

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

7 Eleven Inc. and Gateway Convenience Inc.
d/b/a 7-Eleven Store 33239B,

Respondent.

Docket No. C-15-2647
FDA No. FDA-2015-H-1817

Decision No. CR4462

Date: November 24, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) initiated a \$500 civil money penalty (CMP) action against Respondent for unlawfully selling cigarettes to minors, on two separate occasions, and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, on one occasion, in violation of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140. During the hearing process, Respondent has 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

Respondent timely answered CTP's complaint opposing the CMP and requested a hearing. I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for parties' submissions, including the August 12, 2015 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.

On August 27, 2015, CTP forwarded, via email, the Respondent's Informal Brief to the Departmental Appeals Board. Respondent had mailed its Informal Brief to CTP.

On September 9, 2015, CTP filed a motion to quash respondent's request for production of documents because the request was mailed on August 31, 2015, more than two weeks after the APHO stated that the request must be served. Pursuant to my direction, a September 10, 2015 letter allowed Respondent until September 25, 2015 to file a response to CTP's motion to quash. Respondent did not file a response to CTP's motion to quash respondent's request for production of documents.

CTP served Respondent with its request for documents on August 11, 2015. On September 18, 2015, 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). Then, pursuant to my direction, a September 21, 2015 letter allowed Respondent until October 6, 2015 to file a response to CTP's motion to compel discovery. Respondent did not file a response to CTP's motion. Then, on October 8, 2015, CTP filed a motion to impose sanctions that asked me to strike the Respondent's answer and issue a default judgment in this case.

On October 14, 2015, I issued an Order that explained that CTP's motion to quash was actually a motion for a protective order, and granted CTP a protective order finding that CTP did not need to comply with Respondent's request for production of documents as that request was not timely served and Respondent failed to file a response to CTP's motion. In that Order I also granted CTP's motion to compel discovery. I ordered Respondent to comply with CTP's request for production of documents by November 3, 2015. I did not rule on CTP's motion to impose sanctions to allow Respondent an opportunity to comply with CTP's request for production of documents. Finally, that Order extended the parties' pre-hearing exchange deadlines.

On November 5, 2015, CTP filed an updated status report advising me that "Respondent had not produced any documents responsive to CTP's Request for Production of Documents." CTP requested that I grant its motion to impose sanctions. In a November 18, 2015 Order I again extended the parties' pre-hearing exchange deadlines to allow time for a ruling on CTP's motion to impose sanctions.

II. Striking Respondent's Answer

Respondent failed to file a response to CTP's motion to quash respondent's request for production of documents, to file a response to CTP's motion to compel discovery, and to comply with the October 14, 2015 Order compelling discovery responses to be provided

by November 3, 2015. Respondent did not comply with any of CTP's discovery requests. Respondent has not made any contact with this Court since July 1, 2015, the date Respondent timely filed its answer. Respondent's failure to effectively prosecute and defend actions taken over the course of the proceedings have interfered with the orderly and speedy processing of this case, further warranting imposition of sanctions. *See* 21 C.F.R. § 17.35(a) (1)(2) and (3).

Due to Respondent's noncompliance with the October 14, 2015 Order, I am striking Respondent's Answer, issuing this default decision, and assuming the facts alleged in CTP's complaint to be true. *See* 21 C.F.R. § 17.35(c) (3), 17.11(a). 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 the failure to comply here sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b). Respondent failed to comply with the October 14, 2015 Order, nor did it provide any adequate justification for not doing so.

III. 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 that default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with my orders. 21 C.F.R. § 17.11. Specifically:

- Respondent owns 7-Eleven Store 33239B, an establishment that sells tobacco products and is located at 12011 Gateway Boulevard, Fort Meyers, Florida 33913. Complaint ¶ 3.
- During an inspection of Respondent's establishment on September 26, 2014, at approximately 2:17 PM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Camel Crush Menthol cigarettes . . . [.]" Complaint ¶ 10.
- On October 16, 2014, CTP issued a Warning Letter to Respondent regarding the inspector's observation from September 26, 2014. The letter explained that the observation constituted a violation of the regulation found at 21 C.F.R. § 1140.14(a), 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.

- Lisa Johnson responded to the Warning Letter in an October 21, 2014 letter. “Ms. Johnson stated ‘a minor was able to purchase cigarettes at this establishment on 9-26-14 without being carded.’ Ms. Johnson stated that, as a result, Respondent took disciplinary action against the employee who sold the tobacco product to the minor. Ms. Johnson further stated that all employees were instructed to ‘retake the come of age CBT training’ and to verify the identification of everyone under the age of 30.” Patricia Crowe also responded to the Warning Letter in a January 13, 2015 letter. “Ms. Crowe stated that Respondent took ‘corrective action to address this situation.’ Ms. Crowe stated that Respondent requires all employees to take and pass the state approved training on sales of restricted items entitled ‘Come of Age’ on a yearly basis. Ms. Crowe further stated that Respondent posts ‘notices and reminders’ informing employees ‘to follow proper guidelines and procedures according to the training they have received.’” Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment on January 27, 2015, at approximately 10:22 PM, FDA-commissioned inspectors documented that “a person younger than 18 years of age was able to purchase a package of Marlboro Gold Pack cigarettes . . . [.]” The inspectors also documented that “the minor’s identification was not verified before the sale” Complaint ¶ 1.

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). 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(b)(1).

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 September 26, 2014, and January 27, 2015. On January 27, 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(b)(1). Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine 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