UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. 286,161 bottles, 209 dietary supplement cookie packs, and 45,521 packs, boxes, or granules, more or less, of an article of food, specifically various herbal supplement capsules, tablets, cookies, and teas, as described in Appendix A, manufactured, prepared, packed, held, or distributed by LIFE RISING CORPORATION, Defendants, LIFE RISING CORPORATION, Claimant.	)	No. 19 C 3876 Judge Sara L. Ellis

OPINION AND ORDER

After the Food and Drug Administration ("FDA") noted several regulatory violations during an inspection of Claimant Life Rising Corporation ("Life Rising"), the FDA seized thousands of dietary supplements pursuant to § 334 of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. The government then filed a complaint for forfeiture *in rem* of the seized items. After Life Rising answered the complaint, the government moved for judgment on the pleadings. Because Life Rising's answer admits the essential elements required for condemnation of the seized dietary supplements, the Court grants the government's motion and orders the condemnation and destruction of the seized items.

BACKGROUND[1]

From February 28, 2019, to May 17, 2019, the FDA conducted an inspection of Life Rising, a dietary supplement manufacturer and distributor located at 7884 South Quincy Street, Willowbrook, Illinois, with additional storage and manufacturing operations at 7886 and 7888 South Quincy Street. At the end of the 2019 inspection, the FDA issued a form FDA 483 to Life Rising's quality control manager, outlining twenty-seven objectionable conditions it identified that violated the current good manufacturing practice regulations ("CGMPs") prescribed under 21 C.F.R. Part 111 for operations involving dietary supplements. Although Life Rising disputes some of the identified objectionable conditions, it admits to the following violations:

> (1) failure to have written training procedures;
>
> (2) failure to have written procedures for pest control on the date of the filing of the complaint;
>
> (3) failure to have one person formally designated to supervise overall sanitation procedures;
>
> (4) failure to have written procedures for maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces used to manufacture, package, label, or hold components or dietary supplements;
>
> (5) failure to adequately document any calibration of instruments and controls used to manufacture or test a component or dietary supplement;
>
> (6) failure to establish component specifications for identity, purity, strength, and composition for each component used to manufacture a dietary supplement; and

[1] In resolving the government's motion for judgment on the pleadings, the Court considers the complaint, Life Rising's answer, and the exhibits attached to those pleadings. *See N. Ind. Gun & Outdoor Shows, Inc. v. City of S. Bend*, 163 F.3d 449, 452–53 (7th Cir. 1998). The Court also takes judicial notice of form FDA 483, which the government attached to its motion. *See Bell v. City of Country Club Hills*, 841 F.3d 713, 716 n.1 (7th Cir. 2016) (court may take judicial notice of facts "originat[ing] from a report of an administrative body"); *Gen. Elec. Cap. Corp. v. Lease Resol. Corp.*, 128 F.3d 1074, 1080–81 (7th Cir. 1997) (courts "may only take judicial notice from sources 'whose accuracy cannot reasonably be questioned'" (citing Fed. R. Evid. 201(b))); *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1089 n.1 (N.D. Cal. 2016) (taking judicial notice of form FDA 483 in considering motion to dismiss).

> (7) failure to clearly identify, hold, and control, under a quarantine system for appropriate disposition, packaged and labeled dietary supplements rejected for distribution.

Life Rising affirmatively states, however, that since the filing of the complaint, it has established compliant written training and pest control procedures. It also states that while it did not have one formally designated supervisor of sanitation procedures or written procedures for sanitizing equipment at the time of the inspection, all employees ensured proper sanitation and Life Rising regularly inspected the facilities to ensure sanitary conditions. Finally, Life Rising notes that, as of May 20, 2019, it has ceased manufacturing operations.

At the conclusion of its inspection, the FDA inventoried Life Rising's dietary supplements and placed them under administrative detention. After the filing of this action, the Court issued a warrant for arrest *in rem*, authorizing the seizure of the dietary supplements under administrative detention. Doc. 6. The United States Marshals seized the items on June 14, 2019. Doc. 7. Life Rising admits that the seized items qualify as food under the FDCA, 21 U.S.C. § 321(ff), and consist in whole or in part of components shipped in interstate commerce from outside of Illinois.

LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 12(c), a party may move for judgment on the pleadings after the complaint and answer have been filed. Fed. R. Civ. P. 12(c). When the movant seeks to "dispose of the case on the basis of the underlying substantive merits . . . the appropriate standard is that applicable to summary judgment, except that the court may consider only the contents of the pleadings." *Alexander v. City of Chicago*, 994 F.2d 333, 336 (7th Cir. 1993). The pleadings include the complaint, answer, and documents attached as exhibits to the complaint and answer. *N. Ind. Gun & Outdoor Shows, Inc.*, 163 F.3d at 452–53. The Court should grant a motion for judgment on the pleadings if "no genuine issues of material fact remain

to be resolved" and the movant "is entitled to judgment as a matter of law." *Alexander*, 994 F.2d at 336.

ANALYSIS

21 U.S.C. § 334 allows for the seizure and condemnation of (1) food, drug, or cosmetic articles (2) that are adulterated or misbranded (3) while held for sale after shipment in interstate commerce. The government argues that the pleadings establish that the seized items qualify for condemnation under § 334 because Life Rising has admitted to all the essential elements of the claim. Life Rising, on the other hand, contends that the Court should defer decision on the government's motion to allow it to obtain additional discovery and contest the government's allegations. Unfortunately for Life Rising, however, no additional facts would affect the Court's disposition of this case given the binding judicial admissions in its answer that establish the required elements of the claim. *See Crest Hill Land Dev. LLC v. City of Joliet*, 396 F.3d 801, 805 (7th Cir. 2005) (concession in answer is a "binding judicial admission" that "has the effect of withdrawing the question" from dispute).

Initially, Life Rising does not contest that the seized items qualify as food held for sale after shipment in interstate commerce, admitting to the first and third elements required for condemnation pursuant to § 334. The Court therefore only focuses on the second element, whether the pleadings demonstrate that no issue of fact exists as to whether the seized items meet the statutory definition of adulterated set forth in 21 U.S.C. § 342(g)(1). Under that definition, dietary supplements qualify as adulterated if they have "been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations." 21 U.S.C. § 342(g)(1).

In its answer, Life Rising admitted to seven of the twenty-seven CGMP violations that the FDA identified during its 2019 inspection:

> (1) failure to have written training procedures in violation of 21 C.F.R. §§ 111.8, 111.14;
>
> (2) failure to have written procedures for pest control in violation of 21 C.F.R. § 111.23(b);
>
> (3) failure to have at least one person formally designated to supervise overall sanitation procedures in violation of 21 C.F.R. § 111.15(k);
>
> (4) failure to have written procedures for maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces used to manufacture, package, label, or hold components or dietary supplements in violation of 21 C.F.R. § 111.25(c);
>
> (5) failure to adequately document any calibration of instruments and controls used to manufacture or test a component or dietary supplement in violation of 21 C.F.R. § 111.35(b)(3);
>
> (6) failure to establish component specifications for identity, purity, strength, and composition for each component used to manufacture a dietary supplement in violation of 21 C.F.R. § 111.70(b); and
>
> (7) failure to clearly identify, hold, and control, under a quarantine system for appropriate disposition, packaged and labeled dietary supplements rejected for distribution in violation of 21 C.F.R. § 425.

Life Rising does not contest that it has admitted to these violations and instead tries to distract from them by highlighting the remaining violations that it disputes. But the fact that Life Rising does not agree to all of the violations the FDA identified does not detract from the fact that its admission to seven CGMP violations suffices to render the seized items adulterated. *See Alra Labs., Inc. v. Am. Cyanamid Co.*, No. 92 C 2252, 1996 WL 377070, at *4 (N.D. Ill. July 2, 1996) ("A drug is adulterated if there is a single instance of failing to conform to [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. 1992) ("[S]o long as the government has proved a single violation of the [C]GMP regulations, the seized articles are adulterated as a matter of law.").

Life Rising appears to argue that, even if it has admitted to seven CGMP violations, an issue of fact exists as to whether the violations allow for condemnation of each seized item. But "the government need not establish that any particular [dietary supplement] is actually deficient" as a result of the CGMP violations, only that a CGMP violation occurred, because the FDCA "is concerned with the manner in which a [dietary supplement] is produced as well as its composition and content." *United States v. W. Serum Co.*, 498 F. Supp. 863, 867 (D. Ariz. 1980); *see also Alra Labs.*, 1996 WL 377070, at *4 ("The drug itself does not need to be deficient for a finding of adulteration based on a failure to conform to [C]GMP regulations."). Although the court in *Alra Laboratories* declined to find on summary judgment that "general [C]GMP violations, occurring anywhere in [the claimant's] plant, rendered all drugs manufactured during that time period adulterated as a matter of law," there, the court did not have before it evidence that the cited CGMP violations "specifically affect[ed] the drug in question." 1996 WL 377070, at *4. Here, however, Life Rising has admitted that all of the seized items were located in Life Rising's facilities. Given that the admitted violations affected Life Rising's facilities and manufacturing processes as a whole, only one permissible conclusion exists: all of the seized items qualify as adulterated because Life Rising "prepared, packed or held [the seized items] under conditions" that failed to meet the CGMP regulations. 21 U.S.C. § 342(g)(1); *see 789 Cases*, 799 F. Supp. at 1295–96 (authorizing the seizure of all items manufactured at a facility over a several year time period where the claimant used the same manufacturing process that violated CGMP regulations the entire time).

Life Rising also contends it needs additional discovery to contest the seizure and condemnation. But Life Rising has not shown how any additional discovery could change the outcome of this case, particularly given that Life Rising has not raised any affirmative defenses. For example, the fact that sample testing revealed that the level of toxic elements in several of the seized items had no regulatory significance would not affect the adulteration determination because "[d]rugs produced in violation of . . . CGMP regulations are deemed to be adulterated without the agency having to show that they are actually contaminated." *John D. Copanos & Sons, Inc. v. FDA*, 854 F.2d 510, 514 (D.C. Cir. 1988); *United States v. Undetermined Quantities of Various Articles of Device Consisting in Whole or in Part of Proplast II*, 800 F. Supp. 499, 502 (S.D. Tex. 1992) ("In order to prove a claim of adulteration of a device based upon noncompliance with [C]GMP regulations, the Government need not establish that the device is actually deficient as a result of the [C]GMP violation."). And to the extent discovery would uncover that Life Rising did not commit all of the twenty-seven violations the FDA identified, as noted above, this would not negate the admissions Life Rising has already made because the FDA may demand "absolute compliance with the [C]GMP regulations . . . regardless of any cost or hardship alleged by the claimant." *789 Cases*, 799 F. Supp. at 1287–88; *Proplast II*, 800 F. Supp. at 502 ("[W]hether a manufacturer is, in the Court's estimation, in *substantial* compliance with [C]GMP regulations is immaterial if the FDA, in its discretion, determines that *full* compliance with the regulations is necessary."). Because the pleadings establish the required elements of the government's claim, the Court grants the government's motion and orders the condemnation and destruction of the seized items.

CONCLUSION

For the foregoing reasons, the Court grants the government's motion for judgment on the pleadings [51]. The Court enters judgment for the government and orders the government to provide the Court with a proposed order of condemnation and destruction.

Dated: May 4, 2021

SARA L. ELLIS
United States District Judge