

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant,

v.

Albany Market, LLC  
d/b/a Albany Market,

Respondent.

Docket No. T-18-3468  
FDA No. FDA-2018-H-3455

Decision No. TB3984

Date: June 24, 2019

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an Administrative Complaint on Respondent, Albany Market, LLC d/b/a Albany Market, at 1307 North Albany Avenue, Tampa, Florida 33607, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Albany Market impermissibly sold covered tobacco products to a minor, 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 and covered tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that one of the purchasers was 18 years of age or older. The complaint further alleges that Respondent Albany Market previously admitted to at least four violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks a \$5,591 civil money penalty against Respondent Albany Market for at least five violations within a 36-month period.

During the course of these administrative proceedings, Respondent failed to comply with orders and procedures governing this proceeding and failed to defend its actions, 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, for the reasons discussed below.

## I. Procedural History

On September 13, 2018, CTP served the complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. On October 15, 2018, Respondent timely filed an Answer to CTP's complaint. On October 19, 2018, 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 ¶ 12; *see* 21 C.F.R. § 17.23(a). I warned:

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.

On March 13, 2019, CTP filed its pre-hearing exchange and supporting documents. To date, Respondent has not filed a pre-hearing exchange.

On April 10, 2019, I issued an Order Scheduling a Pre-Hearing Conference, noting: “[CTP] has submitted its pre-hearing exchange and the time for Respondent to submit its pre-hearing exchange has expired.” To resolve certain issues, I ordered both parties to appear for a pre-hearing telephone conference on May 9, 2019, at 11:00 AM. Respondent failed to appear for the pre-hearing telephone conference, as ordered.

On May 9, 2019, I issued an Order to Show Cause due to Respondent's failure to comply with my Order Scheduling a Pre-Hearing Conference. I informed both parties that Respondent had until May 30, 2019 to show cause for its failure to comply with my Order Scheduling a Pre-Hearing Conference. 21 C.F.R. § 17.35(a).

I stated:

I warn Respondent that failure to do so 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.

May 9, 2019 Order to Show Cause. (emphasis in original).

Respondent failed to respond to my Order to Show Cause.

## **II. Striking Respondent's Answer**

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).

Respondent failed to comply with the following orders and procedures governing this proceeding:

- Respondent failed to comply with 21 C.F.R. § 17.23(a) and paragraph 4 of my October 19, 2018 APHO, when it failed to file a pre-hearing exchange.
- Respondent failed to comply with my April 10, 2019 Order Scheduling a Pre-Hearing Conference, when it failed to appear for the pre-hearing telephone conference on May 9, 2019.
- Respondent failed to comply with my May 9, 2019 Order to Show Cause, when it failed to show cause for its failure to comply with my Order Scheduling a Pre-Hearing Conference.

I find that Respondent failed to comply with orders and procedures governing this proceeding, failed to defend its case, and, as a result, interfered with the speedy, orderly, and fair conduct of this proceeding. I conclude that Respondent's conduct establishes a basis for sanctions, pursuant to 21 C.F.R. § 17.35, and that sanctions are warranted.

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 three of my orders, despite my explicit and repeated warnings that its failure could result in sanctions. I specified that those sanctions may include striking its 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.” May 9, 2019 Order to Show Cause. Respondent also failed to defend its actions, despite my express reminders of the opportunity. After timely filing its Answer on October 15, 2018, Respondent has not taken any further action in this matter. Respondent’s repeated failure to comply with orders and failure to defend this action interfered with the speedy, orderly, or fair conduct of this proceeding. I find that Respondent’s actions are 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. 21 C.F.R. § 17.35(c)(3).

### **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 complaint 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:

- On March 6, 2018, CTP initiated a previous civil money penalty action, CRD Docket Number T-18-1520, FDA Docket Number FDA-2018-H-0957,<sup>1</sup> against Respondent for four violations of 21 C.F.R. pt. 1140 within a 36-month period. CTP alleged those violations to have occurred at Respondent’s business establishment located at 1307 North Albany Avenue, Tampa, Florida 33607, on February 7, 2018,<sup>2</sup> November 18, 2017, and April 24, 2017;
- The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon monetary penalty in settlement of that claim. Further, “Respondent expressly waived its right to contest such violations in subsequent actions”;
- At approximately 2:43 PM on June 17, 2018, at Respondent’s business establishment located at 1307 North Albany Avenue, Tampa, Florida 33607, an FDA-commissioned inspector documented Respondent’s staff selling a package of two White Owl Sweets cigars to a person younger than 18 years of age.

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<sup>1</sup> See also FDA Docket Number FDA-2017-H-6683, CRD Docket Number T-18-534, for an earlier civil money penalty action.

<sup>2</sup> Two violations were documented on February 7, 2018.

These facts establish Respondent Albany Market'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 also* 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 or smokeless tobacco and covered tobacco products 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.

Under 21 C.F.R. § 17.2, a \$5,591 civil money penalty is permissible for at least five violations of the regulations found at 21 C.F.R. pt. 1140 within a 36-month period.

### **Order**

For these reasons, I enter default judgment in the amount of \$5,591 against Respondent Albany Market, LLC d/b/a Albany Market. 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/

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Mary M. Kunz  
Administrative Law Judge