

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-1855)

Complainant

v.

Manhar Inc.
d/b/a 7-Eleven Store 32247B,

Respondent.

Docket No. C-15-2670

Decision No. CR4489

Date: December 16, 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, 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 9, 2015, I issued an Acknowledgment and Pre-Hearing Order (APHO) 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

10, 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 part 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 10, 2015. Respondent mailed its "First Request for Production of Documents" by United States mail on August 31, 2015.

CTP forwarded the Respondent's Informal Brief to the Departmental Appeals Board. Respondent mailed its Informal Brief to CTP on August 21, 2015.

On September 14, 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 16, 2015 letter allowed Respondent until September 30, 2015 to file a response to CTP's motion to quash. The September 16, 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 10, 2015. On September 22, 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 25, 2015 letter allowed Respondent until October 13, 2015 to file a response to CTP's motion to compel discovery. Respondent did not file a response to CTP's motion. On October 15, 2015, CTP filed an updated status report stating that Respondent had "neither complied with CTP's Motion to Compel Discovery nor filed a response to CTP's Motion to Compel." CTP requested that I grant its motion to compel.

On October 21, 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 12, 2015. Finally, that Order set the parties' pre-hearing exchange deadlines.

On November 18, 2015, CTP filed an updated status report advising me that "Respondent ha[d] not complied with CTP's Request for Production of Documents as required in the Order." On November 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. In a November 19, 2015 letter, issued at my direction, Respondent was granted until December 7, 2015 to file a response to CTP's motion to impose sanctions. The

November 19, 2015 letter also extended the exchange deadlines. 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 21, 2015 Order compelling discovery responses to be provided by November 12, 2015, and also failed to file a response to CTP's motion to impose sanctions. 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 21, 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 21, 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 6:25 p.m. on September 11, 2014, at Respondent's business establishment, 9650 Cypress Lake Drive, Fort Myers, Florida 33907, an FDA-commissioned inspector observed Respondent's staff selling a package of Camel Crush cigarettes to a person younger than 18 years of age;

- In a warning letter dated October 2, 2014, CTP informed Respondent of the inspector's September 11, 2014 observation, and that such action violates federal law, 21 C.F.R. § 1140.14(a). The letter further warned that Respondent's failure to correct its violation could result in a civil money penalty or other regulatory action;
- At approximately 9:57 p.m. on January 27, 2015, at Respondent's business establishment, 9650 Cypress Lake Drive, 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 32247B'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.

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 Manhar Inc. d/b/a 7-Eleven Store 32247B. 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