

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2018-H-0219)

Complainant

v.

Maynard's Food Center of Westbrook, Inc.
d/b/a Maynard's Food Center,

Respondent.

Docket No. T-18-943

Decision No. TB2988

Date: August 13, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Maynard's Food Center of Westbrook, Inc. d/b/a Maynard's Food Center, at 315 Main Avenue North, Lake Preston, South Dakota 57249, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Maynard's Food Center impermissibly sold cigarettes or smokeless tobacco to minors and failed to verify, by means of photo identification containing a date of birth, that a purchaser was 18 years of age or older, thereby violating 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. CTP seeks to impose a \$279 civil money penalty against Respondent Maynard's Food Center.

I. Background and Procedural History

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on January 19, 2018, CTP served the complaint on Respondent Maynard's Food Center by United Parcel Service. On

February 20, 2018, Respondent timely filed an answer. On March 14, 2018, I issued an Acknowledgment and Pre-Hearing Order (APHO) acknowledging receipt of Respondent's answer and establishing procedural deadlines for this case. The APHO contained a provision that set out instructions regarding a party's request for production of documents. That provision states, in part, that a party had until April 16, 2018, to request that the other party provide copies of documents relevant to this case. The order also stated that a party receiving such a request must provide the requested documents no later than 30 days after the request has been made, pursuant to 21 C.F.R. § 17.23(a).

On April 3, 2018, CTP served its Request for Production of Documents on Respondent. On May 10, 2018, CTP filed a Motion to Compel Discovery stating it has not received a response to its Request for Production of Documents and requesting "an order be entered to require Respondent to comply with the Request for Production of Documents in its entirety."

In a May 11, 2018 letter issued by my direction, Respondent was given until May 25, 2018, to file a response to CTP's Motion to Compel Discovery. Respondent failed to file any response to CTP's Motion to Compel Discovery or otherwise respond to the May 11, 2018 letter. Therefore, in a May 29, 2018 order, I granted CTP's motion and ordered Respondent to comply with CTP's Request for Production of Documents by June 14, 2018. Respondent was warned that a failure to comply 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 June 20, 2018, CTP filed a Motion to Impose Sanctions stating "Respondent has yet to produce a single document in response to the discovery requests." CTP requested I strike Respondent's answer and issue a default judgment imposing a civil money penalty in the amount of \$279 against Respondent. In a June 21, 2018 letter issued by my direction, Respondent was given until July 5, 2018, to file a response to CTP's Motion to Impose Sanctions. To date, Respondent has failed to file any response to CTP's Motion to Impose Sanctions.

Therefore, pursuant to 21 C.F.R. § 17.35, I grant CTP's Motion to Impose Sanctions, and strike Respondent's answer for failing to comply with two judicial directions. Specifically, Respondent failed to comply with my March 14, 2018 APHO and Respondent failed to comply with my May 29, 2018 order to comply with CTP's Request for Production of Documents. This conduct is sufficiently egregious to warrant striking Respondent's answer and issuing an initial decision by default.

II. Default Decision

Striking Respondent's answer leaves the complaint unanswered. Pursuant to 21 C.F.R.

§ 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- At approximately 6:33 p.m. on March 21, 2017, at Respondent's business establishment, 315 Main Avenue North, Lake Preston, South Dakota 57249, 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. The inspector also documented 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 June 8, 2017, CTP informed Respondent of the inspector's March 21, 2017 documented violations, and that such actions violate federal law. 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 2:13 p.m. on December 27, 2017, at Respondent's business establishment, 315 Main Avenue North, Lake Preston, South Dakota 57249, 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 Maynard's Food Center'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); 81 Fed. Reg. 28,974, 28,975-76 (May 10, 2016). Under 21 C.F.R. § 1140.14(a)(1), no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no cigarette or smokeless tobacco purchasers are younger than 18 years of age.

A \$279 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$279 against Respondent Maynard's Food Center of Westbrook, Inc. d/b/a Maynard's Food Center. Pursuant to 21

