

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-R-6098)

Complainant,

v.

Alkathi, Inc.
d/b/a Spirit,

Respondent.

Docket No. T-18-102

Decision No. TB2602

Date: April 6, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Alkathi, Inc. d/b/a Spirit, that alleges facts and legal authority sufficient to justify imposition of a No-Tobacco-Sale Order against Respondent for a period of 30 consecutive calendar days. Respondent, through counsel, filed an answer to the Complaint, but has failed to comply with multiple judicial directions and orders during the administrative proceedings. I therefore strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

Respondent timely answered CTP's Complaint opposing the No-Tobacco-Sale Order and requested a hearing. On November 17, 2017, I issued an Acknowledgment and Pre-Hearing Order that explained to the parties what they must do to present evidence and arguments in this case. I explained that the parties may request copies of documents relevant to this case and that the requesting party must serve the request for documents no

later than December 18, 2017. I further explained that “a party receiving such a request must provide the requested documents no later than 30 days after the request has been made.” As part of the discovery process, CTP served a Request for Production of Documents (RFP) on Respondent on December 7, 2017.

On January 24, 2018, pursuant to 21 C.F.R. § 17.23(a), CTP filed a Motion to Compel Discovery indicating that CTP had not received a response to its request for production of documents. On January 24, 2018, CTP also filed a Motion to Extend Deadlines. A February 2, 2018 letter issued by my direction allowed Respondent until February 9, 2018 to file a response to CTP’s motion to compel discovery. On February 2, 2018, I also issued an Order that extended the parties’ pre-hearing exchange deadlines.

On February 12, 2018, I issued an Order that granted CTP’s motion to compel discovery. I noted that Respondent had not filed a response to CTP’s motion to compel discovery. In that Order, I directed Respondent to comply with CTP’s RFP by February 28, 2018. I warned that “[f]ailure to do so may result in sanctions, including the issuance of an Initial Decision and Default Judgment finding Respondent liable for the violations listed in the Complaint”¹ The February 12, 2018 Order also extended the parties’ pre-hearing exchange deadlines.

On March 5, 2018, CTP filed a Motion to Impose Sanctions advising me that Respondent had not complied with my February 12, 2018 Order and asking me to strike the Respondent’s answer and issue a default judgment in this case. In a March 8, 2018 letter issued by my direction, Respondent was given until March 20, 2018 to file a response to CTP’s motion. The March 8, 2018 letter also extended the parties’ pre-hearing exchange deadlines. To date, Respondent has not filed a response to CTP’s Motion to Impose Sanctions.

II. Striking Respondent’s Answer

As outlined above, Respondent has repeatedly failed to comply with my Orders or otherwise participate in the defense of its case. *See* 21 C.F.R. § 17.35(a). Specifically, Respondent has not complied with the deadline set forth in the Acknowledgment and Pre-Hearing Order for responding to any discovery request, or the order granting CTP’s motion to compel discovery issued on February 12, 2018. Further, I note that Respondent did not avail itself of the opportunity to respond to CTP’s motion to impose sanctions pursuant to the letter issued at my direction on March 8, 2018. 21 C.F.R. § 17.35(a)(2) provides that, in addition to a party’s failure to comply with an order, subpoena, rule, or procedure governing the proceedings, a presiding officer may impose

¹ I note that the February 12, 2018 Order inadvertently referenced imposition of “a civil money penalty.” It should correctly reference imposition of “a no-sale-tobacco order.” *See* February 12, 2018 Order at 2.

sanctions for a party's failure to prosecute or defend an action. Respondent has not only failed to act in response to my orders of November 17, 2017 and February 12, 2018, Respondent has failed to take any action in response to CTP's motions, or to otherwise defend its November 13, 2017 answer. Therefore, sanctions are appropriate in this case. The issue is whether CTP's proposed sanction – striking Respondent's answer and issuing a 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. 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).

Accordingly, I am striking Respondent's answer, issuing this default judgment, and assuming the facts alleged in CTP's Complaint to be true. 21 C.F.R. § 17.11(a).

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 that default judgment is merited based on the allegations of the Complaint and the sanctions imposed on Respondent for failure to comply with my orders. 21 C.F.R. § 17.11. Specifically:

- On November 19, 2015, CTP initiated its first civil money penalty action, FDA Docket Number FDA-2015-H-4181, against Respondent for three² violations of 21 C.F.R. pt. 1140 within a 24-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 first action concluded when Respondent admitted the allegations contained in the Complaint issued by CTP, and paid the agreed upon monetary penalty in

² Two violations were documented on June 28, 2014, and two on August 3, 2015. When determining the number of violations for a civil money penalty, CTP counted the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations, in accordance with customary practice. When determining the number of violations for a No-Tobacco-Sale Order, CTP counted both the June 28, 2014 violations (sale to a minor and failure to verify identification) as Respondent's original violations.

settlement of that claim. Further, “Respondent expressly waived its right to contest such violations in subsequent actions”;

- On September 19, 2016, CTP initiated its second civil money penalty action, CRD Docket Number T-16-1891, FDA Docket Number FDA-2016-H-2660, against Respondent for two additional violations of 21 C.F.R. pt. 1140. CTP alleged those violations to have occurred at Respondent's business establishment, 15303 Fenkell Street, Detroit, Michigan 48227, on February 20, 2016;
- The second action concluded when an Initial Decision and Default Judgment was entered by the administrative law judge, “finding Respondent liable for the February 20, 2016 violations”;
- At approximately 12:39 PM on June 16, 2017, at Respondent's business establishment, 15303 Fenkell Street, Detroit, Michigan 48227, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro Gold Pack 100's 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 that Respondent is liable 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. § 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). The regulations prohibit the sale of cigarettes or smokeless tobacco to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1). The regulations also require retailers to verify, by means of photographic identification containing the purchaser's date of birth, that no cigarette or smokeless tobacco purchaser is younger than 18 years of age. 21 C.F.R. § 1140.14(a)(2)(i).

Under 21 U.S.C. § 333(f)(8), a No-Tobacco-Sale Order is permissible for six repeated violations of the regulations found at 21 C.F.R. pt. 1140. The maximum period of time for the first No-Tobacco-Sale Order received by a retailer is 30 calendar days. *See* Pub. L. 111-31, div. A, title I, § 103(q)(1)(A), June 22, 2009, 123 Stat. 1838, 1839; Food & Drug Admin., Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with Order at 3-4, *available at* <https://www.fda.gov/downloads/Tobacco/Products/Labeling/RulesRegulationsGuidance/UCM446547.pdf> (last updated Aug. 2015); Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers at 5-6, *available at*

