

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-1642)

Complainant

v.

Mi Tiendita, LLC
d/b/a Mi Tiendita Mini Mart,

Respondent.

Docket No. T-16-992

Decision No. TB625

Date: December 19, 2016

**ORDER ON MOTION TO IMPOSE SANCTIONS AND INITIAL DECISION
AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Mi Tiendita, LLC d/b/a Mi Tiendita Mini Mart, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. For the reasons outlined below, CTP's Motion to Impose Sanctions is granted and Respondent's answer to the Complaint is stricken. I therefore enter a default judgment against Respondent and assess a civil money penalty of \$500.

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.¹

CTP served the Complaint on Respondent by United Parcel Service on July 6, 2016, 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 August 1, 2016, Respondent timely filed an answer to the complaint. On August 12, 2016, I issued an Acknowledgment and Pre-Hearing Order establishing a deadline of September 9, 2016 for both parties to serve requests for production of documents. CTP served Respondent with a Request for Production of Documents on September 9, 2016. Respondent failed to comply with the request.

On October 18, 2016, CTP filed Motions to Compel Discovery and Extend Deadlines. I granted these motions on November 7, 2016, and ordered Respondent to comply with CTP's request for production of documents by December 5, 2016. That Order specifically warned Respondent that failure to comply with its provisions could result in sanctions, including the issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations in the complaint.

On December 14, 2016, CTP filed a Motion to Impose Sanctions indicating that Respondent had not produced any documents as requested, and had failed to comply with the November 7, 2016 Order. CTP requested I strike the Respondent's answer and issue a default judgment against Respondent. Respondent has failed to comply with the orders issued in this case, provide discovery responses, or otherwise participate in the defense of this civil action. I am therefore granting CTP's motion for sanctions and striking Respondent's answer. 21 C.F.R. § 17.35 (c)(3).

¹ The Complaint alleges that Respondent impermissibly sold cigarettes to minors and failed to verify that cigarette 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. CTP seeks a civil money penalty of \$500.

II. 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 Mi Tiendita Mini Mart, an establishment that sells tobacco products and is located at 1131 College Park Road, Unit B, Summerville, South Carolina 29486. Complaint ¶¶ 6-7.
- During an inspection of Respondent's establishment on April 17, 2015, at approximately 5:40 PM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes . . . [.]" Complaint ¶ 10.
- On May 21, 2015, CTP issued a Warning Letter to Respondent regarding the inspector's observation from April 17, 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 19, 2015, at approximately 9:52 AM, an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . [.]" 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 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 cigarettes 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 cigarette 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 cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on April 17, 2015, and December 19, 2015. On December 19, 2015, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no cigarette 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.

ORDER

For these reasons, I grant CTP's Motion to Impose Sanctions in full, and enter default judgment in the amount of \$500 against Respondent Mi Tiendita, LLC d/b/a Mi Tiendita Mini Mart. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

 /s/

Bill Thomas
Administrative Law Judge