

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

Center for Tobacco Products,

Complainant

v.

Zavi Links Inc.
d/b/a Citgo Mini Mart,

Respondent.

Docket No. T-16-1251
FDA No. FDA-2016-H-1992

Decision No. TB1673

Date: July 21, 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, Zavi Links Inc. d/b/a Citgo Mini Mart, located at 1338 Hempstead Turnpike, Elmont, New York 11003, 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 Citgo Mini Mart 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 seeks to impose a \$500 civil money penalty against Respondent Citgo Mini Mart.

Respondent has failed to adequately participate in this matter or comply with my orders, 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 dated August 28, 2016. I issued an Acknowledgment and Prehearing Order (APHO) on September 22, 2016, and set deadlines for the parties' submissions, including the October 26, 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 October 24, 2016.

On December 5, 2016, CTP filed a Motion to Compel Discovery stating 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 December 27, 2016, to object to CTP's motion. That letter also suspended the pre-hearing exchange deadlines until resolution of CTP's motion. Respondent did not file an objection, but on January 9, 2017, CTP filed an Updated Status Report stating that it had received the documents requested from Respondent, and asking that pre-hearing exchange deadlines be extended in order to review those documents.

On January 24, 2017, in a letter issued at my direction, I acknowledged Respondent's compliance with CTP's request for documents and imposed new pre-hearing exchange deadlines. That letter provided CTP until February 22, 2017 to file its pre-hearing exchange and provided Respondent until March 14, 2017 to file its pre-hearing exchange. On February 22, 2017, CTP filed its pre-hearing exchange. Respondent failed to file its pre-hearing exchange by the imposed deadline. On March 24, 2017, I issued an order requiring Respondent, no later than April 6, 2017, to either submit its pre-hearing exchange or advise me by report whether it still desired a hearing in this matter. Respondent failed to file its pre-hearing exchange submissions or a status report.

On April 17, 2017, I issued an order scheduling a pre-hearing conference for April 26, 2017 at 11:30 a.m. to be held by telephone. Respondent subsequently failed to appear for the scheduled pre-hearing conference. On May 8, 2017, CTP filed a motion for sanctions.

II. Striking Respondent's Answer Is Appropriate.

In my APHO, I warned the parties that I could issue sanctions pursuant to 21 C.F.R. § 17.35, including but not limited to, dismissal of the complaint or answer, if, among other reasons, a party failed to comply with any order I issued in this matter, or failed to prosecute or defend its case. As outlined above, Respondent has failed to defend its case and repeatedly failed to comply with my Orders. 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).

Respondent's failure to defend its case militates towards a harsher sanction. To date, Respondent has failed to timely produce responsive documents as part of the discovery process,¹ file its pre-hearing exchange, attend a scheduled pre-hearing conference, or respond to any of my directives. In short, Respondent has failed to participate in this case in any meaningful way since the filing of its Answer.

CTP also correctly observes that repeated refusal by a party to comply with my orders is an appropriate ground for issuing judgment against that party. CTP Motion for Sanctions at 2, *citing* 21 C.F.R. § 17.35(d). Respondent has repeatedly failed to comply with my directives in this case. It failed to comply with my initial order I issued requiring timely participation in discovery and submission of a pre-hearing exchange, the order I issued giving Respondent another opportunity to submit a pre-hearing exchange or report articulating its position, and the order I issued scheduling a pre-hearing conference. Respondent's persistent non-compliance with my orders and refusal to minimally participate in the proceeding that it requested in its Answer 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:

- Respondent owns Citgo Mini Mart, an establishment that sells tobacco products and is located at 1338 Hempstead Turnpike, Elmont, New York 11003. Complaint ¶¶ 6-7.

¹ Respondent did eventually provide requested documents to CTP, but only after CTP filed a Motion to Compel, to which Respondent failed to respond.

- During an inspection of Respondent’s establishment on February 22, 2015, at approximately 11:34 a.m., an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . [.]” The inspector also observed that “the minor’s identification was not verified before the sale” Complaint ¶ 10.
- On April 9, 2015, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from February 22, 2015. The letter explained that the observations 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.
- During a subsequent inspection of Respondent’s establishment on January 9, 2016, at approximately 11:55 a.m., 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 inspectors also documented that “the minor’s identification was not verified before the sale” Complaint ¶ 8.

These facts establish Respondent Citgo Mini 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* 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),² 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 \$500 civil money penalty is permissible for three violations of the regulations found at 21 C.F.R. pt. 1140.

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

