

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Red Brick Liquors Corp.
d/b/a Red Brick Liquors,

Respondent.

Docket No. T-17-343
FDA Docket No. FDA-2016-H-3455

Decision No. TB1823

Date: August 21, 2017

**ORDER GRANTING CTP'S MOTION TO IMPOSE SANCTIONS AND
INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Red Brick Liquors Corp. d/b/a Red Brick Liquors, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$5,501. During the hearing process, Respondent failed to comply with my order regarding CTP's discovery request. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

CTP began this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent's staff impermissibly sold tobacco products to minors and failed to verify that tobacco product purchasers were of sufficient age, thereby violating the Federal Food, Drug, and Cosmetic Act (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 civil money penalty of \$5,501.

On October 27, 2016, CTP served the Complaint on Respondent by United Parcel Service (UPS), pursuant to 21 C.F.R. §§ 17.5 and 17.7. In the Complaint and accompanying cover letter, CTP explained that within 30 days, Respondent should pay the penalty, 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 ordering Respondent to pay the full amount of the proposed penalty.

Respondent timely filed an answer. On December 21, 2016, I issued an Acknowledgment and Pre-Hearing Order (APHO) that contained a provision which set out instructions regarding a party's request for production of documents. That provision states, in part, that a party had until January 30, 2017, to request that the other party provide copies of documents relevant to this case. The order also stated that a party receiving such a request must provide the requested documents no later than 30 days after the request has been made, pursuant to 21 C.F.R. § 17.23(a).

On March 9, 2017, CTP filed a Motion to Compel Discovery stating that CTP sent Respondent a Request for Production of Documents on January 30, 2017 via United Parcel Service (UPS). CTP stated that, "the UPS delivery receipt shows that it was signed for by SOSA." CTP further stated "CTP has not received a response to its Request for Production of Documents" and requested that "an [O]rder be entered to require Respondent to comply with the Request for Production of Documents in its entirety."

In a "By Direction" letter dated March 13, 2017, I gave Respondent until March 24, 2017 to file a response to CTP's Motion to Compel Discovery. Respondent failed to reply by the March 24, 2017 deadline. On April 7, 2017, I granted CTP's March 9, 2017 Motion to Compel Discovery. I ordered Respondent to produce the documents requested by April 24, 2017. I also extended the pre-hearing deadlines in this matter instructing CTP to file its pre-hearing exchange by May 5, 2017 and Respondent to file its pre-hearing exchange by May 25, 2017.

On April 25, 2017 CTP filed a Status Report and Motion to Impose Sanctions due to Respondent's failure to abide by the March 13, 2017 BDL and April 7, 2017 Order instructing Respondent to respond to CTP's Request for Production of Documents. On May 4, 2017 CTP filed an Updated Status Report and Motion to Extend Deadlines informing me that on April 28, 2017, Respondent contacted CTP via telephone and left a voicemail stating it did not have any documents responsive to CTP's request. In its Motion, CTP requested another extension of the pre-hearing deadlines to allow me time to consider the April 25, 2017 Motion to Impose Sanctions and allow CTP time to

prepare its pre-hearing exchange in light of Respondent's response. On June 14, 2017 I issued an Order to Show Cause due to Respondent's failure to file its pre-hearing exchange by May 25, 2017. I ordered Respondent to advise me in writing by June 29, 2017 as to whether it still wished to have a hearing in this matter. To date, Respondent has not filed a pre-hearing exchange or any other reply to the June 14, 2017 Order to Show Cause.

II. Striking Respondent's Answer

Respondent has failed to comply with my Orders requiring it to participate in the discovery process. Specifically, Respondent failed to reply to the BDL issued on March 9, 2017. While Respondent did not possess any documents relevant to CTP's request, it did not notify CTP of that fact until four days after the deadline set forth in my April 7, 2017 Order. Respondent did not file a pre-hearing exchange by the May 25, 2017 deadline and Respondent also failed to respond to the Order to Show Cause issued on June 14, 2017 ordering Respondent to advise me whether it wished to proceed to a hearing. Sanction is therefore appropriate in accordance with 21 C.F.R. § 17.35(a).

The issue is whether CTP's proposed sanction – striking Respondent's Answer and issuing a default judgment – is the appropriate one. The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply, and I find here that Respondent's repeated failure to comply is sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b).

As previously discussed, Respondent has failed to comply with my Orders and Directives which afforded it the opportunity to come into compliance and reinstate its interest in participating in the administrative hearing process. Respondent's persistent failure to comply with my Orders and Directives in this matter warrants a severe sanction. Therefore, I am granting CTP's Motion to Impose Sanctions, striking Respondent's Answer, and issue the following default judgment in this case. *See* 21 C.F.R. §§ 17.11(a), 17.35(a)(1), 17.35(c)(3).

III. Default Decision

Striking Respondent's Answer leaves the Complaint unanswered. Therefore, pursuant to 21 C.F.R. § 17.11(a), 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 civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Red Brick Liquors, an establishment that sells tobacco products and is located at 4351 Northwest 7th Street, Miami, Florida 33126. Complaint ¶¶ 6-7.
- CTP initiated the first civil money penalty action, FDA Docket Number FDA-2015-H-4927, against Respondent for three violations of 21 C.F.R. pt. 1140 within a 12-month period. Complaint ¶ 10.
- The previous action concluded when Respondent “admit[ted] all of the allegations in the Complaint and [paid] the agreed upon penalty.” Further, “Respondent expressly waived its right to contest such violations in subsequent actions.” Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment conducted on April 12, 2016, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of 305’s Full Flavor Kings cigarettes . . . at approximately 8:19 PM.” The inspector also documented that “the minor’s identification was not verified before the sale” Complaint ¶ 8.

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 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). The regulations prohibit the sale of tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1). The regulations also require retailers to verify, by means of photographic identification containing the purchaser’s date of birth, that no tobacco product purchaser is younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i).

Taking the above alleged facts as true, Respondent had five violations of regulations found at 21 C.F.R. pt. 1140 within a 36-month period. Respondent violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on March 18, 2015, September 23, 2015, and April 12, 2016. On those same dates, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i). Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

CTP has requested a civil money penalty of \$5,501, which is a permissible penalty under the regulations. 21 C.F.R. § 17.2.

Therefore, I find that a civil money penalty of \$5,501 is warranted and so order one imposed.

 /s/
Steven T. Kessel
Administrative Law Judge