

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2016-H-2660)

Complainant

v.

Alkathi, Inc.  
d/b/a Spirit,

Respondent.

Docket No. T-16-1891

Decision No. TB918

Date: March 7, 2017

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Alkathi, Inc. d/b/a Spirit, at 15303 Fenkell Street, Detroit, Michigan 48227, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Spirit 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. The complaint likewise alleges that Respondent Spirit previously admitted to three violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$5,501 civil money penalty against Respondent Spirit.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on September 20, 2016, CTP served the complaint on Respondent Spirit by United Parcel Service. In the complaint and accompanying cover letter, CTP explained that, within 30 days, Respondent should pay the penalty, file an answer, or request an extension of time in which to file an answer.

CTP warned Respondent that, if it failed to take one of these actions within 30 days, the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering it to pay the full amount of the proposed penalty.

### **I. Procedural History**

On October 20, 2016, Respondent timely filed an answer to CTP's complaint. On October 25, 2016, I issued an Acknowledgment and Pre-hearing Order (APHO) that contained a provision that set out instructions regarding a party's request for production of documents. That provision states, in part, that a party had until December 1, 2016, to request that the other party provide copies of documents relevant to this case. The order also stated that a party receiving such a request must provide the requested documents no later than 30 days after the request has been made, pursuant to 21 C.F.R. § 17.23(a).

On November 21, 2016, CTP served its Request for Production of Documents on Respondent. On January 4, 2017, CTP filed a Motion to Compel Discovery stating it had not received a response from Respondent regarding its Request for Production of Documents. In a January 4, 2017 letter issued by my direction, Respondent was given until January 19, 2017 to file a response to CTP's Motion to Compel Discovery.

Respondent failed to respond to my January 4, 2017 letter. Therefore, on January 24, 2017, I granted CTP's Motion to Compel Discovery, and ordered Respondent to comply with CTP's discovery request by February 8, 2017. Respondent was warned 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.

On February 16, 2017, CTP filed a Motion to Impose Sanctions indicating that Respondent has not complied with my January 24, 2017 order. On February 23, 2017, I issued an order requiring Respondent to show cause for (1) its failure to respond to CTP's discovery request as directed in the January 24, 2017 order, and (2) reasons why CTP's Motion to Impose Sanctions should not be granted. Respondent was given until March 2, 2017 to respond to my February 23, 2017 order. Respondent was again warned that failure to respond may result in sanctions, including striking the answer/request for hearing, and issuing a default judgment. To date, Respondent has not responded to my order.

Therefore, pursuant to 21 C.F.R. § 17.35, I am granting CTP's Motion to Impose Sanctions, and striking Respondent's answer for failing to comply with four separate judicial directions, specifically the deadline set forth in the APHO for responding to any discovery request, the letter sent at my direction on January 4, 2017, the order granting CTP's motion to compel discovery issued on January 24, 2017, and finally the order to

show cause issued on February 23, 2017. This repeated conduct is sufficiently egregious to warrant striking Respondent's answer and issuing an initial decision by default.

## **II. Default Decision**

Striking Respondent's answer leaves the complaint unanswered. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- On November 19, 2015, CTP initiated a previous civil money penalty action, FDA Docket Number FDA-2015-H-4181, 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, 15303 Fenkell Street, Detroit, Michigan 48227, on June 28, 2014, and August 3, 2015;
- The previous action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions." Complaint ¶ 11.
- At approximately 11:18 a.m. on February 20, 2016, at Respondent's business establishment, 15303 Fenkell Street, Detroit, Michigan 48227, 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 Spirit'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, 28975-76 (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.

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<sup>1</sup> Two violations were documented on June 28, 2014, and two on August 3, 2015. 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>.

