

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

M A Z Management LLC
d/b/a Tyrone Shell,

Respondent.

Docket No. C-15-2943
FDA No. FDA-2015-H-2157

Decision No. CR4509

Date: January 20, 2016

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 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 requested, and was granted, an extension of time to file an answer. 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 October 5, 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.

CTP served Respondent with its request for documents on October 5, 2015. On November 17, 2015, CTP filed a motion to compel discovery indicating that Respondent did not respond to its request for production of documents. *See* 21 C.F.R. § 17.23(a). On November 17, 2015, CTP also filed a motion to extend the deadlines. Pursuant to my direction, a November 18, 2015 letter allowed Respondent until December 3, 2015 to file an objection to CTP's motion to compel discovery. On November 18, 2015, I also issued an Order that extended the parties' pre-hearing exchange deadlines.

On December 11, 2015, CTP filed an updated status report stating that Respondent had not filed a response to CTP's motion to compel discovery or produced any documents. CTP requested that I grant its motion to compel discovery and extend any of its deadlines.

On December 15, 2015, I issued an Order that granted CTP's motion to compel discovery. I noted that Respondent had not filed a response to CTP's motion to compel discovery. In that Order, I stated that Respondent shall comply with CTP's request for production of documents by January 6, 2016. I further stated that:

Failure to do so may 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. Within five (5) days of Respondent's deadline to comply with discovery, CTP must file a status report notifying me whether Respondent has complied with discovery.

On January 11, 2016, CTP filed an updated status report advising me that Respondent had not complied with my December 15, 2015 Order. On January 11, 2016, CTP also filed a motion to impose sanctions that asked me to strike the Respondent's answer and issue a default judgment in this case.

II. Striking Respondent's Answer

Respondent failed to file a response to CTP's motion to compel discovery, and to comply with the December 15, 2015 Order compelling discovery responses to be provided by January 6, 2016. Respondent did not comply with CTP's discovery requests. Respondent has not made any contact with this Court since August 26, 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 December 15, 2015 Order compelling discovery, 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 December 15, 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 Tyrone Shell, an establishment that sells tobacco products and is located at 855 Tyrone Boulevard North, St. Petersburg, Florida 33710. Complaint ¶ 3.
- During an inspection of Respondent's establishment on October 20, 2014, at approximately 10:54 AM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Camel Blue cigarettes . . . [.]" Complaint ¶ 10.
- On December 11, 2014, CTP issued a Warning Letter to Respondent regarding the inspector's observation from October 20, 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.

- Angela Landrum responded to the Warning Letter in a December 15, 2014 letter. “Ms. Landrum stated that the employee who sold the tobacco product to the minor ‘apologized over and over for not paying more attention that morning.’ She also stated that she reminded all employees that they must verify the identification of tobacco purchasers under the age of 30.” Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment on February 27, 2015, at approximately 1:23 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Camel Blue cigarettes . . . [.]” The inspector also observed 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 tobacco to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on October 20, 2014, and February 27, 2015. On February 27, 2015, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no tobacco 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