

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Del Prado Gas and Food Mart LLC / Sunoco,

Respondent.

Docket No. C-15-3449
FDA No. FDA-2015-H-2632

Decision No. CR4515

Date: January 29, 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 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 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 28, 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 28, 2015. On November 9, 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 9, 2015, CTP also filed a motion to extend the deadlines. Pursuant to my direction, a November 12, 2015 letter allowed Respondent until November 27, 2015 to file an objection to CTP's motion to compel discovery. The November 12, 2015 letter also extended the parties' pre-hearing exchange deadlines.

On December 1, 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 16, 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. CTP shall file a status report by December 22, 2015, informing me of whether it is seeking sanctions.

Emphasis removed.

On December 18, 2015, CTP filed an updated status report advising me that Respondent had not complied with my December 1, 2015 Order. On December 18, 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 December 1, 2015 Order compelling discovery responses to be provided by December 16, 2015. Respondent did not comply with CTP's discovery requests. Respondent has not made any contact with this Court since August 21, 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 1, 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 1, 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:

- During an inspection of Respondent's establishment on November 19, 2014, at approximately 4:41 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 . . . [.]". The inspector also observed that "the minor's identification was not verified before the sale" Complaint ¶ 10.
- On December 18, 2014, CTP issued a Warning Letter to Respondent regarding the inspector's observation from November 19, 2014. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and (b)(1), 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.

Hamza Rashid responded to the Warning Letter in an undated letter that CTP received on January 7, 2015. "Mr. Rashid stated that he had 'spoken with the cashier in question as well as all the other persons working at the location and advised them that this [would] not be tolerated.' CTP responded to Mr. Rashid by letter dated February 17, 2015, stating that a response was received, but seeking further clarification of the remedial actions taken and reminding [Respondent] of its continuing obligation to be in compliance with the Act and its implementing regulations. CTP did not receive further clarification of Respondent's remedial actions taken." Complaint ¶ 11.

- During a subsequent inspection of Respondent’s establishment on April 6, 2015, at approximately 12:56 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of 305’s Menthol Kings 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 November 19, 2014, and April 6, 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