

**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 section 334 of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.* Life Rising now moves to dismiss the government’s complaint for forfeiture *in rem* pursuant to Federal Rule of Civil Procedure 12(b)(6) and the Supplemental Admiralty or Maritime Claims and Asset Forfeiture Rules E and G for failure to state a claim. Because the government has pleaded sufficient facts to support a reasonable belief that it can prove the seized items are subject to forfeiture, the Court denies Life Rising’s motion to dismiss.

BACKGROUND¹

From February 28, 2019, to May 17, 2019, the FDA conducted an inspection of Life Rising, a dietary supplement distributor located at 7884 South Quincy Street, Willowbrook, Illinois, with additional storage and manufacturing operations at 7886 and 7888 South Quincy Street. Inspectors observed several violations of the current good manufacturing practice regulations (“CGMPs”) prescribed under 21 C.F.R. Part 111 for operations involving dietary supplements. These violations included:

1. No written training procedures;
2. No written procedures for pest control;
3. No written procedures for quality control operations;
4. No written procedures for maintaining, cleaning, and sanitizing equipment;
5. Failure to properly sanitize equipment;
6. Failure to assign one or more employees to supervise overall sanitation;
7. Inadequate batch production records;
8. Failure to establish the reliability of the supplier’s certificate of analysis by confirming the results of the supplier’s tests;
9. Failure to periodically re-confirm supplier’s certificate of analysis;
10. Failure to maintain a certificate of analysis that includes a description of the tests and test results;
11. Failure to verify that finished batches of dietary supplements met specifications for identity, purity, strength, and composition;
12. Failure to establish specifications for identity, purity, strength, and composition of dietary supplements;
13. Failure to prepare a production record for every batch of dietary supplements;

¹ The facts in the background section are taken from the government’s complaint and are presumed true for the purpose of resolving Life Rising’s motion to dismiss. See *Virnich v. Vorwald*, 664 F.3d 206, 212 (7th Cir. 2011); *Local 15, Int’l Bhd. of Elec. Workers, AFL-CIO v. Exelon Corp.*, 495 F.3d 779, 782 (7th Cir. 2007). The Court has also relied on form FDA 483, attached to the government’s response brief. A court normally cannot consider extrinsic evidence without converting a motion to dismiss into one for summary judgment. *Hecker v. Deere & Co.*, 556 F.3d 575, 582–83 (7th Cir. 2009). Where a document is referenced in the complaint and central to plaintiff’s claims, however, the Court may consider it in ruling on the motion to dismiss. *Id.* The Court may also take judicial notice of matters of public record, including reports by administrative agencies. 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. Capital Corp. v. Lease Resolution 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). Life Rising does not contest that the Court can consider form FDA 483.

14. Failure to establish and follow a master manufacturing record for each unique formulation of dietary supplement and for each batch size;
15. Failure to identify the reference standard, calibration method, and calibration readings in calibration documentation;
16. Failure to collect and hold reserve samples of dietary supplements that were distributed;
17. Failure to clearly identify, hold, and control, under a quarantine system for appropriate disposition, packaged and labeled dietary supplements rejected for distribution.

Many of the alleged violations were similar or identical to violations contained in a warning letter the FDA previously issued to Life Rising in 2017.

At the end of the 2019 inspection, on May 17, the FDA issued a form FDA 483 to Life Rising's quality control manager, outlining 27 "objectionable conditions" and giving specific examples of the inspectors' observations. Doc. 1 ¶ 12. The FDA inventoried Life Rising's dietary supplements and placed them under administrative detention.

LEGAL STANDARD

In considering a Rule 12(b)(6) motion to dismiss, the Court accepts as true all well-pleaded facts in the plaintiff's complaint and draws all reasonable inferences from those facts in the plaintiff's favor. *AnchorBank, FSB v. Hofer*, 649 F.3d 610, 614 (7th Cir. 2011). Ordinarily, the complaint need only state a "plausible claim for relief" and provide fair notice to the defendant. *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The Supplemental Rules for Admiralty or Maritime Claims and Asset Forfeiture Actions provide a heightened pleading standard in civil forfeiture actions. First, the government must plead the circumstances giving rise to the action "with such particularity that the defendant or claimant will be able, without moving for a more definite statement, to commence an investigation of the facts and to frame a responsive pleading." Fed. R. Civ. P. Supp. R. E(2)(a). Additionally, the complaint must: (a) be verified; (b) state the grounds for

subject-matter jurisdiction and *in rem* jurisdiction; (c) describe the property with reasonable particularity; (d) state the location where the property was seized; (e) identify the statute under which the forfeiture action is brought; and (f) “state sufficiently detailed facts to support a reasonable belief that the government will be able to meet its burden of proof at trial.” Fed. R. Civ. P. Supp. R. G(2)(a)-(f). The government must carry its burden by a preponderance of the evidence. 18 U.S.C. § 983(c)(1). While the claimant may move to dismiss a forfeiture action under Federal Rule of Civil Procedure 12(b), “the complaint may not be dismissed on the ground that the government did not have adequate evidence at the time the complaint was filed to establish the forfeitability of the property.” Fed. R. Civ. P. Supp. R. G(8)(b)(ii); 18 U.S.C. § 983(a)(3)(D).

ANALYSIS

Life Rising argues that the government fails to state a claim under the heightened pleading requirements for forfeiture actions. Before reaching the substance of Life Rising’s motion to dismiss, the government maintains that the Court does not have the ability to consider the sufficiency of the complaint. The government contends that the Court lacks jurisdiction to review the FDA’s determination to initiate an enforcement action under *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 599–600 (1990), and a dismissal on the pleadings is “no different than the intervention proscribed in *Ewing*.” Doc. 21 at 6. According to the government, the Court may not intervene until the parties have had the opportunity to fully litigate the underlying merits of the case, otherwise “[t]he means which Congress provided to protect consumers against the injurious consequences of protracted proceedings would then be seriously impaired.” *Ewing*, 339 U.S. at 601.

The government misconstrues *Ewing*. *Ewing* held that district courts do not have jurisdiction to review an administrative probable cause determination to initiate enforcement proceedings pursuant to the FDCA. *Id.* at 600 (“Judicial review of this preliminary phase of the administrative procedure does not fit the statutory scheme nor serve the policy of the [FDCA].”). *Ewing* analogized the administrative determination to initiate a seizure proceeding to the return of an indictment in a criminal case:

The impact of an indictment is on the reputation or liberty of a man. The same is true where a prosecutor files an information charging violations of the law. The harm to property and business can also be incalculable by the mere institution of proceedings. Yet it has never been held that the hand of government must be stayed until the courts have an opportunity to determine whether the government is justified in instituting suit in the courts.

Id. at 599. Due process does not require a hearing before the agency can exercise its discretion.

Id. Instead, “[i]t is sufficient, where only property rights are concerned, that there is at some stage an opportunity for a hearing and a judicial determination.” *Id.* That opportunity comes “in the seizure action itself.” *Pharmadyne Labs., Inc. v. Kennedy*, 596 F.2d 568, 571 n.7 (3d Cir. 1979) (“[W]hen seizure actions are pending, the statute provides an exclusive forum in which all constitutional, statutory and factual issues can be raised. That forum is the seizure proceeding.”). The cases the government cites to are inapplicable because they applied *Ewing* in the context of a motion for an injunction. *See United States v. Alcon Labs.*, 636 F.2d 876, 881 (1st Cir. 1981) (“This injunction exceeded the district court’s authority. To prevent this sort of eroding of the agency’s protective powers, the Supreme Court in *Ewing* . . . held that district courts lack jurisdiction to enjoin multiple seizure actions instituted by the FDA under the Act.”); *Parke, Davis & Co. v. Califano*, 564 F.2d 1200, 1206 (6th Cir. 1977) (“[I]t was an abuse of discretion to enjoin the FDA in the circumstances of this case where pending enforcement actions provided an

opportunity for a full hearing before a court.”); *United States v. 18 Cases, More or Less, of an Article of Food, Each Case Containing 120/100 Tablet Bottles*, No. 1:06-cv-0406-GET, 2006 WL 8433081, at *2–3 (N.D. Ga. Mar. 13, 2006); *X-tra Art, Inc. v. Consumer Prod. Safety Comm’n*, No. C-91-1336-MHP, 1991 WL 405183, at *6 (N.D. Cal. June 12, 1991), *aff’d sub nom. X-Tra Art v. Consumer Prod. Safety Comm’n*, 969 F.2d 793 (9th Cir. 1992). Similar to how courts review the sufficiency of an indictment to ensure it apprises a defendant of the charges against him, *see United States v. Khan*, 937 F.3d 1042, 1049 (7th Cir. 2019), the Court can review the sufficiency of the complaint in this case. Fed. R. Civ. P. Supp. R. G(8)(b)(i) (“A claimant who establishes standing to contest forfeiture may move to dismiss the action under Rule 12(b).”).

Turning to the sufficiency of the complaint, Life Rising argues the government has failed to plead sufficient facts to support a reasonable belief that there is probable cause to forfeit the seized objects. Specifically, Life Rising claims that the complaint does not plead with sufficient particularity why all of the seized items are adulterated or how Life Rising’s practices violated the CGMPs. Life Rising points, as an example, to the government’s allegation that Life Rising failed to establish specifications for the identity, purity, strength, and composition of components used to manufacture the dietary supplements. Life Rising posits this is not enough to identify the specific articles that were noncompliant or the reason they were noncompliant, such as “whether the specifications were nonexistent or just incomplete.” Doc. 18 at 6.

At this stage, however, the government need not show that all of the items are subject to forfeiture. Fed. R. Civ. P. Supp. R. G(8)(b)(ii); *see United States v. Aguilar*, 782 F.3d 1101, 1109 (9th Cir. 2015) (“We have consistently instructed district courts to wait until trial to adjudicate arguments that a portion of the property that the government claims is not subject to

forfeiture. . . . The corollary of this instruction is that the government need not show that all of the claimed property is tainted to satisfy Supplemental Rule G(2)(f).”); *United States v. One Parcel of Real Prop.*, 921 F.2d 370, 375 (1st Cir. 1990) (“Whether none, all, or only a portion of the defendant property is forfeitable is not determined at the pleadings stage, but at trial.”). The government need only plead sufficient facts to support “a reasonable belief” that the government can prove its case. Fed. R. Civ. P. Supp. R. G(2)(f). Even so, the government has established sufficient facts to infer that *all* of the seized items were adulterated in this case. Under 21 U.S.C. § 342(g)(1), dietary supplements are considered adulterated if they have “been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.” Here, all of the seized items were located at the facilities on South Quincy Street, and several of the violations seem to render any item within the facilities noncompliant. For example, FDA inspectors noted that Life Rising allegedly failed to maintain written training procedures; written procedures for pest control; written procedures for maintaining, cleaning, and sanitizing equipment; as well as written procedures for quality control operations. As long as the items were located in Life Rising’s facilities, which the government alleges, the items would seem to be “prepared, packed or held under conditions” that failed to meet the CGMPs and were therefore adulterated under the statute. This supports a reasonable belief that the government will be able to carry its burden to prove the seized property was adulterated and subject to forfeiture.

Life Rising moves, in the alternative, for a more definitive statement to allow it to properly prepare a responsive pleading pursuant to Fed. R. Civ. P. 12(e). In a forfeiture case, the Federal Rules of Civil Procedure must be read in light of the Supplemental Rules. *See United States v. \$8,221,877.16 in U.S. Currency*, 330 F.3d 141, 149 (3d Cir. 2003) (“Parties to civil

forfeiture proceedings are the servants of two procedural masters: the Supplemental Rules specially devised for admiralty and in rem proceedings, and the generally applicable Federal Rules of Civil Procedure. . . . The balance between the two is struck in favor of the Supplemental Rules[.]”); *United States v. One Gulfstream G-V Jet Aircraft*, 941 F. Supp. 2d 1, 13 (D.D.C. 2013) (“Although the Supplemental Rules govern, the normal set of rules may help to clarify any ambiguity.”). Rule E requires the government to plead the circumstances giving rise to the action with sufficient particularity that the claimant can frame a responsive pleading and undertake an investigation. Fed. R. Civ. P. Supp. R. E(2)(a). “Although the language of Rule E differs from Rule G, in practice courts have applied the same ‘reasonable belief’ standard to both rules.” *United States v. Funds in the Amount of Twenty-Two Thousand, Two Hundred Forty Dollars (\$22,240)*, No. 11-C-00148, 2011 WL 5169980, at *4 (N.D. Ill. Oct. 31, 2011) (citing *United States v. Mondragon*, 313 F.3d 862, 865 (4th Cir. 2002)). But to the extent Rule E requires more, it must give the claimant “a point from which to begin” their investigation and responsive pleading. *United States v. \$39,000 In Canadian Currency*, 801 F.2d 1210, 1221–22 (10th Cir. 1986). Courts have mostly examined Rule E’s particularity requirement in the context of criminal cases and found that allegations regarding “the date and time of the seizure, a description of the property seized, and detailed information regarding the circumstances and investigation leading up to the seizure” to be sufficient. *Funds in the Amount of Twenty-Two Thousand*, 2011 WL 5169980, at *4; see *United States v. Funds in the Amount of Forty-Five Thousand Fifty Dollars (\$45,050.00)*, No. 06 C 6948, 2007 WL 2323307, at *7 (N.D. Ill. Aug. 9, 2007) (allegations that identified “the date, time and location of the seizure; describe[d] the amount of money seized; and set forth the reasons for the seizure” were enough to allow claimant to investigate the facts and frame a responsive pleading). Here, the complaint includes

the date, time, and location of the seizure, a description of the items seized, and the reasons for the seizure. This satisfies the particularity requirements under Rule E.

If there were any doubt about the complaint's sufficiency in this respect, the government has also provided form FDA 483, which provides specific examples of the alleged violations. *See* Doc. 21 at 21 (noting, for example, that: "The production of SKIN-S powder, lot 190304, and ZGC powder, lot 190322, were observed during this inspection. The production area and utensils utilized in the compounding of powder, and in the production of the capsules, are cleaned without the use of detergents and sanitizers."). Life Rising asserts this is still insufficient but does not explain what more the government need provide. The government, however, has pleaded enough facts to state a claim and may proceed with its case.

CONCLUSION

For the foregoing reasons, the Court denies Life Rising's motion to dismiss [18].

Dated: February 3, 2020

A handwritten signature in black ink, appearing to read 'S L ELLIS', written over a horizontal line.

SARA L. ELLIS
United States District Judge