

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Cornhusker Liquor and Tobacco, LLC
d/b/a Cornhusker Liquor and Tobacco,

Respondent.

Docket No. T-16-1044
FDA Docket No. FDA-2016-H-1717

Decision No. TB765

Date: January 25, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Cornhusker Liquor and Tobacco, LLC d/b/a Cornhusker Liquor and Tobacco, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. Respondent failed to comply with judicial directions 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 the 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 impermissibly sold cigarettes to minors, 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 (2013). CTP seeks a civil money penalty of \$250.

On July 12, 2016, CTP served the Complaint on Respondent by United Parcel Service, 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 proposed 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 to CTP's complaint. On August 18, 2016, I issued an Acknowledgment and Pre-hearing Order that contained a provision that set out instructions regarding a party's request for production of documents. That provision states, in part, that a party had until September 19, 2016, 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 September 19, 2016, CTP served its Request for Production of Documents on Respondent. On October 27, 2016, CTP filed a Motion to Compel Discovery stating it has not received a response from Respondent regarding its Request for Production of Documents. In an October 28, 2016 letter issued by my direction, Respondent was given until November 14, 2016 to file a response to CTP's Motion to Compel Discovery.

Respondent failed to respond to my October 28, 2016 letter. Therefore, on November 17, 2016, I granted CTP's Motion to Compel Discovery, and ordered Respondent to comply with CTP's discovery request by December 14, 2016. Respondent was warned that failure to comply with CTP's discovery request could result in sanctions, including the issuance of an Initial Decision and Default Judgment, finding Respondent liable for the violations listed in the complaint and imposing a civil money penalty.

On December 23, 2016, CTP filed a Motion to Impose Sanctions indicating that Respondent has not produced any of the documents requested. On December 29, 2016, I issued an Order to Show Cause requiring Respondent to either respond to CTP's motion or produce the requested documents by January 11, 2017. Respondent was warned that if it fails to respond to CTP's motion or produce the requested documents, I will dismiss the hearing request and enter a default judgment in favor of CTP. To date, Respondent has not responded to CTP's motion or produced the requested documents as ordered. Therefore, pursuant to 21 C.F.R. § 17.35, I am granting CTP's Motion to Impose Sanctions, and striking Respondent's answer for failing to comply with my order.

II. Default Decision

Striking Respondent's answer leaves the complaint unanswered. 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 Cornhusker Liquor and Tobacco, an establishment that sells tobacco products and is located at 601 Rodeo Road, North Platte, Nebraska 69101. Complaint ¶ 6-7.
- During an inspection of Respondent's establishment on July 10, 2015, at approximately 11:55 AM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Camel White cigarettes . . . [.]" Complaint ¶ 10.
- On July 30, 2015, CTP issued a Warning Letter to Respondent regarding the inspector's observation from July 10, 2015. The letter explained that the observation constituted a violation of regulations, and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violation, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10-11.
- During a subsequent inspection of Respondent's establishment on December 23, 2015, at approximately 2:07 PM, an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]" 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 distributed or offered for sale in any state 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). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a).

Taking the above alleged facts as true, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on July 10, 2015, and December 23, 2015.

Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a civil money penalty of \$250, which is a permissible penalty under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

 /s/
Steven T. Kessel
Administrative Law Judge