Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2017-H-4691)

Complainant

v.

Hollow Mini Market LLC d/b/a Hollow Mini Market.

Respondent.

Docket No. T-17-5687

Decision No. TB2430

Date: February 7, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty of \$2,236 against Respondent, Hollow Mini Market LLC d/b/a Hollow Mini Market, located at 359 Harral Avenue, Bridgeport, Connecticut 06604, for four violations 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, within a twenty-four month period.

CTP alleges that Hollow Mini Market violated the Act by: Impermissibly selling cigarettes to minors, failing to verify, by means of photo identification containing date of birth, that a purchaser was 18 years of age or older, and selling individual cigarettes.

For the reasons discussed below, I impose a civil money penalty of \$2,236 against Respondent, Hollow Mini Market.

I. Procedural History

CTP began this matter by serving an administrative complaint seeking a \$2,236 civil money penalty on Respondent Hollow Mini Market (Respondent) at 359 Harral Avenue, Bridgeport, Connecticut 06604, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. Respondent filed a timely Answer on September 5, 2017, in which it denied the allegations in the complaint as alleged by CTP. On September 12, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO). The APHO explained that parties may request copies of documents relevant to this case and that the requesting party must serve the request for documents no later than October 19, 2017. The APHO 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. 21 C.F.R. § 17.23(a).

On November 30, 2017, CTP filed a Motion to Compel Discovery. In its motion, CTP stated that on October 12, 2017, CTP served a Request for Production of Documents on Respondent, but had not received a response to its request. On that same date, CTP also filed a Motion to Extend Deadlines. A December 1, 2017 letter issued by my direction allowed Respondent until December 15, 2017 to file a response to CTP's Motion to Compel Discovery. On that same date, I also issued an Order that granted CTP's Motion to Extend Deadlines and extended the parties' pre-hearing exchange deadlines.

On December 21, 2017, 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 and ordered Respondent to comply with CTP's Request for Production of Documents by January 4, 2018. I further stated that "[f]ailure to comply by this date may result in sanctions against Respondent, including striking Respondent's September 5, 2017 Answer and issuing an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty." My December 21, 2017 Order also extended the parties' pre-hearing exchange deadlines.

On January 8, 2018, CTP filed Complainant's Status Report and Motion to Impose Sanctions. In its January 8, 2018 Motion, CTP indicated that Respondent had not complied with my December 21, 2017 Order and requested that Respondent's Answer be struck and that I issue a default judgment. On that same date, CTP also filed a Motion to Extend the pre-hearing exchange deadlines. In a January 9, 2018 letter issued by my direction, Respondent was given until January 19, 2018 to file an objection to CTP's Motion to Impose Sanctions.

To date, Respondent has not filed a response to CTP's Motion to Impose Sanctions.

II. Striking Respondent's Answer

I grant CTP's Motion to Impose Sanctions and strike Respondent's Answer due to a failure to comply with multiple judicial orders and applicable rules.

Pursuant to 21 C.F.R. § 17.35(a), I may sanction a party for:

- (1) Failing to comply with an order, subpoena, rule, or procedure governing the proceeding;
- (2) Failing to prosecute or defend an action; or
- (3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

Here, Respondent did not comply with the deadlines established in my orders on September 12, 2017 and December 21, 2017. Respondent also failed to respond to the January 9, 2018 letter, issued by my direction, soliciting a response to CTP's Motion to Impose Sanctions. Respondent has failed to comply with my orders and the procedures governing this proceeding which constitutes misconduct that has interfered with the speedy, orderly, or fair conduct of this proceeding. 21 C.F.R. § 17.35(a)(1), (a)(3). I, therefore, find that sanctions are appropriate under 21 C.F.R. § 17.35.

The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure. 21 C.F.R. § 17.35(b). I find and conclude that Respondent's misconduct is sufficiently egregious to warrant striking the September 5, 2017 Answer and issuing a decision without further proceeding. 21 C.F.R. §§17.35(c)(3), 17.11(a).

III. Default Decision

Striking Respondent's Answer leaves the Complaint unanswered. I am, therefore, 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 as alleged in the complaint are true. As such, I conclude that default judgment is merited based on the allegations in the Complaint and the sanctions imposed on Respondent. 21 C.F.R. § 17.11. Specifically:

• At approximately 12:04 p.m. on December 13, 2016, at Respondent's business establishment, 359 Harral Avenue, Bridgeport, Connecticut 06604, an FDA-commissioned inspector documented Respondent's staff selling two individual Newport 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 December 22, 2016, CTP informed Respondent of the inspector's December 13, 2016 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 10:43 a.m. on July 25, 2017, at Respondent's business establishment, 359 Harral Avenue, Bridgeport, Connecticut 06604, an FDA-commissioned inspector documented Respondent's staff selling three individual Newport 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.

These facts establish Hollow Mini Market'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 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 purchasers are younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(4), retailers are prohibited from breaking or otherwise opening any cigarette package to sell or distribute individual cigarettes.

Under 21 C.F.R. § 17.2, a \$2,236 civil money penalty is permissible for four violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$2,236 against Respondent Hollow Mini Market LLC d/b/a Hollow Mini Market. 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/ Wallace Hubbard Administrative Law Judge