

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2018-H-1786)

Complainant,

v.

Mount Rainier Dollar and Food Mart Inc.
d/b/a Alife Dollar Food Mart,

Respondent.

Docket No. T-18-2158

Decision No. TB3625

Date: March 20, 2019

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Mount Rainier Dollar and Food Mart Inc. d/b/a Alife Dollar Food Mart, at 3847 34th Street, Mount Rainier, Maryland 20712, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Alife Dollar Food Mart impermissibly sold a covered tobacco product to a minor and failed to verify, by means of photo identification containing a date of birth, that the 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. The complaint also alleges that Respondent previously 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. The complaint further alleges that Respondent Alife Dollar Food Mart previously was found liable for three violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$5,591 civil money penalty against Respondent Alife Dollar Food Mart.

I. Background and Procedural History

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on May 10, 2018, CTP served the complaint on Respondent Alife Dollar Food Mart by United Parcel Service. On June 8, 2018, Mr. Solomon Bekele, an attorney for Respondent, filed a Notice of Appearance and a timely answer. On June 11, 2018, I issued an Acknowledgment and Prehearing 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 July 12, 2018, to request that the other party provide copies of documents relevant to this case. APHO ¶ 12. 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). *Id.*

On June 22, 2018, CTP served its Request for Production of Documents on Respondent. On August 8, 2018, CTP filed a Motion to Compel Discovery (Motion to Compel Discovery) stating it had not received a response to its Request for Production of Documents and requested "an order be entered compelling Respondent to respond to CTP's Request for Production of Documents in its entirety."

In an August 10, 2018 letter issued by my direction, Respondent was given until August 24, 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 August 10, 2018 letter. Therefore, in an August 29, 2018 order, I granted CTP's motion and ordered Respondent to comply with CTP's Request for Production of Documents by September 13, 2018. I also extended the parties' prehearing exchange deadlines by thirty days. I warned Respondent that a failure to comply might 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 September 13, 2018, Respondent filed its Production of Documents and Explanation. Subsequently, on October 30, 2018, CTP filed an Unopposed Motion to Extend Deadlines and Notice of Pending Settlement. In its Motion, CTP stated that the parties "have agreed to settle this matter," and that "CTP understands that payment is forthcoming from Respondent." CTP requested again "that all deadlines in this case be extended for thirty (30) days, so that Respondent can pay the agreed-upon civil money penalty, and CTP can process [Respondent's] payment." In an October 31, 2018 order, I granted a thirty-day extension. The thirty-day extension granted Respondent a December 24, 2018 deadline for its prehearing exchange.

On December 6, 2018, CTP filed its prehearing exchange, including an Informal Brief of Complainant, Complainant's List of Proposed Witnesses and Exhibits, and thirteen proposed exhibits. Respondent's deadline of December 24, 2018, passed without it filing

a prehearing exchange. On January 7, 2019, I issued an order notifying the parties that I had received a prehearing exchange from CTP, but had not received a prehearing exchange from Respondent. Further, I informed the parties that I would hold a prehearing conference on Wednesday, January 23, 2019, at 11:00 AM Eastern time.

On January 23, 2019, I held a prehearing conference. Counsel for CTP appeared for the scheduled prehearing conference, but Respondent did not appear at the prehearing conference or provide any response to the Order that scheduled the conference. I issued an Order to Show Cause on January 23, 2019, informing Respondent that it had until February 8, 2019, to show cause for its failure to appear at the prehearing conference. I also informed Respondent that failure to show cause “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.” To date, Respondent has failed to file any response to my Order to Show Cause.

The issue before me is whether my 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). Respondent initially failed to comply with my Acknowledgement and Prehearing Order as discovery materials requested by the Complainant were not provided as set forth by that order. After I issued an Order to Compel, Respondent provided the material requested by the Complainant. Respondent failed to appear at the January 23, 2019 prehearing conference or respond in any manner to said scheduling order. On January 23, 2019, I issued an Order to Show Cause. The Respondent failed to reply to that order. This conduct is sufficiently egregious to warrant striking Respondent’s answer and issuing an initial decision by default. Therefore, pursuant to 21 C.F.R. § 17.35, I strike Respondent’s answer for failing to comply with three judicial orders.

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:

- On October 31, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-18-245, FDA Docket Number FDA-2017-H-6299, 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, 3847 34th Street, Mount Rainier, Maryland 20712, on January 4, 2017, and October 23, 2017;

¹ One violation was documented on January 4, 2017, and two on October 23, 2017.

- 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”;
- At approximately 12:36 PM on April 10, 2018, at Respondent’s business establishment, 34th Street, Mount Rainier, Maryland 20712, an FDA commissioned inspector documented Respondent’s staff selling a Black & Mild cigar 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 Alife Dollar Food Mart’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) and 21 C.F.R. § 1140.14(b)(1), no retailer may sell cigarettes, smokeless tobacco, or covered tobacco products to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(a)(2)(i) and 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 cigarette, smokeless tobacco, or covered tobacco product purchasers are younger than 18 years of age.

Under 21 C.F.R. § 17.2, a \$5,591 civil money penalty is permissible for five violations of the regulations found at 21 C.F.R. pt. 1140.

Order

For these reasons, I enter default judgment in the amount of \$5,591 against Respondent Mount Rainier Dollar and Food Mart Inc. d/b/a Alife Dollar Food Mart. 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