

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Alkram Grocery Mart LLC
d/b/a Snack Shop,

Respondent.

Docket No. T-17-4922
FDA No. FDA-2017-H-3816

Decision No. TB2535

Date: March 16, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Alkram Grocery Mart LLC d/b/a Snack Shop, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$559. CTP began this case by serving the Complaint on Respondent and 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 cigarettes to minors and failed to verify, by means of photo identification containing a date of birth, that cigarette 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. CTP seeks a civil money penalty of \$559.

During the course of the administrative proceedings, Respondent failed to comply with two judicial orders and failed to defend its case, which interfered with the speedy, orderly, or fair conduct of this proceeding. 21 C.F.R. § 17.35(a). Accordingly, pursuant to 21 C.F.R. § 17.35(c)(3), I strike Respondent's Answer and issue this decision of default judgment.

I. Procedural History

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on June 29, 2017, CTP served the Complaint on Respondent Snack Shop by United Parcel Service. Respondent timely answered CTP's Complaint on July 31, 2017. On August 18, 2017, I issued an Acknowledgement and Pre-Hearing Order (APHO) that set deadlines for the parties' filings and exchanges, including a schedule for discovery. I directed that a party receiving a discovery request must provide the requested documents within 30 days of the request. APHO at ¶ 12; 21 C.F.R. § 17.23(a). I warned that I may impose sanctions if a party failed to comply with any order, including the APHO. APHO at ¶ 16.

In accordance with the deadlines set forth in the APHO, CTP served Respondent with its Request for Production of Documents on September 28, 2017. On November 3, 2017, CTP filed a Motion to Compel Discovery asserting that Respondent had not responded to its discovery request. Pursuant to 21 C.F.R. § 17.32(c), Respondent had 15 days in which to respond to CTP's motion. APHO at ¶ 19. Respondent did not respond.

On November 29, 2018, I issued an Order to Compel Discovery granting CTP's motion and ordering Respondent to comply with CTP's Request for Production of Documents by December 8, 2017. I warned Respondent that:

If Respondent fails to comply, **I will impose sanctions**, which may include striking Respondent's filings and issuing an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing a civil money penalty. 21 C.F.R. § 17.35.

(Emphasis in original.)

In my APHO, as amended by my November 1, 2017, and November 29, 2017, orders, I required CTP to file its pre-hearing exchange by January 8, 2018, and Respondent to file its pre-hearing exchange by January 29, 2018. CTP timely filed its exchange including a brief and 19 proposed exhibits. Respondent did not file its exchange as required.

On February 5, 2018, I issued an Order to Show Cause, in which I required Respondent to show cause for its failure to comply with my order and its failure to defend its case, citing 21 C.F.R. § 17.35(a). I provided Respondent until February 20, 2018, to respond. I warned Respondent that:

Failure to [comply] may **result in sanctions**, including striking Respondent's Answer and issuing an Initial Decision and Default Judgment finding Respondent liable for the violations

listed in the Complaint and imposing the **\$559** civil money penalty CTP seeks.

(Emphasis in original.)

To date, Respondent has not responded to my Order to Show Cause.¹ Indeed, Respondent has been silent since its July 31, 2017 Answer.

II. Striking Respondent's Answer

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.

21 C.F.R. § 17.35(a).

Here, Respondent failed to:

- Comply with my August 18, 2017, APHO, as amended by my November 1, 2017, and November 29, 2017, orders when it failed to file its pre-hearing exchange by January 29, 2018; and
- Comply with my February 5, 2018, Order to Show Cause when it failed to show cause for its failure to comply with my order and its failure to defend its case.

Respondent failed to comply with two judicial orders, despite warning of sanctions if it failed to comply. I find that Respondent failed to comply with orders and procedures governing this proceeding and failed to defend its action, which has interfered with the speedy, orderly, or fair conduct of this proceeding. 21 C.F.R. § 17.35(a). I conclude that Respondent's conduct establishes a basis for sanctions pursuant to 21 C.F.R. § 17.35 and that sanctions are warranted.

¹ All orders and guidance were mailed to Respondent at its address of record. However, the US Postal Service returned the APHO and Order to Compel Discovery, noting "VACANT." To date, the US Postal Service has not returned the other guidance or orders issued.

The harshness of the sanctions I impose must relate to the nature and severity of the misconduct or failure to comply. 21 C.F.R. § 17.35(b). Here, Respondent repeatedly failed to comply with my orders, despite my explicit warning that its failure could result in sanctions and I specified that those sanctions may include “striking Respondent’s Answer and issuing an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint and imposing the \$559 civil money penalty CTP seeks.” (Emphasis in original.) I find that Respondent’s misconduct is sufficient to warrant striking its Answer and issuing a decision by default, without further proceedings. 21 C.F.R. § 17.35(b), (c)(3). Accordingly, I strike Respondent’s Answer, and issue this Initial Decision and Default Judgment, assuming the facts alleged in CTP’s complaint to be true. 21 C.F.R. §§ 17.35(c)(3), 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, provided that the complaint is sufficient to justify a penalty. 21 C.F.R. § 17.11(a). Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the [C]omplaint to be true” and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Snack Shop, an establishment that sells tobacco products and is located at 801 North Woodington Road, Baltimore, Maryland 21229. Complaint ¶¶ 7-8.
- During an inspection of Respondent’s establishment on October 20, 2016, at approximately 2:48 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” The inspector also documented that “the minor’s identification was not verified before the sale” Complaint ¶ 11.
- On February 16, 2017, CTP issued a Warning Letter to Respondent regarding the inspector’s documented violations from October 20, 2016. The letter explained that the documented violations constituted violations of regulations, and that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶¶ 11-12.

- During a subsequent inspection of Respondent’s establishment on May 5, 2017, at approximately 4:28 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes” The inspector also documented that “the minor’s identification was not verified before the sale” Complaint ¶ 9.

These facts establish that Respondent is liable under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under section 906(d) of the Act. 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). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1). The regulations also require retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i).

Taking the above alleged facts as true, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on October 20, 2016, and May 5, 2017. On those same dates, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i). Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

CTP has requested a civil money penalty of \$559, which is a permissible penalty under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$559 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge