

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Halftime, Inc.

d/b/a Halftime Food and Beverage,

Respondent.

Docket No. T-16-1679

FDA Docket No. FDA-2015-H-4932

Decision No. TB707

Date: January 9, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Halftime, Inc. d/b/a Halftime Food and Beverage, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. During the hearing process, Respondent failed to comply with a judicial direction 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 tobacco products to minors and failed to verify that tobacco product purchasers were 18 years of age or older, 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 \$500.

On January 15, 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.

On January 25, 2016, Respondent timely filed an answer. This case was transferred to me on September 9, 2016. On September 14, 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 October 13, 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 October 13, 2016, CTP served its Request for Production of Documents on Respondent. On November 28, 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 a November 28, 2016 letter issued by my direction, Respondent was given until December 13, 2016 to file a response to CTP's Motion to Compel Discovery.

On December 19, 2016, I issued an Order to Show Cause requiring Respondent to either respond to CTP's Motion to Compel Discovery or produce the requested documents by December 30, 2016. 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 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 Halftime Food and Beverage, an establishment that sells tobacco products and is located at 57641 Murray Street, Mattawan, Michigan 49071. Complaint ¶ 7-8.

- In a warning letter dated July 2, 2015, CTP alleged that on May 28, 2015, Respondent committed a violation for sale to a minor (21 C.F.R. § 1140.14(a)).¹ The letter further warned that Respondent’s failure to correct the violation may result in a civil money penalty or other regulatory action. Complaint ¶ 10.
- During a subsequent inspection of Respondent’s establishment on September 24, 2015, at approximately 5:03 PM, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]” The inspectors also documented that “the minor’s identification was not verified before the sale” Complaint ¶ 9.

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); 81 Fed. Reg. 28,974, 28975-76 (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 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).

Taking the above alleged facts as true, 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 May 28, 2015, and September 24, 2015. On September 24, 2015, 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 \$500, which is a permissible penalty under the regulations. 21 C.F.R. § 17.2.

¹ I note that CTP’s complaint does not describe in detail the circumstances giving rise to the alleged violation that occurred on May 28, 2015. The UPS records show that the Warning Letter was received on July 3, 2015.

