

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

J.A.C. Fine Wine and Spirits, Inc.
d/b/a Friendly Liquors,

Respondent.

Docket No. T-16-170
FDA No. FDA-2016-H-0454

Decision No. TB393

Date: October 19, 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 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. I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for parties' submissions, including the June 3, 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 June 3, 2016. On July 13, 2016, CTP filed a motion to compel discovery indicating that CTP had not received a response to its request for production of documents. *See* 21 C.F.R. § 17.23(a). On July 13, 2016, CTP also filed a motion to extend the deadlines. Pursuant to my direction, a July 15, 2016 letter allowed Respondent until July 29, 2016 to file a response to CTP's motion to compel discovery. On July 15, 2016, I also issued an Order that extended the parties' pre-hearing exchange deadlines.

On August 10, 2016, 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 September 2, 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.

On September 14, 2016, CTP filed a motion to impose sanctions advising me that Respondent had not complied with my August 10, 2016 Order and asked me to strike the Respondent's answer and issue a default judgment in this case. On September 14, 2016, CTP also filed a motion to extend deadlines that asked me to extend any deadlines for either 30 days or a period of time sufficient for me to rule on CTP's motion to impose sanctions. On September 22, 2016, I issued an Order that allowed Respondent until October 5, 2016 to file a response to CTP's motion to impose sanctions. In the September 22, 2016 Order I also extended the parties' pre-hearing exchange deadlines.

II. Striking Respondent's Answer

Respondent failed to file a response to CTP's motion to compel discovery, failed to comply with the August 10, 2016 Order compelling discovery responses to be provided by September 2, 2016, and failed to file a response to CTP's motion to impose sanctions. Respondent did not comply with CTP's discovery requests. Respondent has not made any contact with this Court since May 2, 2016, 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 August 10, 2016 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 August 10, 2016 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 order. 21 C.F.R. § 17.11. Specifically:

- Respondent owns Friendly Liquors, an establishment that sells tobacco products and is located at 1567 Acushnet Avenue, New Bedford, Massachusetts 02746. Complaint ¶ 6-7.
- During an inspection of Respondent's establishment on August 1, 2015, at approximately 11:47 AM, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]". The inspector also observed that "the minor's identification was not verified before the sale" Complaint ¶ 10.
- On August 13, 2015, CTP issued a Warning Letter to Respondent regarding the inspector's observations from August 1, 2015. The letter explained that the observations constituted violations of regulations, and that the named violations were 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 violations, 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 November 22, 2015, at approximately 2:37 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 . . . [.]". 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). 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 August 1, 2015, and November 22, 2015. On those same dates, 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