Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2015-H-1922)

Complainant

v.

7 Eleven Inc. d/b/a 7-Eleven Store 34153A.

Respondent.

Docket No. C-15-2657

Decision No. CR4482

Date: December 4, 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 has 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. On July 15, 2015, I issued an Acknowledgment and Pre-Hearing Order that explained to the parties what they must do to present evidence and arguments in this case. I explained that the parties may request copies of documents relevant to this case and that the requesting party

must serve the request for documents no later than August 12, 2015. I further explained that a party receiving such a request must provide the requested documents no later than 30 days after the request has been made. As party of the discovery process, both CTP and Respondent served Requests for Production of Documents on each other. CTP served a request for documents on August 11, 2015. Respondent mailed its First Request for Production of Documents by United States mail on August 31, 2015.

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.

On September 15, 2015, CTP filed a motion to quash respondent's request for production of documents because the request was mailed on August 31, 2015, more than two weeks after the APHO stated that the request must be served. Pursuant to my direction, a September 17, 2015 letter allowed Respondent until October 1, 2015 to file a response to CTP's motion to quash. The September 17, 2015 letter also suspended the exchange deadlines set forth in the APHO pending the resolution of the motion to quash. Respondent did not file a response to CTP's motion to quash respondent's request for production of documents.

CTP served Respondent with its request for documents on August 11, 2015. On September 18, 2015, 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). Then, pursuant to my direction, a September 21, 2015 letter allowed Respondent until October 6, 2015 to a file a response to CTP's motion to compel discovery. Respondent did not file a response to CTP's motion. On October 9, 2015, CTP filed a motion to impose sanctions that asked me to strike the Respondent's answer and issue a default judgment in this case.

On October 14, 2015, I issued an Order that explained that CTP's motion to quash was actually a motion for a protective order, and granted CTP a protective order finding that CTP did not need to comply with Respondent's request for production of documents as that request was not timely served and Respondent failed to file a response to CTP's motion. In that Order, I also granted CTP's motion to compel discovery. I ordered Respondent to comply with CTP's request for production of documents by November 3, 2015. I did not rule on CTP's motion to impose sanctions to allow Respondent an opportunity to comply with CTP's request for production of documents. Finally, that Order set the parties' pre-hearing exchange deadlines.

On November 9, 2015, CTP filed an updated status report advising me that "Respondent ha[d] not produced any documents responsive to CTP's Request for Production of Documents." CTP requested that I grant its motion to impose sanctions. In a November 10, 2015 Order, I stayed the parties' pre-hearing exchange deadlines pending a ruling on CTP's motion to impose sanctions. In that Order I also allowed Respondent until

November 27, 2015 to file a response to CTP's motion to impose sanctions. Respondent did not file a response to CTP's motion to impose sanctions.

II. Striking Respondent's Answer

Respondent failed to file a response to CTP's motion to quash respondent's request for production of documents, to file a response to CTP's motion to compel discovery, to comply with the October 14, 2015 Order compelling discovery responses to be provided by November 3, 2015, and also failed to file a response to CTP's motion to impose sanctions. Respondent did not comply with any of CTP's discovery requests. Respondent has not made any contact with this Court since July 1, 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 14, 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 October 14, 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:

• At approximately 5:11 p.m. on September 16, 2014, at Respondent's business establishment, 11700 South Cleveland Avenue, Fort Myers, Florida 33907, an FDA-commissioned inspector observed Respondent's staff selling a package of Camel Crush Menthol cigarettes to a person younger than 18 years of age. The inspector also observed that staff failed to verify, by means of photographic

identification containing a date of birth, that the purchaser was 18 years of age or older;

- In a warning letter dated October 9, 2014, CTP informed Respondent of the inspector's September 16, 2014 observations, and that such actions violate federal law, 21 C.F.R. § 1140.14(a) and (b)(1). The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;
- At approximately 9:16 p.m. on January 27, 2015, at Respondent's business establishment, 11700 South Cleveland Avenue, Fort Myers, Florida 33907, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro Gold Pack cigarettes to a person younger than 18 years of age.

These facts establish Respondent 7-Eleven Store 34153A's liability under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387f(d); see 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). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age.

A \$250 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$250 against Respondent 7 Eleven Inc. d/b/a 7-Eleven Store 34153A. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/
Margaret G. Brakebusch
Administrative Law Judge