UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

NOT FOR PUBLICATION

UNITED STATES OF AMERICA,
Plaintiff,

– against –

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

Defendants.

MEMORANDUM & ORDER

19–CV–3073 (ERK) (SIL)

KORMAN, *J.*:

I assume familiarity with the underlying facts and procedural history of this case. On January 28, 2021, I granted plaintiff's motion for summary judgment on its complaint seeking a permanent injunction against defendants after finding that defendants violated current good manufacturing practice ("cGMP") regulations that govern the production and distribution of dietary supplements. ECF No. 30. Plaintiff claimed that numerous FDA inspections over the past decade had revealed that defendants failed to properly establish criteria for determining the identity and purity of the ingredients in their products. Plaintiff also claimed that the testing methods that defendants used were inadequate to verify that the ingredients in defendants' supplements were what they purported to be. Because of the long history of defendants' compliance failures, plaintiff sought 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 agreed and was prepared to sign off on all but two provisions of the plaintiff's proposed injunction. The provisions that I found to be appropriate included prospective measures such as:

1. conditioning defendants' resumption of operations on their retaining a cGMP expert at their own expense who would inspect defendants' facilities and certify compliance with the appropriate regulations;

2. defendants' retaining an auditor who would conduct an inspection every six months for not less than five years after defendants resume operations;

3. authorizing FDA to cease defendants' operations or mandate a recall if defendants violate the applicable regulations or the injunction in the future;

4. permitting the FDA to conduct inspections without prior notice to defendants as the FDA deems necessary and mandating that defendants bear the cost of such inspections;

5. defendants' posting a copy of the injunction in a conspicuous location at their facilities and providing a copy to all of its directors, agents, and employees by personal service or certified mail;

6. defendants' holding a meeting with all its employees describing their obligations under the injunction; and

7. subjecting defendants to a $7,500 per day fine in the event they violate the injunction in the future.

ECF No. 22.

Despite the comprehensive prospective relief described above, there were two provisions of the proposed injunction that appeared to be overbroad. That proposal required defendants to recall and destroy all supplements and raw materials received, prepared, packed, repacked, labeled, held, or distributed after March 23, 2016 (which the government modified at the hearing to February 2018), including those that the FDA did not find violated cGMP regulations. According to defendants, such a recall and destruction would cost $3,353,525.39, which would shut Confidence down entirely. ECF No. 26 ¶¶ 46–47. Under these circumstances, it seemed appropriate to set the case down for a hearing limited to whether the recall and destruction provisions of plaintiff's proposed injunction were overbroad.

After considering the arguments of the parties, I conclude that the following provisions of the plaintiff's proposed injunction order are overbroad:

> [Paragraph 5C] Defendants [shall] recall and destroy, under FDA's supervision and in accordance with the procedures provided in paragraph 6, 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 this Order.
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> [Paragraph 6] Within fifteen (15) business days after entry of this Order, Defendants, under FDA's supervision, and pursuant to a destruction plan which FDA has approved in writing, shall destroy all dietary supplements (including raw and in-process materials and finished products) that are in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and the costs of FDA's supervision. Defendants shall not dispose of any products in

> a manner contrary to the provisions of the Act, any other federal law, or the laws [of] any state or territory, as defined in the Act, in which the products are disposed.

ECF No. 22.

Several factors weigh in favor of removing the above provisions from the injunction order. First, as plaintiff notes, Confidence's dietary supplements have a shelf-life of three years. Tr.[1] at 3:7–24 7:7–25. As a result, the only supplements manufactured by Confidence that are currently in the stream of commerce have been produced after the beginning of 2018. *Id.* Since 2018, Confidence has manufactured its dietary supplements under the guidance of the consulting firm REJIMUS and its chief operating officer Jim Lassiter. Lassiter, who has over 40 years' experience in the dietary supplement regulatory industry and who has published numerous articles in trade journals concerning dietary supplement manufacturing and current good manufacturing procedure ("cGMP") compliance, testified at the hearing.

Lassiter testified that, since 2018, REJIMUS has assisted Confidence revise its operating procedures. *Id.* at 30:23–31:15. Specifically, REJIMUS has provided Confidence with direction to improve its specification, establishment, and testing requirements. *Id.* at 36:14–20. According to Lassiter, Confidence has been cooperative throughout each step of the process and has implemented REJIMUS's

[1] Tr. refers to the transcript of the hearing held on February 17, 2021.

suggestions. *Id.* at 37:15–24. Based on several in-person and virtual audits[2] undertaken in the past three years, Lassiter opines that Confidence has been in compliance with cGMP regulations since 2018, and the products that it has produced since that time, which plaintiff seeks to have destroyed, do not pose a risk to the public. *Id.* at 38:5–15. Based on Lassiter's testimony, there is no need to require Confidence to recall and destroy the supplements that it has produced or the raw materials that it has received in the last three years to ensure compliance with cGMP regulations going forward.

Separate and apart from Lassiter's testimony, which is credible, independent testing of Confidence's products manufactured before 2018 further suggests that plaintiff's proposed injunction is overbroad. During a 2017 inspection, the FDA objected to Confidence's rotational testing system, in which the company periodically tested one ingredient in its finished products on a rotational basis before releasing the product to the public without further testing. In early 2018, as part of a response to the FDA's 2017 Inspection findings, Confidence had a third-party laboratory conduct "confirmatory testing" of products manufactured between March 2016 and October 2017. According to Lassiter, the purpose of the confirmatory test was to evaluate whether the products that passed Confidence's rotational testing

[2] The reason why Lassiter's most recent audits have been virtual is due to the Covid-19 pandemic. Tr. at 22:12–15, 32:2–6.

system met each individual specification requirement. Tr. at 59:23–60:4. Out of the 289 samples that were subject to confirmatory testing, only eight were found to be below specifications. 97% were within specification. *See* ECF No. 23-15 at 337–38. Although Confidence's confirmatory testing only applied to products manufactured prior to 2018, the testing results corroborate Lassiter's testimony about Confidence's cGMP compliance since 2018. Confidence has also discontinued all products that failed confirmatory testing. ECF No. 27 ¶¶ 47–50. Because of the 97% pass rate of Confidence's confirmatory tests, in combination with Lassiter's testimony, which I credit, I find that recall and destruction of all its supplements manufactured in the last 3 years is not necessary to protect the public.

In sum, the broad prospective enforcement provisions of plaintiff's proposed injunction are sufficient to ensure defendants' compliance with the FDCA moving forward. The recall and destruction provisions are not "narrowly tailored to fit specific legal violations," and "impose unnecessary burdens on lawful activity." *United States 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)). Although plaintiff has expressed skepticism about whether the cost of a recall would shut Confidence down, it has not presented any evidence to support its argument that Confidence's cost projections are inaccurate. While breakdown of recall-related costs was produced to plaintiff during settlement

discussions and is therefore not part of the record, Tr. 67:1–5, defendant Chao submitted an uncontroverted affidavit that a recall would cost Confidence over $3.3 million. ECF No. 26 ¶¶ 46–47. In any event, at the hearing, plaintiff did not deny that it would seek the same relief even if the recall provisions would result in closing a small business that employs between 10 to 20 people. Tr. at 66:12–25, 76:9–10. Invoking the "considerable discretion" that I have in crafting an injunction, *United States v. N.Y. Fish, Inc.*, 10 F. Supp. 3d 355, 380 (E.D.N.Y. 2014), I will delete from plaintiff's proposed injunction paragraphs 5C and 6. The injunction will be filed along with this opinion.

SO ORDERED.

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

Brooklyn, New York
March 3, 2021