

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2017-H-6798)

Complainant,

v.

Mr. Tango Enterprises Inc.  
d/b/a National Tobacco and Shisha,

Respondent.

Docket No. T-18-612

Decision No. TB2966

Date: August 3, 2018

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP or Complainant) filed an Administrative Complaint (complaint) against Mr. Tango Enterprises Inc. d/b/a National Tobacco and Shisha (Respondent). In its complaint, Complainant alleges that Respondent impermissibly sold covered tobacco products to a minor, 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 previously admitted to three violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, Complainant seeks to impose a \$2,236 civil money penalty against Respondent. Respondent filed an answer to the complaint, but has failed to comply with multiple judicial orders and directions during the hearing process. I therefore strike Respondent's answer and issue this decision of default judgment.

## I. Procedural History

On December 13, 2017, Complainant began this matter by serving a complaint on Respondent, seeking a \$2,236 civil money penalty. On January 10, 2018, Respondent's counsel timely filed a notice of appearance and a motion requesting an extension of the deadline to file its answer. On January 12, 2018, I issued an order that granted the extension and provided Respondent with a new deadline to file its answer. On February 12, 2018, Respondent timely filed its Answer and Affirmative Defenses (Answer), and two Exhibits, Exhibits A-B inclusive. In its Answer, Respondent made a counterclaim for malicious prosecution. *See* Answer at 9<sup>1</sup>.

On February 13, 2018, I issued an Acknowledgment and Pre-Hearing Order (APHO) that gave the parties the deadline dates for several filings, including the dates for discovery. Specifically, the APHO 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 March 23, 2018. *See* APHO ¶ 12. As indicated in the APHO, a party who received such a request was required to provide the requested documents no later than 30 days after the request had been made. The APHO also explained that sanctions may be imposed if a party failed to comply with any order, including the APHO. *See id.* ¶ 16.

On March 14, 2018, Complainant's counsel filed a notice of appearance, a Motion to Dismiss Respondent's Counterclaim (motion) and one exhibit, Exhibit 1. The next day, with Respondent's permission, Complainant filed a joint status report indicating that the parties were unable to reach a settlement and intended to proceed to a hearing. On March 20, 2018, a letter issued by my direction, gave Respondent until April 3, 2018,<sup>2</sup> to file a response to Complainant's motion. To date Respondent has not filed a response.

On May 3, 2018, Complainant filed an Unopposed Motion to Extend Deadlines. On that same date, pursuant to 21 C.F.R. § 17.23(a), Complainant also filed a Motion to Compel Discovery (MTC) and three exhibits, A-C inclusive. In that motion, Complainant stated that it served a Request for Production of Documents (RFP) on Respondent on March 23, 2018 and indicated it had not received a response to its request. On May 4, 2018, I issued an order that extended the parties' pre-hearing exchange deadlines. On that same date, a letter was issued by my direction, which provided Respondent with a deadline of May 21, 2018 to file a response to Complainant's MTC. To date Respondent has not filed a response to Complainant's motion.

On May 31, 2018, I issued an order that granted Complainant's motion and ordered Respondent to comply with Complainant's RFP by June 8, 2018. For the second time,

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<sup>1</sup> The Answer pages are not numbered.

<sup>2</sup> A typographical error erroneously gave Respondent until April 3, **3018** instead of April 3, **2018**, to file its Response.

Respondent was warned that a failure to comply with my order “may 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.” The order also extended the parties’ pre-hearing exchange deadlines.

On June 11, 2018, Complainant filed Complainant’s Status Report and Motion to Impose Sanctions (MTIS) advising me that Respondent had not complied with my May 31, 2018 order. Complainant asked me to strike the Respondent’s Answer and issue a default judgment in this case. On that same date, Complainant also filed a motion requesting that I extend the pre-hearing exchange deadlines. In a June 12, 2018 letter issued by my direction, Respondent was given until June 26, 2018 to file a response to Complainant’s MTIS. In an order issued the same day, I also extended the parties’ pre-hearing exchange deadlines. To date Respondent has not filed a response to Complainant’s MTIS.

## **II. Striking Respondent’s Answer**

Pursuant to 21 C.F.R. § 17.35, I am granting Complainant’s MTIS, and striking Respondent’s Answer, including the malicious prosecution counterclaim, for failing to comply with multiple judicial orders and directions. Specifically, Respondent has not complied with: (1) the deadline set forth in the APHO for responding to a discovery request; nor (2) the order granting Complainant’s motion to compel discovery issued on May 31, 2018. Further, I note that Respondent did not avail itself of the opportunity to respond to Complainant’s Motion to Dismiss Respondent’s Counterclaim and Complainant’s MTIS pursuant to the letters issued, by my direction, on March 20, 2018, and June 12, 2018, respectively.

Further, 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 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 February 13, 2018, and May 31, 2018, Respondent has failed to take any action in response to Complainant’s motions, or to otherwise defend its February 12, 2018 Answer. Sanctions, therefore, are appropriate in this case. The issue is whether Complainant’s proposed sanction – striking Respondent’s Answer and issuing a default judgment – is fitting. The harshness of the sanctions I impose upon either party must relate to the nature and severity of the misconduct or failure to comply. *See* 21 C.F.R. § 17.35(b). 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 id.*

## **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 May 1, 2017, CTP initiated a previous civil money penalty action, CRD Docket Number T-17-3690, FDA Docket Number FDA-2017-H-2469, against Respondent for three<sup>3</sup> violations of 21 C.F.R. pt. 1140. CTP alleged those violations to have occurred at Respondent's business establishment, 6905 West 12th Avenue, Hialeah, Florida 33014, on August 29, 2016, and December 11, 2016. Complaint ¶ 11.
- The previous action was closed 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 ¶ 12.
- At approximately 11:55 AM on November 25, 2017, at Respondent's business establishment, 6905 West 12th Avenue, Hialeah, Florida 33014, an FDA-commissioned inspector documented Respondent's staff selling a Black & Mild cigar to a person younger than 18 years of age. Complaint ¶ 9.

These facts establish Respondent National Tobacco and Shisha'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(b)(1), no retailer may sell covered tobacco products to any person younger than 18 years of age.

Under 21 C.F.R. § 17.2, a \$2,236 civil money penalty is permissible for four violations of the regulations found at 21 C.F.R. pt. 1140.

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<sup>3</sup> Two violations were documented on August 29, 2016, and two on December 11, 2016. 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.

**ORDER**

For these reasons, I enter default judgment in the amount of \$2,236 against Respondent Mr. Tango Enterprises Inc. d/b/a National Tobacco and Shisha. 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/

Catherine Ravinski  
Administrative Law Judge