

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2018-H-1030)

Complainant

v.

Kamrul C. Inc.  
d/b/a 7-Eleven Store 34590A,

Respondent.

Docket No. T-18-1568

Decision No. TB3190

Date: October 24, 2018

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint (Complaint) on Respondent, Kamrul C. Inc. d/b/a 7-Eleven Store 34590A, at 4048 Forest Hill Boulevard, Palm Springs, Florida 33406, and by filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that 7-Eleven Store 34590A impermissibly 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, 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 to impose a \$2,236 civil money penalty against Respondent 7-Eleven Store 34590A.

During the course of the administrative proceedings, despite being apprised of the potential consequences, Respondent failed to comply with two separate judicial orders, and failed to defend its case. These actions interfered with the speedy, orderly, fair conduct of a hearing in this matter. 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 March 12, 2018, CTP served the Complaint on Respondent 7-Eleven Store 34590A by United Parcel Service. On April 10, 2018, Donald C. Anderson, III, filed what he termed an Answer purportedly requesting a hearing on behalf of Respondent, Kamrul C. Inc. d/b/a 7-Eleven Store 34590A. Mr. Anderson signed the purported Answer, but included no identification as to his relationship to Respondent, nor did he include any contact information.

On April 12, 2018, I issued an Acknowledgement and Pre-Hearing Order (APHO) that set deadlines for the parties' filings and exchanges and warned that:

I may impose sanctions including, but not limited to, dismissal of the complaint or answer, if a party fails to comply with any order (including this order), fails to prosecute or defend its case, or engages in misconduct that interferes with the speedy, orderly, or fair conduct of the hearing. 21 C.F.R. § 17.35.

APHO ¶ 16. Specifically, I ordered counsel representing either party to file a signed Notice of Entry of Appearance by May 4, 2018. APHO ¶ 1. CTP filed its Notice of Appearance on May 14, 2018. However, Mr. Anderson failed to file a Notice of Appearance.

On May 15, 2018, I ordered Mr. Anderson to file a Notice of Appearance to comply with the APHO and to complete the requirements of 21 C.F.R. § 17.9(b). I stated:

**I warn Mr. Anderson that if he is unable to file a Notice of Entry of Appearance to complete the answer requirements of 21 C.F.R. § 17.9(b) by the May 23, 2018 deadline, the Complaint will be unanswered and I will move to default judgement. 21 C.F.R. § 17.11.**

May 15, 2018, Order (emphasis in original). On May 23, 2018, Mr. Anderson filed a Notice of Appearance and an Amended Notice of Appearance. Each document contained the correct case caption but listed an incorrect respondent in the body of the filing. The filings nonetheless met the requirements of 21 C.F.R. § 17.9(b), and my orders. *See* APHO ¶ 1; May 15, 2018, Order. Accordingly, I accepted Mr. Anderson's appearance on behalf of Respondent Kamrul C. Inc. d/b/a 7-Eleven Store 34590A.

On June 19, 2018, CTP counsel filed an Unopposed Motion to Extend Deadlines and Notice of Pending Settlement. CTP asserted that the parties agreed to a settlement and sought an extension of the pre-hearing exchange deadlines to effectuate the settlement agreement. On June 20, 2018, I granted the motion and extended the pre-hearing exchange deadlines. CTP timely filed its pre-hearing exchange. Respondent did not file a pre-hearing exchange by its September 7, 2018 deadline, or at any time thereafter.

On September 26, 2018, I issued an Order Scheduling Pre-Hearing Conference. I ordered the parties to appear for a telephone pre-hearing conference on October 3, 2018, at 11:00 AM Eastern Time, to resolve certain issues and schedule a hearing for this case. Counsel for Respondent did not respond to my order or indicate that he was unable to appear. Yet, counsel for Respondent did not appear at the pre-hearing conference as I ordered.

Accordingly, on October 3, 2018, I issued an Order to Show Cause, in which I provided Respondent until October 10, 2018, to show cause for its failure to comply with my Order Scheduling Pre-Hearing Conference and failure to defend this case. I warned that:

. . . failure to show cause 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 a civil money penalty.

October 3, 2018, Order to Show Cause (emphasis in original).

Respondent did not file a response to my Order to Show Cause.

## 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 September 26, 2018, Order Scheduling Pre-Hearing Conference, and failed to respond to the subsequent Order to Show Cause, or to

demonstrate good cause for its failure to appear at the pre-hearing conference. 21 C.F.R. § 17.35(a)(1), (2).

I find that Respondent failed to comply with two separate judicial orders governing this proceeding and failed to defend its action. 21 C.F.R. § 17.35(a)(1), (2). These actions interfered with the speedy, orderly, and fair conduct of a hearing in this matter. 21 C.F.R. § 17.35(a)(3). I conclude that Respondent's conduct establishes a basis for sanctions and is sufficiently egregious to warrant them. 21 C.F.R. § 17.35.

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 failed to comply with my order to appear for a pre-hearing conference and failed to demonstrate good cause for this failure, despite my explicit warning that this failure could result in sanctions. October 3, 2018, Order to Show Cause. I specified that those sanctions might 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 a civil money penalty." *Id.* Respondent also failed to defend its action of failing to appear at the pre-hearing conference. In fact, counsel for Respondent did not file a pre-hearing exchange, and has had no participation in this case since filing his notice of appearance on May 23, 2018.

I find that Respondent's actions are sufficient to warrant striking Respondent's 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). Accordingly, I must first 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 (but not its conclusory statements) and I conclude that default judgment is merited based on the allegations of the Complaint. 21 C.F.R. § 17.11. Specifically:

- On June 29, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-4934, FDA Docket Number FDA-2017-H- 3828, against Respondent for two violations of 21 C.F.R. pt. 1140. CTP alleged those violations to have occurred at Respondent's business establishment, 4048 Forest Hill Boulevard, Palm Springs, Florida 33406, on October 10, 2016, and May 20, 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 5:11 PM on February 26, 2018, at Respondent’s business establishment, 4048 Forest Hill Boulevard, Palm Springs, Florida 33406, an FDA-commissioned inspector documented Respondent’s staff selling a package of Newport 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.

These facts establish Respondent 7-Eleven Store 34590A’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), no retailer may sell cigarettes 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 or smokeless tobacco purchasers are younger than 18 years of age.

A \$2,236 civil money penalty is permissible under 21 C.F.R. § 17.2.

### **Order**

For these reasons, I enter default judgment in the amount of \$2,236 against Respondent Kamrul C. Inc. d/b/a 7-Eleven Store 34590A. 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.

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/s/  
Catherine Ravinski  
Administrative Law Judge