

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant,

v.

Jesse Foods, Inc.  
d/b/a Express Food Mart,

Respondent.

Docket No. T-19-282  
FDA No. FDA-2018-H-4046

Decision No. TB3945

Date: June 7, 2019

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an Administrative Complaint on Respondent, Jesse Foods, Inc. d/b/a Express Food Mart, at 10134 Madison Avenue, Cleveland, Ohio 44102, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Express Food Mart impermissibly sold cigarettes or smokeless tobacco 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 one of the purchasers was 18 years of age or older. The complaint further alleges that Respondent Express Food Mart previously admitted to at least three violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks a \$5,591 civil money penalty against Respondent Express Food Mart for at least five violations within a 36-month period.

During the course of these administrative proceedings, Respondent, through counsel, 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.

## **I. Procedural History**

On October 29, 2018, CTP served the complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. Respondent, through counsel, timely answered CTP's complaint.<sup>1</sup> On December 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 January 16, 2019, CTP filed a Status Report which stated it had "attempted to contact Respondent to discuss the filing of a Joint Status Report, but was unable to reach Respondent." In accordance with the deadlines set forth in the APHO, CTP served Respondent with its Request for Production of Documents on January 3, 2019, via United Parcel Service at Respondent's counsel's office, located at the address listed on the Answer, 12910 Taft Avenue, Floor 2, Cleveland, Ohio 44108.

On February 7, 2019, CTP filed a Motion to Compel Discovery asserting that Respondent had not responded to its discovery request. By letter issued at my direction, Respondent's counsel was informed that Respondent had until March 8, 2019, to file a response to CTP's Motion to Compel Discovery. *See also* 21 C.F.R. § 17.32(c); APHO ¶ 19. Respondent's counsel did not respond.

Additionally, on February 7, 2019, CTP also filed a Motion to Extend Deadlines, requesting "that any deadlines, including the March 11, 2019 due date for CTP's pre-

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<sup>1</sup> After timely filing the Answer, Respondent's counsel failed to take any further action. Respondent, acting alone or through counsel, repeatedly failed to respond to orders I issued, and comply with letters issued at my direction.

hearing exchange, be extended thirty (30) days. . . .” I issued an Order extending CTP’s pre-hearing exchange to Respondent until April 10, 2019, and Respondent’s pre-hearing exchange to CTP until May 1, 2019.

On April 4, 2019, I issued an Order to Compel Discovery in which I granted CTP’s motion and ordered Respondent to produce responsive documents to CTP’s Request for Production of Documents by April 11, 2019. The order also extended the parties’ pre-hearing exchange deadlines. I stated:

I warn Respondent that failure to comply may **result in sanctions** which may include striking its 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.

April 4, 2019 Order to Compel Discovery (emphasis in original).

On April 16, 2019, CTP filed a Motion to Impose Sanctions. CTP advised that Respondent had not complied with my Order to Compel Discovery, and asked that I strike Respondent’s Answer as a sanction and issue an Initial Decision and Default Judgment. By letter issued at my direction on April 17, 2019, I informed both parties that Respondent had until May 2, 2019, to file a response to CTP’s Motion to Impose Sanctions. Respondent’s counsel did not respond.

## 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 12 of my APHO, when Respondent failed to respond to CTP’s Request for Production of Documents within 30 days; and

- Respondent failed to comply with my April 4, 2019 Order to Compel Discovery, when it failed to submit the documents responsive to CTP's Request for Production of Documents by April 11, 2019.

Respondent failed to defend its action despite the following opportunities:

- By letter issued at my direction on March 1, 2019, Respondent was informed that it had until March 8, 2019, to file a response to CTP's Motion to Compel Discovery. Respondent did not defend its action; and
- By letter issued at my direction on April 17, 2019, Respondent was informed that it had until May 2, 2019, to file a response to CTP's Motion to Impose Sanctions. Respondent did not defend its action.

I find that Respondent, through counsel, 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 two 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." April 4, 2019 Order to Compel Discovery. Respondent, through counsel, also failed to defend its actions, despite my express reminders of the opportunity. Respondent's repeated misconduct 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 August 8, 2018, CTP initiated a previous civil money penalty action, CRD Docket Number T-18-3210, FDA Docket Number FDA-2018-H-3093, against Respondent for violations of 21 C.F.R. pt. 1140, three<sup>2</sup> of which occurred within the 36-month period relevant here. CTP alleged those violations to have occurred at Respondent's business establishment located at 10134 Madison Avenue, Cleveland, Ohio 44102, on October 13, 2017, and June 8, 2018;
- 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 7:50 PM on October 2, 2018, at Respondent's business establishment located at 10134 Madison Avenue, Cleveland, Ohio 44102, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box 100s 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 Express 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 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), 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.

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.

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<sup>2</sup> One violation was documented on October 13, 2017, and two on June 8, 2018.

