

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-1424)

Complainant

v.

Andre Paulino
d/b/a La Costena Market,

Respondent.

Docket No. T-16-780

Decision No. TB747

Date: January 17, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Andre Paulino d/b/a La Costena Market, alleging facts and legal authority sufficient to justify imposing a civil money penalty of \$500. During the hearing process, Respondent failed to comply with two separate judicial directions regarding CTP's discovery request. I therefore strike Respondent's answer and enter a default judgment against Respondent and assess a civil money penalty in the amount of \$500.

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 cigarettes to minors and failed to verify that cigarette 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 \$500.

I. Procedural History

CTP began this matter by serving an administrative complaint, seeking a \$500 civil money penalty, on Respondent Andre Paulino d/b/a La Costena Market, at 324 West Geer Street, Durham, North Carolina 27701. Respondent filed an answer to CTP's complaint on July 12, 2016. I issued an Acknowledgement and Prehearing Order (APHO) on July 22, 2016, that set deadlines for parties' submissions, including the August 22, 2016 deadline to request that the opposing party provide copies of documents relevant to this case. Additionally, the APHO stated that a party receiving such a request must provide the requested documents no later than 30 days after the request. CTP served Respondent with its request for documents on August 22, 2016.

On September 29, 2016, CTP filed a Motion to Compel Discovery indicating that Respondent did not respond to its request within the time limit. *See* 21 C.F.R. § 17.23(a). On the same date, CTP also filed a motion requesting that all pre-hearing exchange deadlines be extended for 30 days. In an October 6, 2016 letter issued by my direction, Respondent was given until October 31, 2016, to object to CTP's motion. I also extended the pre-hearing exchange deadlines providing CTP until November 9, 2016 to file its pre-hearing exchange and the Respondent until November 30, 2016 to file its pre-hearing exchange. CTP filed their pre-hearing exchange on November 9, 2016. On December 8, 2016 I issued an Order to Show Cause instructing Respondent to inform me as to whether they wished to retain their right to a hearing no later than December 22, 2016. To date, Respondent has not filed an objection to CTP's Motion to Compel Discovery, a pre-hearing exchange, nor a response to the December 8, 2016 Show Cause Order.

II. Default Decision

Striking Respondent's Answer leaves the Complaint unanswered. Therefore, I am required to issue an initial decision by default if the complaint is sufficient to justify a penalty. 21 C.F.R. § 17.11(a). Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

For purposes of this decision, I assume the facts alleged in the Complaint are true and conclude the default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with the orders. 21 C.F.R. § 17.11. Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns La Costena Market, an establishment that sells tobacco products and is located at 324 West Geer Street, Durham, North Carolina 27701. Complaint ¶¶ 6-7.

- During an inspection of Respondent’s establishment on August 30, 2015, at approximately 1:08 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 October 15, 2015, CTP issued a Warning Letter to Respondent regarding the inspector’s observation from August 30, 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 6, 2015, at approximately 11:42 AM, 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 . . . [.]” The inspector also observed 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 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 August 30, 2015, and December 6, 2016. On December 6, 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 fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$500 is warranted and so order one imposed.

 /s/
Steven T. Kessel
Administrative Law Judge