Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products, (FDA No. FDA-2017-H-3436)

Complainant

v.

73 HN Grocery Corp. d/b/a 73 H and N Grocery,

Respondent.

Docket No. T-17-4573

Decision No. TB2300

Date: December 14, 2017

ORDER GRANTING COMPLAINANT'S MOTION FOR SANCTIONS AND INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint (Complaint) on Respondent, 73 HN Grocery Corp. d/b/a 73 H and N Grocery, located at 73 East Kingsbridge Road, Bronx, New York 10468, and by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. CTP alleges in its Complaint that 73 H and N Grocery impermissibly sold tobacco products to minors, failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, and violated the prohibition against opening packages of cigarettes to sell or distribute individual cigarettes, 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. The Complaint likewise alleges that Respondent 73 H and N Grocery previously admitted to four (4) violations of regulations found at 21 C.F.R. pt. 1140. Therefore, CTP seeks to impose an \$11,182 civil money penalty against Respondent 73 H and N Grocery.

Respondent has failed to adequately participate in this matter or comply with my orders, despite being given ample opportunities to do so. I therefore grant CTP's Motion for Sanctions, strike Respondent's Answer, and issue this decision of default judgment.

I. Procedural History

After being properly served with CTP's Complaint in this matter and after being granted an extension for which to file an Answer electronically, Respondent filed an Answer on July 25, 2017. I issued an Acknowledgment and Prehearing Order (APHO) on July 31, 2017, and set deadlines for the parties' submissions, including the September 7, 2017 deadline to request relevant documents from the opposing party. The APHO provided that a party receiving such a request had to provide the requested documents no later than 30 days after the request was made. CTP served Respondent with its request for documents on September 1, 2017.

On October 11, 2017, CTP filed a Motion to Compel Discovery stating that Respondent did not respond to its request within the 30 days afforded by my APHO. *See* 21 C.F.R. § 17.23(a). In a letter issued at my direction, Respondent was given until October 27, 2017, to object to CTP's motion. Respondent did not file an objection. Thus, on October 30, 2017, I issued an Order that granted CTP's Motion to Compel Discovery and ordered that Respondent had until November 9, 2017 to comply with CTP's document requests. I warned Respondent that failure to comply might result in sanctions. Respondent failed to provide any documents to CTP.

On November 15, 2017, CTP filed a Motion for Sanctions. In a letter issued at my direction, Respondent was given until December 1, 2017 to respond to CTP's motion. Respondent did not respond.

II. Striking Respondent's Answer Is Appropriate

In my APHO, I warned the parties that I could issue sanctions pursuant to 21 C.F.R § 17.35, including but not limited to, dismissal of the Complaint or Answer, if, among other reasons, a party failed to comply with any order I issued in this matter or failed to prosecute or defend its case. As outlined above, Respondent has failed to defend its case and failed to comply with my orders. Sanction is therefore appropriate pursuant to 21 C.F.R. § 17.35(a). The issue is whether CTP's proposed sanction – striking Respondent's Answer and issuing default judgment – is the appropriate one. 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 be sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b).

Respondent's failure to defend its case weighs towards a harsher sanction. To date, Respondent has failed to produce responsive documents as part of the discovery process or to respond to any of my directives. In short, Respondent has failed to participate in this case in any meaningful way since the filing of its Answer.

CTP also correctly observes that repeated refusal by a party to comply with my orders is an appropriate ground for issuing judgment against that party. CTP Motion for Sanctions at 2, *citing* 21 C.F.R. § 17.35(a). More specifically, CTP points out that I may strike the pleadings of a party for failing to comply with a discovery order. *Id.*, *citing* 21 C.F.R. § 17.35(c)(3).

Respondent has repeatedly failed to comply with my directives in this case. It failed to comply with my APHO requiring timely participation in discovery and my Order compelling discovery. Respondent's persistent non-compliance with my orders and directives and refusal to minimally participate in the proceeding that it requested in its Answer warrant a severe sanction. Accordingly, I find it appropriate to strike Respondent's Answer and issue a default decision. *See* 21 C.F.R. §§ 17.11(a), 17.35(a)(1), 17.35(c)(3).

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 the orders. 21 C.F.R. § 17.11. Specifically:

On July 11, 2016, CTP initiated a previous civil money penalty action, CRD Docket Number T-16-1026, FDA Docket Number FDA-2016-H-1723, against Respondent for four¹ violations of 21 C.F.R. pt. 1140 within a twelve-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 73 East Kingsbridge Road, Bronx, New York 10468, on September 19, 2015, and December 26, 2015;

¹ Three violations were documented on September 19, 2015, and three on December 26, 2015. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

- The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and agreed to pay a monetary penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions";
- At approximately 8:17 p.m. on March 20, 2017, at Respondent's business establishment, 73 East Kingsbridge Road, Bronx, New York 10468, 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.

These facts establish Respondent'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)², no retailer may sell tobacco products to any person younger than 18 years of age. Under 21 C.F.R. § 140.14(a)(2)(i), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age. In addition, under 21 C.F.R. § 1140.14(a)(4), no retailer may open packages of cigarettes to sell or distribute individual cigarettes.

Under 21 C.F.R. § 17.2, a \$11,182 civil money penalty is permissible for seven violations of the regulations found at 21 C.F.R. pt. 1140.

ORDER

For the foregoing reasons, I grant CTP's Motion to Impose Sanctions, strike Respondent's Answer, and enter default judgment in the amount of \$11,182 against Respondent 73 H and N Grocery. 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

 $^{^{2}}$ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: https://federalregister.gov/a/2016-10685.