

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Cape Coral Petroleum Inc.
d/b/a Cape Coral Shell,

Respondent.

Docket No. C-15-2960
FDA No. FDA-2015-H-2099

Decision No. CR4473

Date: December 1, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) initiated a \$250 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 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 31, 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.

CTP served Respondent with its request for documents on August 28, 2015. On October 5, 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 5, 2015, CTP also filed a motion to extend the deadlines. Pursuant to my direction, an October 6, 2015 letter allowed Respondent until October 20, 2015 to file an objection to CTP's motion to compel discovery. That letter also extended the parties' pre-hearing exchange deadlines.

On October 27, 2015, CTP filed an updated status report requesting that I grant its motion to compel and extend CTP's deadlines. The status report stated that Respondent had not filed an objection to the motion to compel and that Respondent had not produced any documents in response to CTP's request for production of documents.

On October 30, 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 November 20, 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.

On November 25, 2015, CTP filed an updated status report advising me that Respondent had not complied with my October 30, 2015 Order. On November 25, 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 October 30, 2015 Order compelling discovery responses to be provided by November 20, 2015. Respondent did not comply with CTP's discovery requests. Respondent has not made any contact with this Court since July 23, 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 30, 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 30, 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 Cape Coral Shell, an establishment that sells tobacco products and is located at 2231 Del Prado Boulevard South, Cape Coral, Florida 33990. Complaint ¶ 3.
- During an inspection of Respondent's establishment on October 27, 2014, at approximately 2:33 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 inspectors also documented that "the minor's identification was not verified before the sale" Complaint ¶ 10.
- On November 13, 2014, CTP issued a Warning Letter to Respondent regarding the inspector's observations from October 27, 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.

- Arif Ahmed responded to the Warning Letter in a December 8, 2014 letter. “Mr. Ahmed stated, ‘The employee has admitted to me that he sold the cigarettes to the minor due to his poor judgment of age appearance.’ He also stated that the establishment’s management took disciplinary action against the employee, and explained to all employees that they must verify the identification of all tobacco purchasers under the age of 27. Mr. Ahmed also stated that the establishment has ‘We Card’ signage on the door and at the cash registers.” Complaint ¶ 11.
- During a subsequent inspection of Respondent’s establishment on February 23, 2015, at approximately 10:37 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . [.]” 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 27, 2014, and February 23, 2015. On October 27, 2014, 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 \$250, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/

Steven T. Kessel
Administrative Law Judge