

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

Center for Tobacco Products,
(FDA No. FDA-2016-H-4438)

Complainant

v.

Whistlin' Jack Lodge, Inc.
d/b/a Whistlin' Jack Lodge,

Respondent.

Docket No. T-17-1283

Decision No. TB1715

Date: August 1, 2017

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint (Complaint) on Respondent, Whistlin' Jack Lodge, Inc. d/b/a Whistlin' Jack Lodge, located at 20800 State Route 410, Naches, Washington 98937, 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 Whistlin' Jack Lodge 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 an \$11,002 civil money penalty against Respondent, Whistlin' Jack Lodge.

During the pre-hearing process, Respondent failed to comply with my Orders regarding participation in the scheduled pre-hearing telephone conferences, despite being given multiple opportunities to do so. I therefore 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 February 6, 2017. I issued an Acknowledgment and Pre-Hearing Order (APHO) on February 8, 2017, and set deadlines for the parties' submissions.

On March 10, 2017, CTP filed a Joint Status Report stating that the parties had been unable to reach a settlement in this case and that the parties intended to proceed to a hearing. That same day, Respondent filed its pre-hearing exchange. On May 1, 2017, CTP filed its pre-hearing exchange.

In its pre-hearing exchange Respondent admitted all of CTP's allegations of noncompliance. Respondent offered no evidence that controverts those allegations.

On May 26, 2017, I issued an Order Scheduling a Pre-Hearing Conference for June 8, 2017 at 10:30 a.m. Eastern Time to be held by telephone. My purpose in scheduling the call was to determine whether Respondent had any evidence or arguments that it wished to make on its behalf. Respondent failed to appear at the scheduled pre-hearing conference. On June 8, 2017, I issued an Order informing Respondent that it had until June 20, 2017 to show cause for his failure to appear at the scheduled pre-hearing telephone conference. On June 20, 2017, Respondent filed a response, averring that it did not receive the Order Scheduling a Pre-Hearing Conference due to changes in its management. Subsequently, I issued an Order Rescheduling the Pre-Hearing Conference for July 18, 2017 at 1:00 p.m. Eastern Time. Respondent again failed to appear at the scheduled pre-hearing telephone conference and offered no excuse for its failure to appear.

II. Striking Respondent's Answer Is Appropriate.

Respondent failed to appear at both of the scheduled pre-hearing conferences. Nor did it contact my office with an excuse for its failure to appear at the July 18, 2017, telephone conference. In my APHO, I warned the parties that I could issue sanctions pursuant to 21 C.F.R. § 17.35. Further, I informed Respondent that such sanctions included, but were 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. Sanction is therefore appropriate pursuant to 21 C.F.R. § 17.35(a).

The issue is whether the sanction of striking Respondent's Answer and issuing a default judgment in an 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 I find here that Respondent's repeated failure to comply is sufficiently egregious to warrant striking the Answer and issuing a decision without further proceedings. *See* 21 C.F.R. § 17.35(b).

As previously discussed, Respondent failed to participate in either of the scheduled pre-hearing telephone conferences in this case. Respondent's failure to appear or otherwise defend its case weighs towards a strict sanction. Further, with regard to the second pre-hearing telephone conference scheduled for July 18, 2017, Respondent has not communicated with this office to provide an explanation for its failure to appear. In short, Respondent has failed to participate in this case in any meaningful way since the filing of its pre-hearing exchanges. I conclude that Respondent either has abandoned its request for hearing or is without a defense. In either event, its failure to participate in this case or otherwise comply with my Orders provides grounds for striking Respondent's Answer.

III. Default Decision

Striking Respondent's Answer leaves the Complaint unanswered. Therefore, I am required to "assume facts alleged in the [C]omplaint to be true" and if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. 21 C.F.R. § 17.11(a). Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Whistlin' Jack Lodge, an establishment that sells tobacco products and is located at 20800 State Route 410, Naches, Washington 98937. Complaint ¶¶ 6-7.
- CTP initiated a previous civil money penalty action, CRD Docket Number C-15-3410, FDA Docket Number FDA-2015-H-2588 (*see also*, CRD Docket Number C-15-625, FDA Docket Number FDA-2014-H-2149; CRD Docket Number C-14-752, FDA Docket Number FDA-2014-H-0262), against respondent for five violations of 21 C.F.R. pt. 1140 within a 36-month period. Complaint ¶ 10.
- The previous action concluded when Respondent "admitted all of the allegations in the Complaint and paid the agreed upon penalty." Further, "Respondent expressly waived its right to contest such violations in subsequent actions." Complaint ¶ 11.
- During a subsequent inspection of Respondent's establishment on June 9, 2016, at approximately 1:41 p.m., an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes" Complaint ¶ 8.

These facts establish Respondent Whistlin' Jack Lodge'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),¹ 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.

Taking the above alleged facts as true, Respondent had six violations of regulations found at 21 C.F.R. pt. 1140 within a 48-month period. Respondent violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on March 10, 2013, September 9, 2013, June 17, 2014, March 30, 2015, and June 9, 2016. On June 17, 2014, Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i). Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

Under 21 C.F.R. § 17.2, an \$11,002 civil money penalty is permissible for six violations of the regulations found at 21 C.F.R. pt. 1140.

ORDER

For the foregoing reasons, I strike Respondent's Answer and enter default judgment in the amount of \$11,002 against Respondent Whistlin' Jack Lodge. 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/
Steven T. Kessel
Administrative Law Judge

¹ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.