testing measures the cloudiness of a solution as a way of determining whether a substance is what it purports to be. ECF No. 23-32 ¶ 33c. According to the FDA, this type of testing alone is insufficient to confirm the identity of certain extracts like Ginger Root 10:1 because extraneous material in the tested substance can cause an inaccurate result. *Id.* Consequently, the FDA inspectors concluded that Confidence could not verify the identity of Ginger Root 10:1 by using this testing method. *Id.* Defendants admit that turbidity testing was used to identify this ingredient in its Liver Defense supplement, which was primarily produced for export and was discontinued in November 2017. ECF No. 25 ¶¶ B33–35.

3. Failure to Verify Finished Product Specifications

Plaintiff also argues that defendants have failed to verify that their finished dietary supplement products met specifications, in violation of 21 C.F.R. § 111.75(c). Specifically, plaintiff alleges, and defendants admit, that Confidence did not verify the presence of dietary ingredients in supplements that contain "proprietary blends." ECF No. 25 ¶ A73. A proprietary blend is "a combination of ingredients used exclusively by one supplement manufacturer."[2] During the 2017

[2] WebMD, *FAQs About Dietary Supplements*, https://www.webmd.com/vitamins-and-supplements/supplement-faq#1 (last visited Jan. 28, 2021).

Inspection, the FDA found that defendants did not have documentation to establish how product specifications for proprietary blends could be met without such verification. ECF Nos. 23-18 at 15–16, 23-32 ¶ 35. During the follow-up 2018 Inspection, FDA inspectors observed that defendants similarly failed to verify the presence of dietary ingredients in their supplement Ultra Dunaliella. *Id.*; ECF No. 23-4 at 11.

Defendants contend that "[a]ll proprietary blends related to products in FDA inspections have been discontinued." ECF No. 25 ¶ B53. Nevertheless, a review of Confidence's website demonstrates that it currently uses proprietary blends in other products such as "Cleanser Max" and "Prostate-7."[3] Defendants also state that although they did not verify the presence of dietary ingredients in finished dietary supplement proprietary blends, they "did document how product specifications for the 'proprietary blends' in question could be met with[out][4] verification." *Id.*

[3] *See* http://www.confidenceusa.com/eshop/ (last visited Jan. 28, 2021). "[A] court may take judicial notice of information publicly announced on a party's website, as long as the website's authenticity is not in dispute and it is capable of accurate and ready determination." *Wells Fargo Bank v. Wrights Mill Holdings*, 127 F. Supp. 3d 156, 167 (S.D.N.Y. 2015) (internal quotation omitted).

[4] There appears to be a typographical error in defendants' papers in which they mistakenly use the phrase "with verification" when what they really mean is "without verification." Defendants seem to be arguing that 21 C.F.R. §111.75(d) is applicable to their proprietary blends. *See* ECF No. 28 ¶¶ 48–49. Under 21 C.F.R. § 111.75(d), a manufacturer may exempt one or more product specifications from the verification requirements of §111.75(c) if "there is no scientifically valid method

Specifically, defendants point to reference standards that they received from their Chinese supplier that they could use to identify ingredients in the proprietary blends. *Id.* They also rely on a declaration from an expert, which states that "[t]here are no scientifically analytical methods available to quantitate these blends in the finished product so [Confidence is] reliant on process controls," to ensure that specifications are met in the finished product, which is permitted by the cGMP regulations. ECF No. 28 ¶¶ 48–49; *see* 21 C.F.R. §111.75(d).

With respect to Confidence's failure to verify the ingredients in Ultra Dunaliella, Jessie Huang, Confidence's Quality Control and Assurance Manager, told investigators that Ultra Dunaliella was a "prototype" and was only manufactured in a small batch to see how it would perform in sales. ECF No. 23-4 at 11. Confidence's attorney claimed that the product was manufactured for sale in China and that it was ultimately destroyed because the Chinese customer was unable to obtain an import certificate. *Id.* Confidence, however, had no purchase orders, invoices, or other documents to confirm that the product was manufactured for a Chinese customer, and Chao claimed that he made the product at the request of the customer via telephone. *Id.*

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for testing or examining such exempted product specification at the finished batch stage," so long as it documents how "any component and in-process testing, examination, or monitoring, and any other information, will ensure that such exempted product specification *is met without verification* through periodic testing of the finished batch." (emphasis added).

Plaintiff also argues that defendants violated 21 C.F.R. § 111.75(c) based on their use of a "rotational testing plan." ECF No. 21 at 22. Under this plan, Confidence would choose a single ingredient in its finished products and test whether that ingredient was present in the appropriate purity, strength, and composition. ECF No. 25 ¶¶ A59–60. If the ingredient passed the test, then the whole lot of the finished product was released to the public without further testing for other ingredients. *Id.* As part of its response to the FDA's 2017 Inspection findings, Confidence conducted "confirmatory testing" of products manufactured between March 2016 and October 2017 that had passed its rotational testing plan. ECF Nos. 23-15, 25 at ¶ A63–69. Plaintiff argues that the results of the confirmatory testing revealed that Confidence's rotational testing plan was ineffective at ensuring that some of its dietary supplements met pre-established ingredient specifications. For example, the label on a prenatal multivitamin manufactured by Confidence indicates that the supplement contains 15 mg of zinc and 18 mg of iron per two tablets. ECF No. 25 ¶ A61. But confirmatory testing revealed that the product defendants sold to consumers only had 0.103 mg of zinc and 9.58 of iron per two tablets, which means that Confidence's customers received only a fraction of the minerals that they believed they were getting. *Id.* ¶ A63. Confirmatory testing for three other products revealed similar discrepancies. *Id.* ¶¶ A64–69.

Defendants dispute the FDA's assertions that its rotational testing plan was ineffective. They note that the confirmatory testing yielded a more than 97% accuracy rate and that only eight of the 289 confirmatory tests yielded results that fell below specifications. ECF Nos. 26 ¶¶ 35–38, 27 at 50. Defendants suggest that the reason ingredients like zinc and iron fell below specified levels in certain supplements was due to chemical interference with other components in the tested products. ECF Nos. 27 ¶ 47, 28 ¶ 46. They further argue that "[t]he confirmatory testing employed by the third-party laboratory may not have been specifically validated for" the products that fell below specification, "and so unavoidable testing errors is [sic] highly probable." ECF No. 27 ¶ 47. Out of an abundance of caution, Confidence discontinued three of the four products that failed the confirmatory testing, including the prenatal multivitamin described above. ECF No.27 ¶¶ 47, 50. The fourth product was revised formulaically but ultimately discontinued for economic reasons. ECF No. 27 ¶ 49. Nevertheless, in its response to the FDA's 2018 Inspection findings, Confidence reiterated that it would continue to rely on its rotational testing plan in which it only tested one ingredient per finished product. ECF No. 23-15 at 1. Confidence stated that it would supplement this testing by conducting a full test for all ingredients in one lot of each of its products every 12 months. *Id.* Defendants now represent that as of January 2019, they abandoned their

rotational testing plan altogether and all products currently undergo full label claim testing that is carried out by a qualified third-party laboratory. ECF No. 27 ¶ 18.

4. Failure to Follow Written Procedures and Maintain Records

Finally, plaintiff argues that the confirmatory testing results that showed that some of Confidence's supplements did not meet specifications demonstrates that it failed to follow written procedures for investigating why a particular lot of dietary supplement failed to meet specifications and for making decisions regarding how to dispose of each failed lot, in violation of 21 C.F.R. § 111.03. ECF No. 21 at 23–24. Specifically, plaintiff argues that Confidence's records failed to demonstrate that its quality control personnel conducted any "material review" of the products that did not meet specifications before it decided how to dispose of the products. *Id.* at 24. Defendants dispute this allegation and point to destruction reports from 2018 to support their position that they conducted a material review before deciding to destroy three of the four supplements that failed confirmatory testing. ECF Nos. 25 ¶ B61, 27-9. Defendants' expert conceded in his declaration, however, that there were what he described as "minor shortfalls" with respect to Confidence's "documentation of activities performed as required by" the cGMP regulations and that "the FDA's dissatisfaction with the performance of the quality operation at Confidence appears based on a lack of documentation at the ready," which apparently means that Confidence had the proper documentation somewhere in its

facilities but that such documentation was not readily available for the FDA inspectors to review. ECF No. 28 ¶¶ 45, 55, 60.

Confidence responded three times to the FDA's 2017 Inspection findings and three times to the 2018 Inspection. In these responses, Confidence admitted that it had indeed violated cGMP regulations. For example, in a response dated February 3, 2017, Confidence outlined "the Corrective and Preventive Action plans developed in accordance with [cGMP], which address the actions Confidence has taken and will take to address the remaining observations" investigators made during the 2017 Inspection. ECF No. 23-31 at 1. On February 28 and May 1, 2017, Confidence reiterated that its attorneys were "working together to assist Confidence in correcting the [FDA's] observations . . ." and to "prevent recurrence." ECF Nos. 23-29 at 1, 23-30 at 1. In response to the 2018 Inspection, Confidence's attorney admitted that one of the FDA's observed violations resulted in a product recall due to "the company's inadvertent failure to include the coating process in product manufacturing records" and that there were "discrete deficiencies, related to documentation that was maintained and available, but not included in batch records and . . . a process that is already in place but requires further reinforcement." ECF No. 23-17 at 1.

C. Confidence's Claimed Remedial Actions

Defendants argue that the FDA's inspectional findings that form the basis for plaintiff's requested injunction are outdated and that Confidence has taken significant steps to comply with cGMP regulations. Defendants represent that over 85% of all products inspected by the FDA from 2011–2018 are either expired, were destroyed, or have been discontinued. ECF Nos. 26 ¶ 29, 27 ¶ 19. Specifically, all products based on Traditional Chinese Medicine—which were the subject of the majority of the FDA's violation findings—have been discontinued. ECF Nos. 26 ¶ 21, 27 ¶ 30. As a result, Confidence claims that it only continues to produce 6 of the 42 dietary supplements that the FDA found to be manufactured in violation of the cGMP regulations, and those products have been reformulated and retested. ECF Nos. 26 ¶¶ 29–31; 27 ¶ 58.

Defendants also claim that they have altered their testing methods. As described above, while defendants maintain that their rotational testing plan was effective, they assert that as of January 2019 they have abandoned that approach and that a qualified laboratory now conducts full label claim testing for all products. ECF Nos. 26 ¶ 18; 27 ¶ 18. Also, as noted earlier, defendants further state that they no longer conduct organoleptic or turbidity testing to identify ingredients, since those testing methods were only performed on products that have since been discontinued. ECF Nos. 26 ¶ 20, 27 ¶¶ 15–17.

In addition to discontinuing allegedly adulterated products and revising their testing strategy, defendants retained a consulting firm, REJIMUS, in 2017 to assist Confidence with cGMP compliance. ECF No. 28. REJIMUS's consultancy relationship with Confidence is ongoing. ECF No. 26 ¶ 10. Jim Lassiter, REJIMUS's chief operating officer who has over 40 years' experience in the dietary supplement regulatory industry and who has published numerous articles in scientific journals concerning dietary supplement manufacturing and cGMP compliance, submitted a declaration in opposition to plaintiff's summary judgment motion. ECF No. 28 ¶¶ 1–12. Lassiter claims that he and his team of regulatory compliance consultants reviewed all of Confidence's operations and created a customized cGMP plan for Confidence to address issues raised by the FDA. *Id.* ¶¶ 13–14.

Lassiter also conducted an in-person inspection and an audit of defendants' Port Washington manufacturing facility in 2018 and 2019, respectively. ECF No. 28. ¶ 13. He was scheduled to perform another physical audit in August 2020, but, due to the Covid-19 pandemic, he performed a remote inspection of Confidence's cGMP compliance instead. *Id.* at ¶¶74–76; ECF No. 26 ¶ 74. During his 2018 inspection, which preceded the FDA inspection later that year, Lassiter found "minor issues" with Confidence's operation, such as inconsistent temperature monitoring in operational areas, but concluded that "Confidence operated in a manner that

exceeded the standards commonly found within the industry regarding cGMP." ECF No. 28 ¶¶ 65–66. During his 2019 audit, Lassiter "observed additional steps in Confidence's overall approach to quality assurance," which included "establishment of appropriate specifications for their finished form dietary supplements with complete testing against all established specifications for each batch of product produced." *Id.* ¶ 67. Lassiter concluded that Confidence's testing practices "exceed[] the allowances of the regulations regarding such testing and [are] beyond common industry practices." *Id.* Finally, following his remote inspection in August 2020, Lassiter determined that "the activities performed in the manufacture of Confidence dietary supplement products are in conformance with the regulations," and "the level of compliance in place at Confidence is vastly different from how the FDA has described it in consideration of production of products intended for sale in the United States." *Id.* ¶¶ 75–76.

DISCUSSION

A. Standard of Review

Summary judgment may be granted only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "In determining whether there is a genuine dispute as to a material fact, [I] resolve all ambiguities and draw all inferences in

favor of the non-moving party." *Vincent v. The Money Store*, 736 F.3d 88, 96 (2d Cir. 2013) (internal citation omitted).

The FDCA authorizes district courts to provide injunctive relief to restrain violations of the statute. 21 U.S.C. § 332(a). Injunctive relief "is appropriate when the government has demonstrated that defendants have violated [the FDCA] and that there is some reasonable likelihood that the violations may recur." *United States v. Hakim*, 462 F. Supp. 3d 418, 433 (S.D.N.Y. 2020) (citing *United States v. Diapulse Corp.*, 457 F.2d 25, 28–29 (2d Cir. 1972)). "The Court [] has considerable discretion in crafting an injunction." *United States v. N.Y. Fish, Inc.*, 10 F. Supp. 3d 355, 380 (E.D.N.Y. 2014).

B. Defendants' Request for Discovery

Before addressing whether plaintiff has established that defendants have violated the FDCA and, if so, whether such violations are reasonably likely to recur, defendants argue that plaintiff is not entitled to summary judgment because they have not had an opportunity to conduct discovery. ECF No. 24 at 16–17. Specifically, defendants ask that they be permitted to depose three FDA investigators who inspected Confidence's facilities between 2010 and 2018. *Id.* Defendants fail to show that this request for discovery justifies delaying ruling on plaintiff's summary judgment motion. As an initial matter, defendants did not make their request by declaration or affidavit as required by Fed. R. Civ. P. 56(d), and instead

argue their need to depose the FDA inspectors in their memorandum in opposition to plaintiff's summary judgment motion. "A reference . . . to the need for additional discovery in a memorandum of law in opposition to a motion for summary judgment is not an adequate substitute for a Rule 56[d] affidavit . . . and the failure to file an affidavit under Rule 56[d] is itself sufficient grounds to reject a claim that the opportunity for discovery was inadequate." *Paddington Partners v. Bouchard*, 34 F.3d 1132, 1137 (2d Cir. 1994).

Moreover, defendants agreed to a briefing schedule over a year before plaintiff filed its summary judgment motion. ECF No. 11. Defendants thus had ample time to pursue discovery and chose not to do so. "A party who both fails to use the time available and takes no steps to seek more time until after a summary judgment motion has been filed need not be allowed more time for discovery absent a strong showing of need." *Burlington Coat Factory Warehouse. v. Esprit De Corp.*, 769 F.2d 919, 928 (2d Cir. 1985). Defendants fail to make such a showing. They claim that they need to depose the FDA investigators "in order to develop a fuller record showing that specific remedial measures taken by Confidence has mooted this case and whether the measures taken show that the alleged violations identified by the government will not recur." ECF No. 24 at 16–17. But defendants fail to explain how the FDA investigators, none of whom have inspected Confidence's facilities in over two years, would have any knowledge of the purported remedial measures that

defendants have taken to make their operations cGMP compliant. Thus, "whatever discovery went undone was the consequence of [defendants'] own conduct and was in any event inconsequential." *Burlington Coat Factory*, 769 F.2d at 925. I therefore decline to postpone deciding plaintiff's summary judgment motion to permit defendants to depose the FDA investigators and turn now to the merits of plaintiff's motion.

C. Defendants' FDCA Violations

As described above, plaintiff alleges that defendants violate the FDCA by distributing adulterated dietary supplements in interstate commerce and by causing their dietary supplements to become adulterated while holding them for sale after shipment of one or more of their components in interstate commerce. *See* 21 U.SC. §§ 331(a), (k). Defendants admit that the products they manufacture are dietary supplements and thus food within the meaning of the FDCA. ECF No. 25 ¶ A35. They also admit that they manufacture their dietary supplements from components shipped in interstate commerce and that they distribute their products in interstate commerce. *Id.* ¶¶ A24–26. Yet defendants argue that summary judgment should be denied because "genuine issues of material facts [sic] exist as to the accuracy of the FDA inspection findings at Confidence and whether they adequately reflect Confidence's operations today." ECF No. 24 at 16.

First, defendants argue that some of the FDA's inspectional observations are erroneous because it found violations for products that are not subject to cGMP regulations. Specifically, defendants argue that some products the FDA identified as violating the cGMP regulations during its last three inspections were not subject to cGMP regulations because they were "export only" products or were created for "promotional" or "research and development" purposes and thus "not intended for human consumption." ECF No. 24 at 17–18. For this reason, defendants contend, "at least nine inspectional observations are without merit and should not be held against Confidence." *Id.* at 18.

Even assuming that the cGMP regulations do not apply to the products that were the subject of these nine inspectional observations, defendants fail to raise a genuine issue of material fact that their operations were cGMP compliant at the time of the FDA inspections. To begin, the FDA made a total of 21 inspectional observations during its last three inspections of Confidence's facilities. *See* ECF Nos. 23-13, 23-27, 23-24. Even if the FDA erroneously applied the cGMP regulations to products that were the subject of 9 of its observations that defendants challenge, it still found 12 additional violations in a three-year span. "A single violation provides a sufficient basis for the government to seek injunctive relief." *N.Y. Fish, Inc.*, 10 F. Supp. 3d at 369–70. Indeed, defendants admit to the conduct that formed the basis of many of the FDA's violation findings as they relate to dietary

supplements that were intended for sale in interstate commerce. *See, e.g.*, Nos. 26 ¶¶ 38–41 (admitting that confirmatory testing revealed that four products that passed Confidence's rotational testing scheme fell below specifications); 27 ¶¶ 14–18 (admitting that Confidence used challenged organoleptic and turbidity testing methods to identify ingredients in now discontinued Traditional Chinese Medicine products); *id.* ¶ 34 (admitting to using material provided by Chinese supplier as reference standard to verify dietary ingredients); *id* ¶ 36 (admitting to not verifying the presence of dietary ingredients in Traditional Chinese Medicine "proprietary blends"); *id.* ¶ 41 (admitting recordkeeping violations and process control issues during most recent inspection); ECF No. 23-17 at 1 (admitting that one of the FDA's observed violations resulted in a product recall due to "the company's inadvertent failure to include the coating process in product manufacturing records").

"Courts have accorded deference to the FDA's determination that a firm is in violation of the [c]GMP regulations." *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves, an Article of Device*, 799 F. Supp. 1275, 1287 (D.P.R. 1993). Defendants' arguments about the legal significance of facts (the existence of which they concede), such as whether their testing regime was appropriate or whether they satisfy cGMP verification requirements for products containing proprietary blends, thus cannot defeat plaintiff's summary judgment motion. *See* James T. O'Reilly & Katharine A. Van Tassel, *Food & Drug Administration*, § 7:21

(4th Ed. 2014) (citing *United States v. Richlyn Labs.*, 827 F. Supp. 1145 (E.D. Pa. 1992)). "Agencies (unlike courts) have unique expertise, often of a scientific or technical nature, relevant to applying a regulation to complex or changing circumstances." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2413 (2019) (internal quotations omitted). Because "[t]he court itself is not expert on the . . . scientific issues which must be explored" to determine whether defendants' manufacturing practices were sufficient to verify the identity, purity, strength, and composition of the ingredients in their dietary supplements, I defer to the FDA's findings in six inspections throughout the past decade that defendants have repeatedly failed to comply with the cGMP regulations. *Diapulse*, 457 F.2d at 29.

Defendants also argue that a genuine issue of material fact exists because two observations the FDA made during the 2018 Inspection were erroneously cited as "repeat observations." ECF No. at 19. Whether the violations the FDA found during the 2018 Inspection were repeat or new is irrelevant to whether plaintiff is entitled to summary judgment. Indeed, as described above, a single violation can be sufficient to entitle the government to injunctive relief. *N.Y. Fish, Inc.*, 10 F. Supp. 3d at 369–70. In any event, even though the observed violations at issue in the 2018 Inspection involved a product not at issue in prior inspections, they did relate to the same type of conduct—namely, defendants' failure to verify dietary ingredient and finished product specifications—that the FDA observed in prior inspections. ECF

No. 23-13 at 1–2. Thus, FDA inspectors did not err when they labeled these observations as "repeat observations." ECF No. 24 at 19.

Finally, defendants argue that "Confidence's current revitalized testing regime includes numerous in-process controls and accountability to abide by" the cGMP regulations, as demonstrated by their expert's August 2020 remote inspection, and thus the FDA's "inspectional observations specific to manufacturing operations no longer exist as alleged violations." ECF No. 24 at 19–20. Even assuming that Confidence has, in fact, improved its cGMP compliance since the FDA's last inspection, that is not enough to and avoid the issuance of an injunction. "It is clear . . . that a court's power to grant injunctive relief survives discontinuance of the illegal conduct." *Hakim*, 462 F. Supp. 3d at 433 (granting injunctive relief on summary judgment) (citing *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953)). Having established defendants' long history of cGMP regulations, whether an injunction should be issued turns on "the likelihood of continuing violation or recommencement of the offensive behavior," *Diapulse*, 457 F.2d at 28–29, an inquiry to which I now turn.

D. Reasonable Likelihood of Recurrence

Plaintiff argues that despite defendants' claimed voluntary remedial measures, there is a reasonable likelihood that cGMP violations will recur absent an injunction. ECF No. 21 at 24–25. "In deciding whether injunctive relief is appropriate after a

defendant claims to have voluntarily c[e]ased illegal behavior, it is key that there be some 'cognizable danger of recurrent violation.'" *Hakim*, 462 F. Supp. 3d at 433 (quoting *W.T. Grant Co.*, 345 U.S. at 633). Before granting a statutory injunction, courts consider "all the circumstances," including the following factors "(1) the bona fides of the expressed intent to comply; (2) the effectiveness of the discontinuance; and (3) in some cases, the character of the past violations." *Id.; see also EEOC v. KarenKim, Inc.*, 698 F.3d 92, 100 (2d Cir. 2012). One important indicator of the likelihood of recurrent violation is a past record of noncompliance. *Diapulse*, 457 F.2d at 29. "Courts should be particularly cautious when faced with corrective measures that appear to take place in anticipation of or in reaction to legal action." *Hakim*, 462 F. Supp. 3d at 434 (citing *United States v. Or. State Med. Soc'y*, 343 U.S. 326 (1952)). Defendants accordingly "face a heavy burden to establish mootness in such cases because otherwise they would simply be free to return to their old ways after the threat of a lawsuit ha[s] passed." *Iron Arrow Soc'y v. Heckler*, 464 U.S. 67, 72 (1983) (internal quotation omitted).

Here, Confidence's multiple cGMP regulation violations over the course of many years weighs in favor of finding that its noncompliant behavior would recur absent an injunction. Moreover, Chao claims that the FDA and DOJ advised him that they intended to file suit "shortly after October 2017." ECF No. 26 ¶ 79. Confidence took many of its remedial measures only after being informed of the

government's intention to litigate, which also weighs in favor of issuing an injunction. These remedial measures include (1) discontinuing all dietary supplements based on Traditional Chinese Medicine, which were the subject of a majority of the FDA's observed violations; (2) stopping organoleptic and turbidity testing as a means of identifying dietary ingredients; (3) abandoning Confidence's rotational testing plan in favor of conducting full label claim testing; and (4) implementing recommendations of its third-party cGMP compliance consultant REJIMUS. ECF Nos. 26 ¶¶ 18–21, 69–71. Indeed, many of the violations the FDA observed from its most recent inspections are for violations of the same regulations that were the subject of its 2012 civil *in rem* forfeiture action, such as failure to conduct appropriate tests to verify the identity of a product ingredient and failure to ensure that finished batches of dietary supplements met product specifications. ECF No. 23-41 ¶¶ 17–18.

Defendants argue that the amount of time that has elapsed since the FDA's last inspection of defendants' facilities also raises questions of fact about whether the FDA's findings accurately represent the current manufacturing conditions at Confidence. They point to the fact that plaintiff did not file its complaint until 286 days after the FDA's last inspection, and over two years have passed since that inspection. Defendants similarly raise a laches defense in this case, which must be rejected. ECF No. 7 at Affirmative Defense #8. "The principle that the United States

are not . . . barred by any laches of their officers, however gross, in a suit brought by them as a sovereign government to enforce a public right, or to assert a public interest, is e[s]tablished past all controversy or doubt." *United States v. Beebe*, 127 U.S. 338, 344 (1888); *see also Davila v. Lang*, 343 F. Supp. 3d 254, 283 (S.D.N.Y. 2018) (laches defense is not generally available against federal government); *United States v. Berst*, 2012 WL 4361408, at *3 (D. Or. Aug. 2, 2012), *report and recommendation adopted* 2012 WL 4361559 (D. Or. Sept. 20, 2012) (rejecting laches defense and granting summary judgment and injunction against defendant's sale of dietary supplements despite seven-year gap between FDA inspection and filing of complaint). Thus, despite defendants' claim that they no longer engage in conduct that violates the cGMP regulations, their long history of noncompliance weighs in favor of granting an injunction.

Nevertheless, there are aspects of plaintiff's requested injunction that caution against issuing an injunction of the scope plaintiff proposes. Plaintiff's proposed injunction would permanently restrain defendants from receiving, manufacturing, preparing, packing, repacking, labeling, holding, or distributing dietary supplements in interstate commerce unless and until certain conditions are met. ECF No. 22 ¶ 5. One of those conditions is that defendants "recall and destroy, under FDA's supervision . . . *all* dietary supplements (including raw and in-process materials and finished products) that were received, manufactured, prepared, packed, repacked,

labeled, held, or distributed between March 23, 2016 and the date of entry" of the injunction. *Id.* ¶ 5C (emphasis added). Defendants have performed a financial analysis of such a mandatory recall and estimate that it would cost $3,353,525.39, which would shut Confidence down entirely. ECF No. 26 ¶¶ 46–47. While the possibility of defendants going out of business cannot defeat an injunction—*see Diapulse*, 457 F.2d at 29—"[i]njunctive relief should be narrowly tailored to fit specific legal violations," and "should not impose unnecessary burdens on lawful activity." *U.S. v. Blue Ribbon Smoked Fish, Inc.*, 56 F. App'x 542, 543 (2d Cir. 2003) (quoting *Soc'y For Good Will To Retarded Children, Inc. v. Cuomo*, 737 F.2d 1239, 1251 (2d Cir. 1984)).

A more narrowly tailored injunction may be appropriate. Confidence claims that it currently manufactures 31 dietary supplements, only 6 of which have led to FDA inspectional observations of noncompliance with cGMP regulations. ECF No. 26 ¶¶ 15, 29–34. Indeed, defendants have represented that they have already destroyed or discontinued 85% of the products that the FDA found were manufactured in violation of the cGMP regulations. *Id.* ¶ 29. Moreover, as mentioned earlier, the confirmatory tests conducted by a third-party laboratory, which Confidence provided to the FDA, demonstrated that more than 97% of 289 tested product samples met specifications. ECF No. 23-15. Considering these data, it is unclear how the recall and destruction of all Confidence's dietary supplements,

including those that were never the subject of FDA inspectional observations, is necessary to advance the goals of the FDCA when a more limited recall that would be less burdensome to defendants may be sufficient.

Plaintiff argues that, in the absence of their proposed injunction, "it would be easier and far less expensive for Defendants to reverse their alleged compliance measures, begin manufacturing their allegedly discontinued products, begin distributing domestically their alleged export-only products, and discontinue their association with an outside consultant." ECF No. 29 at 9. That certainly may be the case, especially considering that defendants themselves represent that they have "expended millions of dollars on cGMP regulatory compliance efforts." ECF No. 26 at 42. But the reverse may also be true. The amount of money defendants have already allegedly sunk into updating their compliance regime, as well as the transaction costs associated with reintroducing lines of products that they know will invite scrutiny from the FDA, may well deter defendants from returning to a state of operation that was in place when the FDA last inspected their facilities over two years ago. A hearing to discuss the scope of an injunction would thus be beneficial.

In sum, plaintiff has demonstrated defendants' history of non-compliance with cGMP regulations and that a permanent injunction is appropriate. Even though an injunction is necessary, however, plaintiff's proposed injunction may be overbroad insofar as it would require recall and destruction of all of defendants'

dietary supplements, including those that the FDA did not observe as being manufactured in violation of the cGMP regulations. Under these circumstances, my case manager will set the case down for (virtual) oral argument solely limited to whether the condition in paragraph 5C of plaintiff's proposed injunction order, which requires defendants to recall and destroy all dietary supplements it manufactured after March 23, 2016, is appropriate.[5]

CONCLUSION

Plaintiff's motion for summary judgment is granted. Plaintiff has established that a permanent injunction is appropriate. My case manager will schedule a virtual hearing to determine if the condition in paragraph 5C of plaintiff's proposed injunction order is appropriate.

SO ORDERED.

Edward R. Korman
Edward R. Korman
United States District Judge

Brooklyn, New York
January 28, 2021

[5] Although defendants demand a jury trial—ECF No. 7—an action for an injunction under 21 U.S.C. § 332(a) is purely equitable in nature and a jury trial on the injunction is not required under the Seventh Amendment.