

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Suzanne Wilson and Richard Wilson
d/b/a Smoke Signals,

Respondent.

Docket No. C-15-2730
FDA No. FDA-2015-H-1893

Decision No. CR4492

Date: December 17, 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 one occasion, and using a self-service display in a non-exempt facility, on two separate occasions, 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 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 September 14, 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 September 14, 2015. On October 21, 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 October 21, 2015, CTP also filed a motion to extend the deadlines. Pursuant to my direction, an October 22, 2015 letter allowed Respondent until November 6, 2015 to file a response to CTP's motion to compel discovery. On October 22, 2015, I also issued an Order that extended the parties' pre-hearing exchange deadlines.

On November 18, 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 December 9, 2015. 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.

The November 18, 2015 Order granting CTP's motion to compel discovery also extended the parties' pre-hearing exchange deadlines.

On December 15, 2015, CTP filed an updated status report advising me that Respondent had not complied with my November 18, 2015 Order. On December 15, 2015, 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 November 18, 2015 Order compelling discovery responses to be provided by December 9, 2015. Respondent did not comply with CTP's discovery requests. Respondent has not made any contact with this Court since July 17, 2015, the date Respondent's counsel timely filed its answer and notice of appearance. 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 November 18, 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 November 18, 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 Smoke Signals, an establishment that sells tobacco products and is located at 409 East Allen Street, Tombstone, Arizona 85638. Complaint ¶ 3.
- During an inspection of Respondent's establishment on July 22, 2014, an FDA-commissioned inspector "observed customer-accessible shelving units on the main sales floor containing cigarette tobacco and smokeless tobacco for sale." And, "[d]uring the inspection, the most responsible person on duty told the inspector that minors were allowed to enter with an adult." Complaint ¶ 10.
- On September 11, 2014, CTP issued a Warning Letter to Respondent regarding the inspector's observation from July 22, 2014. The letter explained that the observation constituted a violation of the regulation found at 21 C.F.R. § 1140.16(c), 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.
- Suzanne Wilson responded to the Warning Letter by telephone on September 23, 2014. "Ms. Wilson stated that Respondent would change the establishment to an adult only facility where no minors are present or permitted. Ms. Wilson also

stated that Respondent would add signage and inform its customers and employees that the establishment is age restricted.” Complaint ¶ 11.

- A subsequent two-part inspection of Respondent’s establishment occurred on January 27, 2015 and January 28, 2015. On January 27, 2015, at approximately 2:58 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . [.]” Further, on January 28, 2015, the inspector also “observed customer-accessible displays of cigarette tobacco and smokeless tobacco on the main sales floor.” And, “[o]n January 27, 2015, a person younger than 18 years of age was able to enter the establishment” 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). Pursuant to 21 C.F.R. § 1140.16(c), self-service displays are prohibited in facilities where, at any time, persons younger than 18 years of age are present or permitted to enter.

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 January 27, 2015. Respondent violated the prohibition against using a self-service display in a facility where minors were permitted to enter, 21 C.F.R. § 1140.16(c), on July 22, 2014, and January 28, 2015. 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