

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-H-1483)

Complainant,

v.

Ameer LLC
d/b/a Quicky's Discount,

Respondent.

Docket No. T-17-2795

Decision No. TB2424

Date: February 5, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Ameer LLC d/b/a Quicky's Discount, that alleges that Quicky's Discount impermissibly sold cigarettes or smokeless 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. Therefore, CTP seeks to impose a \$550 civil money penalty against Respondent Quicky's Discount. Respondent filed an Answer to the Complaint, but has failed to comply with multiple judicial directions and orders during the hearing process. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

On March 20, 2017, CTP began this matter by serving a Complaint on Respondent Quicky's Discount, seeking a \$550 civil money penalty. On April 19, 2017, Respondent timely filed its answer to CTP's Complaint in the DAB E-File system. On April 28, 2017, an Acknowledgment and Pre-Hearing Order (APHO) was issued. The APHO generally explained to the parties what they must do to present evidence and arguments in this case. Specifically, it 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 May 29, 2017. As indicated in the APHO, a party who received such a request was required to provide the requested documents no later than 30 days after the request had been made. CTP has provided evidence to show that it served a Request for Production of Documents (RFP) on Respondent on May 26, 2017.

On June 28, 2017, CTP filed a Motion to Extend Deadlines. In that motion, CTP indicated that it had not received a response to its RFP and intended to file a Motion to Compel Discovery (MTC). Judge Bill Thomas, the Administrative Law Judge previously assigned to this case, postponed ruling on the Motion to Extend Deadlines until CTP filed the MTC. Subsequently, on July 13, 2017, CTP filed the MTC. *See* 21 C.F.R. § 17.23(a). On July 17, 2017, CTP filed a Notice of Pending Settlement and Unopposed Motion to Extend Deadlines. An Order was issued on July 18, 2017, extending CTP's pre-hearing exchange deadline to August 17, 2017, and Respondent's pre-hearing exchange deadline to September 7, 2017. On August 17, 2017, CTP filed its pre-hearing exchange. To date, Respondent has not filed its pre-hearing submission.

On October 31, 2017, an Order was sent by U.S. Mail to Respondent's counsel of record, scheduling a pre-hearing telephone conference (PHC) for November 16, 2017 at 1:00 PM Eastern Time. On the scheduled date and time for the PHC, neither Respondent nor its counsel appeared to participate in the conference call. In an Order dated November 20, 2017, the PHC was rescheduled for December 14, 2017. The order for the rescheduled PHC was sent to CTP, and both Respondent (by DAB E-File) and Respondent's counsel (by U.S. Mail). Neither Respondent nor its counsel appeared at the rescheduled PHC on December 14, 2017. On December 18, 2017, this matter was transferred from Judge Thomas to me, and on December 19, 2017, I issued an Order to Show Cause giving Respondent until January 3, 2018 to file a written explanation for its failure to appear at the scheduled PHCs. In the Order, I also noted:

... on December 13, 2017, CTP filed its Renewed Motion to Compel Discovery (Renewed Motion). At this time, I will hold CTP's Renewed Motion in abeyance pending the expiration of the deadline for Respondent's submission of its written explanation in response to this Order. Should Respondent fail to show cause for its failure to appear at the

pre-hearing conference, CTP's Renewed Motion would be moot, and an Initial Decision and Default Judgment would be rendered

To date, Respondent has not filed a response to my Order to Show Cause.

II. Striking Respondent's Answer

Pursuant to 21 C.F.R. § 17.35, I am striking Respondent's Answer for failing to comply with multiple judicial orders/directions. Specifically, Respondent has not complied with the deadline set forth in the Acknowledgment and Pre-Hearing Order for responding to any discovery request and submission of pre-hearing exchange documents; the order granting CTP's motion to extend deadlines issued on July 18, 2017; the orders scheduling and rescheduling pre-hearing conferences issued on October 31, 2017, and November 20, 2017; and finally the Order to Show Cause issued on December 19, 2017. 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 here that Respondent's repeated failure to comply is sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b).

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:

- At approximately 6:16 PM on July 13, 2016, at Respondent's business establishment, 1535 Franklin Avenue, New Orleans, Louisiana 70117, an FDA-commissioned inspector documented Respondent's staff selling a package of Doral Menthol Box 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. Complaint ¶ 9.
- In a warning letter dated July 28, 2016, CTP informed Respondent of the inspector's July 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. Complaint ¶¶ 9-10.

- At approximately 6:54 PM on October 5, 2016, at Respondent's business establishment, 1535 Franklin Avenue, New Orleans, Louisiana 70117, 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. Complaint ¶ 7.

These facts establish Respondent Quicky's Discount'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)¹, no retailer may sell cigarettes and/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 and/or smokeless tobacco purchasers are younger than 18 years of age.

Under 21 C.F.R. § 17.2, a \$550 civil money penalty is permissible for three violations of the regulations found at 21 C.F.R. pt. 1140.

ORDER

For these reasons, I enter default judgment in the amount of \$550 against Respondent Ameer LLC d/b/a Quicky's Discount. 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

¹ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.