

**Department of Health and Human Services  
DEPARTMENTAL APPEALS BOARD  
Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2016-H-2163)

Complainant

v.

Ecru Express LLC,

Respondent.

Docket No. T-16-1411

Decision No. TB1106

Date: April 11, 2017

**ORDER GRANTING COMPLAINANT'S MOTION FOR SANCTIONS AND  
ISSUING INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint (Complaint) on Respondent, Ecru Express LLC, located at 141 Main Street, Ecru, Mississippi 38841, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. CTP alleges in its Complaint that Ecru Express LLC impermissibly sold tobacco products to minors and failed to verify, by means of photo identification containing a date of birth, that the 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 likewise alleges that Respondent Ecru Express LLC previously admitted to three violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, seeks to impose a \$5,501 civil money penalty against Respondent Ecru Express. As discussed below, Respondent has failed to participate in the discovery process in this case, despite being given several opportunities to do so. I therefore grant CTP's Motion for Sanctions, strike Respondent's Answer, and issue this decision of default judgment.

## I. Procedural History

After being properly served with CTP's complaint in this matter, Respondent timely filed its Answer on November 2, 2016. I issued an Acknowledgment and Prehearing Order (APHO) on November 4, 2016, and set deadlines for the parties' submissions, including the December 7, 2016 deadline to request relevant documents from the opposing party. The APHO provided that a party receiving such a request had to provide the requested documents no later than 30 days after the request was made. CTP served Respondent with its request for documents on December 7, 2016.

On January 13, 2017, CTP filed a Motion to Compel Discovery indicating that Respondent did not respond to its request within the 30 days afforded by my order. *See* 21 C.F.R. § 17.23(a). In a letter issued at my direction, Respondent was given until January 30, 2017, to object to CTP's motion. Respondent did not file an objection.

On February 7, 2017, I issued an Order granting CTP's Motion to Compel Discovery and extended the pre-hearing exchange deadlines to allow Respondent another opportunity to produce the requested documents. That Order gave Respondent until February 21, 2017 to comply with CTP's discovery request. I explicitly warned Respondent that failure to comply with CTP's discovery request could 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. CTP subsequently filed a Motion to Impose Sanctions on February 23, 2017, indicating that Respondent did not comply with the Order Granting CTP's Motion to Compel. On February 24, 2017, I directed a letter be issued that provided Respondent until March 10, 2017, to object to CTP's motion.

On March 10, 2017, Respondent emailed the staff attorney assigned to this case and stated that it objected to CTP's motion and refused to produce requested documents on the ground that it was not obligated to produce evidence against itself. On March 15, 2017, I issued an Order informing Respondent that it had a duty to participate in the discovery process and affording Respondent another opportunity to comply with my Order. I again explained that failure to participate in the discovery process could 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. I again extended Respondent's deadline to comply with CTP's discovery requests, to March 27, 2017. On April 5, 2017, CTP filed an updated status report and renewed its request for sanctions, noting that Respondent did not respond to the March 15, 2017 Order, and had not responded in any fashion to CTP's Request for Production of Documents.

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

Respondent has failed to produce documents in response to CTP's Requests for Production or otherwise comply with my Orders requiring it to participate in the discovery process. Sanction is therefore appropriate pursuant to 21 C.F.R. § 17.35(a). The issue is whether CTP's proposed 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, and be sufficiently egregious to warrant striking the answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b).

As noted above, Respondent has failed to produce any documents, object to any of the requests, or file a motion to protect any documents requested by CTP. The only action Respondent did take was to contact my staff attorney by e-mail and indicate it did not believe it was required to produce any documents requested by CTP. Despite the patent inaccuracy of this assertion, I explained the need for Respondent to participate in the discovery process, warned it of the consequences of failing to do so, and provided Respondent additional time to comply with CTP's discovery request. Yet, Respondent failed to file a response to my order or produce any documents responsive to CTP's requests.

Respondent has failed to comply with the APHO, my order granting CTP's Motion to Compel, the directive I issued ordering production of documents, and my last order giving Respondent another opportunity to come into compliance. Respondent's persistent non-compliance with my orders and unwavering refusal to participate in the discovery process in this matter warrant a severe sanction. Accordingly, I find it appropriate to strike Respondent's Answer and issue a default decision. *See* 21 C.F.R. §§ 17.11(a), 17.35(a)(1), 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 if the complaint is sufficient to justify a penalty. 21 C.F.R. § 17.11(a). Accordingly, I must 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 and conclude the default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with the orders. 21 C.F.R. § 17.11. Specifically:

- On March 4, 2015, CTP initiated a previous civil money penalty action, CRD Docket Number C-15-1480, FDA Docket Number FDA-2015-H-0660, against

Respondent for three<sup>1</sup> 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, 141 Main Street, Ecu, Mississippi 38841, on June 24, 2014, and October 13, 2014. Complaint ¶ 10.

- The previous action concluded when an Initial Decision and Default Judgment was entered by an Administrative Law Judge which found that all of the violations alleged in the Complaint occurred. Complaint ¶ 11.
- At approximately 5:49 p.m. on January 19, 2016, at Respondent's business establishment, 141 Main Street, Ecu, Mississippi 38841, FDA-commissioned inspectors documented Respondent's staff selling a package of Newport Non-Menthol Box cigarettes to a person younger than 18 years of age. The inspectors 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. Complaint ¶ 8.

These facts establish Respondent Ecu Express LLC'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),<sup>2</sup> no retailer may sell 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 tobacco product purchasers are younger than 18 years of age.

Under 21 C.F.R. § 17.2, a \$5,501 civil money penalty is permissible for five violations of the regulations found at 21 C.F.R. pt. 1140.

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<sup>1</sup> Two violations were documented on June 24, 2014, and two on October 3, 2014. In accordance with customary practice, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

<sup>2</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

**ORDER**

For the foregoing reasons, I grant CTP's Motion to Impose Sanctions, strike Respondent's Answer, and enter default judgment in the amount of \$5,501 against Respondent Ecrú Express LLC. 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/

Bill Thomas  
Administrative Law Judge