

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-R-4669)

Complainant

v.

US Liberty Inc.  
d/b/a Loch Raven Gulf,

Respondent.

Docket No. T-17-5661

Decision No. TB2642

Date: April 17, 2018

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, US Liberty Inc. d/b/a Loch Raven Gulf, that alleges facts and legal authority sufficient to justify the imposition of a No-Tobacco-Sale Order against Respondent for a period of 30 consecutive calendar days.

During the course of these administrative proceedings, Respondent repeatedly failed to comply with orders and directives and failed to defend its case. Furthermore, Respondent's misconduct has interfered with the speedy and orderly conduct of the hearing process. 21 C.F.R. § 17.35(a). Accordingly, pursuant to 21 C.F.R. § 17.35(c)(3), I strike Respondent's answer and issue this decision of default judgment. I therefore enter default judgment against Respondent and impose a No-Tobacco-Sale Order against Respondent for a period of 30 consecutive calendar days.

## I. Procedural History

CTP began this case by serving a Complaint on Respondent on August 7, 2017. The Complaint alleges that Respondent's staff impermissibly sold cigarettes or smokeless tobacco to minors and failed to verify that the purchasers were of sufficient age, thereby violating the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 301 et seq., and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140. CTP seeks a No-Tobacco-Sale Order against Respondent for a period of 30 consecutive calendar days.

In the Complaint and accompanying cover letter, CTP explained that within 30 days, Respondent should file an answer or request an extension of time within which to file an answer. CTP warned Respondent that if it failed to take one of these actions within 30 days an Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision imposing a No-Tobacco-Sale-Order against Respondent. Respondent failed to file an answer to the Complaint. Accordingly, on September 28, 2017, I issued an Initial Decision and Default Judgment against Respondent in the form of a No-Tobacco-Sale Order for a period of 30 consecutive calendar days. *See CTP v. US Liberty Inc. d/b/a Loch Raven Gulf*, DAB No. TB1999 (2017).

On October 27, 2017, before the Initial Decision and Default Judgment became final and binding upon the parties, 21 C.F.R. § 17.11(b), our office received Respondent's Motion to Reopen. Absent objection from CTP, I found that extraordinary circumstances prevented Respondent from timely filing an answer. On November 3, 2017,<sup>1</sup> I granted Respondent's motion, withdrew my September 28, 2017, Initial Decision and Default Judgment, Decision No. TB1999, and I granted Respondent an opportunity to answer CTP's Complaint pursuant to 21 C.F.R. § 17.11(d). On December 4, 2017, Respondent filed an answer to CTP's Complaint, within the time I permitted. On December 6, 2017, I issued an Acknowledgement and Pre-Hearing Order (APHO) that set deadlines for the parties' filings and exchanges, including a schedule for discovery. I directed that a party receiving a discovery request must provide the requested documents within 30 days of the request. APHO at ¶ 12; 21 C.F.R. § 17.23(a).

In accordance with the deadlines set forth in the APHO, CTP served Respondent with its Request for Production of Documents on December 20, 2017. On January 26, 2018, CTP filed a Motion to Compel Discovery asserting that Respondent had not responded to its discovery request. By Order of January 29, 2018, I informed Respondent that it had until February 12, 2018, to file a response to CTP's Motion to Compel Discovery. 21 C.F.R. § 17.32(c). Respondent did not respond.

---

<sup>1</sup> Although the order was dated November 4, 2017, it was issued on November 3, 2017.

Accordingly, on February 15, 2018, I issued an Order to Compel Discovery granting CTP's motion and ordering Respondent to comply with CTP's Request for Production of Documents by February 26, 2018. I warned Respondent that:

[F]ailure to comply may **result in sanctions** which may include striking its filings and issuing an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing the requested No-Tobacco-Sale order. 21 C.F.R. § 17.35.

Emphasis in original.

On March 6, 2018, CTP filed a Motion to Impose Sanctions. CTP advised that Respondent had not complied with my Order to Compel Discovery. CTP requested that I strike Respondent's answer and issue a default judgment in its favor. On March 7, 2018, at my direction, Respondent was advised that it had until March 21, 2018, to file a response to CTP's Motion to Impose Sanctions.<sup>2</sup> Again, Respondent was warned that if it failed to file a response, I "may grant CTP's Motion to Impose Sanctions in its entirety." Respondent did not respond.

## II. Striking Respondent's Answer

Pursuant to 21 C.F.R. § 17.35(a), I may sanction a party for:

- (1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;
- (2) Failing to prosecute or defend an action; or
- (3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

21 C.F.R. § 17.35(a).

Respondent failed to comply with the following orders and procedures governing this proceeding:

- Respondent failed to respond to CTP's December 20, 2017, Request for Production of Documents within 30 days in violation of 21 C.F.R. § 17.23(a) and my December 6, 2017, APHO; and

---

<sup>2</sup> Although Respondent is participating in this administrative proceeding through our internet-based electronic case file system, I directed that a courtesy copy of this letter be sent to Respondent by US Mail.

- Respondent failed to comply with my February 15, 2018, Order to Compel Discovery requiring a response by February 26, 2018.

Respondent failed to defend its action despite the following opportunities:

- By Order of January 29, 2018, I informed Respondent that it had until February 12, 2018, to file a response to CTP's Motion to Compel Discovery. Respondent did not defend its action.
- On March 7, 2018, Respondent was advised at my direction that it had until March 21, 2018, to file a response to CTP's Motion to Impose Sanctions. Respondent did not defend its action.

I find that Respondent has failed to comply with orders and procedures governing this proceeding, has failed to defend its case, and, as a result, has interfered with the speedy, orderly, and fair conduct of this proceeding. I therefore grant CTP's Motion to Impose Sanctions. 21 C.F.R. § 17.35(a)(1)-(3).

The harshness of the sanctions I impose must relate to the nature and severity of the misconduct or failure to comply. 21 C.F.R. § 17.35(b). I find Respondent's repeated failures to comply, despite multiple warnings, is sufficiently egregious to warrant striking the answer and issue a decision by default, without further proceedings. 21 C.F.R. §§ 17.35(c)(3), 17.11(a). Due to Respondent's noncompliance, I strike Respondent's answer, and issue this Initial Decision and Default Judgment, assuming the facts alleged in CTP's complaint to be true. 21 C.F.R. §§ 17.35(c)(3), 17.11(a).

### **III. Default Decision**

Striking Respondent's answer leaves the Complaint unanswered. Therefore, I am required to "assume the facts alleged in the [C]omplaint to be true" and, if those facts establish liability under the Act, issue a default judgment and impose a No-Tobacco-Sale-Order. 21 C.F.R. § 17.11(a). Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- On December 17, 2014, CTP initiated the first civil money penalty action, CRD Docket Number C-15-686, FDA Docket Number FDA-2014-H-2208, against Respondent for three<sup>3</sup> violations of 21 C.F.R. pt. 1140 within a 24-month period. CTP alleged those violations to have occurred at Respondent's business

---

<sup>3</sup> Respondent's original violations occurred on February 26, 2014 (selling tobacco products to a minor and failing to verify identification).

establishment, 8623 Loch Raven Boulevard, Baltimore, Maryland 21286, on February 26, 2014 and July 9, 2014;

- The first action concluded when an Initial Decision and Default Judgment was entered by an Administrative Law Judge, “finding Respondent liable for the February 26, 2014 and July 9, 2014 violations”;
- On July 20, 2015, CTP initiated the second civil money penalty action, CRD Docket Number C-15-3183, FDA Docket Number FDA-2015-H-2350, against Respondent for five violations of 21 C.F.R. pt. 1140 within a 36-month period. CTP alleged those violations to have occurred at Respondent’s business establishment, 8623 Loch Raven Boulevard, Baltimore, Maryland 21286, on February 26, 2014, July 9, 2014, and April 22, 2015;<sup>4</sup>
- The second action concluded when an Initial Decision and Default Judgment was entered by an Administrative Law Judge on September 16, 2015, “finding Respondent liable for the April 22, 2015 violations”;
- On September 6, 2016, CTP initiated the third civil money penalty action, CRD Docket Number T-16-1821, FDA Docket Number FDA-2016-H-2571, against Respondent for six violations of 21 C.F.R. pt. 1140 within a 48-month period. CTP alleged those violations to have occurred at Respondent’s business establishment, 8623 Loch Raven Boulevard, Baltimore, Maryland 21286, on February 26, 2014, July 9, 2014, and April 22, 2015; and January 12, 2016;
- The third action concluded when an Initial Decision and Default Judgment was entered by an Administrative Law Judge on November 3, 2016, “finding Respondent liable for the January 12, 2016 violation[.]”;
- At approximately 1:44 PM on January 19, 2017, at Respondent’s business establishment, 8623 Loch Raven Boulevard, Baltimore, Maryland 21286, an FDA-commissioned inspector documented Respondent’s staff selling a package of Newport Box 100s cigarettes to a person younger than 18 years of age. The inspector also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

These facts establish that Respondent is liable under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded

---

<sup>4</sup> Although the Complaint states that the inspection was conducted on April 22, 2014, it subsequently states, and it is clear from the record that the inspection was conducted on April 22, 2015. *See* Complaint ¶¶ 1, 10, 12(a)-(b).

if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010); 81 Fed. Reg. 28,974, 28,975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1),<sup>5</sup> no retailer may sell tobacco products to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age.

Taking the above alleged facts as true, Respondent had seven repeated violations of regulations found at 21 C.F.R. pt. 1140 within a 36-month period. Respondent violated the prohibition against selling cigarettes or smokeless tobacco to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on February 26, 2014, and repeated those violations on July 9, 2014, April 22, 2015, January 12, 2016, and January 19, 2017. Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no cigarette or smokeless tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(a)(2)(i), on February 26, 2014, and repeated those violations on July 9, 2014, April 22, 2015, and January 19, 2017. Therefore, Respondent's actions constitute violations of law that merit a No-Tobacco-Sale Order.

Under 21 U.S.C. § 333(f)(8), a No-Tobacco-Sale Order is permissible for seven repeated violations of the regulations found at 21 C.F.R. pt. 1140. The maximum period for the first No-Tobacco-Sale Order received by a retailer is 30 consecutive calendar days. *See* Pub. L. 111-31, div. A, title I, § 103(q)(1)(A), June 22, 2009, 123 Stat. 1838, 1839; Food & Drug Admin., Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with Order at 3-4, *available at* <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM446547.pdf> (last updated Aug. 2015); Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers at 5-6, *available at* <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm447308.htm> (last updated Dec. 15, 2016).

### **Order**

For these reasons, I enter default judgment against Respondent US Liberty Inc. d/b/a Loch Raven Gulf, in the form of a No-Tobacco-Sale Order, for a period of 30 consecutive calendar days. During this period of time, Respondent shall stop selling cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and covered tobacco products regulated under the Federal Food, Drug, and Cosmetic Act. Pursuant to

---

<sup>5</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

