

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division**

Center for Tobacco Products,
(FDA No. FDA-2017-H-1295)

Complainant

v.

D and L One Stop Grocery LLC
d/b/a One Stop Grocery,

Respondent.

Docket No. T-17-2622

Decision No. TB2020

Date: October 4, 2017

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

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, D and L One Stop Grocery LLC d/b/a One Stop Grocery, located at 2944 East Preston Street, Baltimore, Maryland 21213, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Respondent impermissibly sold tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 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. The complaint likewise alleges that a default judgment was previously entered against Respondent One Stop Grocery for three violations of regulations found at 21 C.F.R. pt. 1140. Throughout this administrative process, Respondent has failed to comply with multiple judicial directions regarding CTP's discovery request. Therefore, I grant Complainant's Motion to Impose Sanctions, strike Respondent's answer, and issue this decision of default judgment against Respondent.

I. Procedural History

On March 16, 2017, CTP properly served an administrative complaint seeking a \$2,200 civil money penalty on Respondent, D and L One Stop Grocery LLC d/b/a One Stop Grocery. On April 11, 2017, Respondent timely filed an answer to CTP's complaint. On April 25, 2017, I issued an Acknowledgment and Prehearing Order (APHO) that set deadlines for parties' actions, including the May 24, 2017, deadline to request relevant documents from the opposing party. CTP sent its request for documents to Respondent on May 24, 2017.

On July 5, 2017, CTP filed a Motion to Compel Discovery indicating that Respondent did not respond to its request within the time allotted by the APHO. *See* 21 C.F.R. § 17.23(a). On July 6, 2017, a letter issued by my direction instructed that Respondent had until July 20, 2017, to file a response to CTP's Motion to Compel Discovery. Respondent did not file a response.

On August 8, 2017, I issued an Order granting CTP's Motion to Compel Discovery and extended the pre-hearing exchange deadlines to allow Respondent another opportunity to produce the requested documents. That Order allowed Respondent until August 21, 2017, to comply with CTP's discovery request. I explicitly warned Respondent that failure to comply with CTP's discovery request could 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. Respondent did not comply with the CTP's discovery request within the time provided by the August 8, 2017 Order.

On August 23, 2017, CTP filed a Status Report and Motion to Impose Sanctions. In its Motion to Impose Sanctions, CTP stated that "Respondent has been provided with ample opportunity to respond to CTP's Request for Production of Documents, but has not done so." Accordingly, CTP asked that I strike "the Answer entered by Respondent in this case" and issue "a default judgment imposing a civil money penalty in the amount of \$2,200 against Respondent." Motion to Impose Sanctions at 3, 4. In an August 30, 2017 letter issued by my direction, I allowed Respondent until September 8, 2017, to respond to CTP's motion. Respondent has to date failed to file a response to CTP's motion. Also on August 30, 2017, I issued an order staying all procedural deadlines pending a ruling on the Motion to Impose Sanctions.

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 participate in the defense of its case and repeatedly failed to comply with my Orders. Sanctions are 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. *See* 21 C.F.R. § 17.35(b).

Here, I find Respondent’s failure to participate in the defense of its case and its refusal to comply with orders sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. First, Respondent has failed to produce any documents, object to any request for documents, or file responses to motions. This refusal to participate has caused unnecessary delay in the adjudicative process. Second, Respondent has failed to comply with orders issued to address its failure to participate in its defense. Specifically, Respondent failed to comply with my initial APHO requiring responses to discovery requests; failed to respond to CTP’s Motion to Compel; and failed to produce documents in compliance with my order granting CTP’s Motion to Compel. Respondent’s persistent non-compliance with my orders and refusal to participate in the defense of its case warrants severe sanction. *See* 21 C.F.R. §§ 17.35(a)(1), 17.35(c) (3); 17.35(d).

Accordingly, I am striking Respondent’s Answer, issuing this default decision, and assuming the facts alleged in CTP’s complaint to be true. 21 C.F.R. § 17.11(a).

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 the 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, CTP alleges the following facts in its Complaint:

- On May 2, 2016, CTP initiated a previous civil money penalty action, CRD Docket Number T-16-292, FDA Docket Number FDA-2016-H-0583, against Respondent for three¹ violations of 21 C.F.R. pt. 1140 within a twenty-four month period. CTP alleged those violations to have occurred at Respondent’s business establishment, 2944 East Preston Street, Baltimore, Maryland 21213, on January 29, 2015, and October 31, 2015;

¹ Two violations were documented on January 29, 2015, and two on October 31, 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 an Initial Decision and Default Judgment was entered by an Administrative Law Judge, “finding that all of the violations alleged in the Complaint occurred”;
- During a subsequent inspection of Respondent’s establishment on September 22, 2016, at approximately 4:20 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes . . . [.]”

These facts establish Respondent One Stop Grocery’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. § 1140.14(b)(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.

Under 21 C.F.R. § 17.2, a \$2,200 civil money penalty is permissible for four violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I grant Complainant’s Motion to Impose Sanctions, strike Respondent’s Answer, and enter default judgment in the amount of \$2,200 against Respondent, D and L One Stop Grocery, LLC d/b/a One Stop 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/
Margaret G. Brakebusch
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>.