

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2018-H-1413)

Complainant

v.

Stogie's, Inc.
d/b/a Stogie's,

Respondent.

Docket No. T-18-1863

Decision No. TB3211

Date: November 2, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

I hereby impose a civil money penalty (CMP) in the amount of \$5,591, against Respondent, Stogie's, Inc. d/b/a Stogie's (Respondent), for five violations of federal tobacco regulations over a period of 36months.

I. Background

The Center for Tobacco Products ("Complainant" or "CTP") seeks to impose a civil money penalty (CMP) in the amount of \$5,591, against Respondent, located at 17 Washington Avenue, Huntington, West Virginia 25701, for five violations of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140, within a 36-month period. The complaint alleges that Respondent impermissibly sold cigarettes and smokeless tobacco to minors, failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, and used a self-service display in a non-exempt facility, thereby violating the Act, and its implementing regulations at 21 C.F.R. pt. 1140.

As provided in 21 C.F.R. §§ 17.5 and 17.7, on April 9, 2018, Complainant served the complaint on Respondent Stogie's by United Parcel Service. On May 11, 2018, the Civil Remedies Division received Respondent's answer, which was forwarded by the Food and Drug Administration (FDA). Respondent requested that the complaint be dismissed for failure to state a claim upon which relief may be granted. On May 16, 2018, I issued an Acknowledgment and Pre-hearing Order (APHO) acknowledging receipt of Respondent's answer and setting forth case procedures and deadlines. The APHO 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 June 15, 2018, 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 July 13, 2018, Complainant filed a Motion to Compel Discovery stating that it served its Request for Production of Documents on Respondent on May 25, 2018. It also stated that it had not received a response from Respondent regarding its Request for Production of Documents and requested that I issue an order requiring Respondent to comply with its Request for Production of Documents. In a July 17, 2018 letter issued by my direction, Respondent was given until August 2, 2018, to file a response to Complainant's Motion to Compel Discovery.

Respondent failed to file a response to Complainant's Motion to Compel Discovery. Accordingly, in an order dated August 15, 2018, I granted Complainant's Motion to Compel Discovery and ordered Respondent to comply with Complainant's Request for Production of Documents by August 30, 2018.¹ Respondent was warned that failure 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 and imposing a penalty.

On September 18, 2018, Complainant filed a Motion to Impose Sanctions indicating that Respondent had not complied with my August 15, 2018 order. On September 18, 2018, CTP also filed a Motion to Extend Deadlines. In a September 24, 2018 letter issued by my direction, Respondent was given until October 9, 2018, to file a response to Complainant's Motion to Impose Sanctions. Also, by Order dated September 24, 2018, I

¹ On September 10, 2018, Respondent filed a Motion to Withdraw. In the motion, Respondent requested that the order granting CTP's Motion to Compel Discovery be withdrawn, and it be given an opportunity to respond to CTP's motion. Respondent claimed that it never received a copy of the letter issued at my direction on July 17, 2018, allowing for an earlier opportunity to respond to CTP's Motion to Compel Discovery. In support of this assertion, Respondent submitted a document not related to this case, which he states he received and ignored. On September 12, 2018, I denied Respondent's Motion to Withdraw.

granted CTP's Motion to Extend Deadlines. To date, Respondent has not responded to Complainant's Motion to Impose Sanctions or the September 24, 2018 letter.

Therefore, pursuant to 21 C.F.R. § 17.35, I am granting Complainant's Motion to Impose Sanctions, and striking Respondent's answer for failing to comply with multiple judicial directives. Specifically, Respondent failed to comply with the deadline set forth in the APHO for responding to a discovery request, and the order granting Complainant's motion to compel discovery issued on August 15, 2018. Respondent also did not respond to the letter sent by my direction on September 24, 2018. 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:

- At approximately 5:21 PM on May 28, 2015, at Respondent's business establishment, 17 Washington Avenue, Huntington, West Virginia 25701, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro 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;
- In a warning letter dated July 2, 2015, CTP informed Respondent of the inspector's May 28, 2015 documented violations, and that such actions violate federal law. The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;
- During a subsequent inspection, at approximately 6:57 PM on July 11, 2017, at Respondent's business establishment, 17 Washington Avenue, Huntington, West Virginia 25701, an FDA-commissioned inspector documented Respondent's staff selling a package of Sonoma 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;
- In a warning letter dated August 31, 2017, CTP informed Respondent of the inspector's July 11, 2017 documented violations, and that such actions violate federal law. The letter further warned that Respondent's failure to correct its violations could result in a civil money penalty or other regulatory action;

- On March 19 and 28, 2018, a two-part inspection was conducted at Respondent's business establishment, 17 Washington Avenue, Huntington, West Virginia 25701. Specifically on March 19, 2018, an FDA-commissioned inspector documented Respondent's staff selling a package of Skoal Long Cut X-tra Wintergreen smokeless tobacco into 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. Further, on March 28, 2018, an inspector observed customer-accessible shelves containing multiple varieties of smokeless tobacco, including but not limited to Red Man smokeless tobacco, Beech-Nut smokeless tobacco, and Trophy smokeless tobacco, located on the main sales floor of the establishment.

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). Under 21 C.F.R. § 1140.14(a)(1)², no retailer may sell cigarettes or smokeless tobacco 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 cigarettes or smokeless tobacco purchasers are younger than 18 years of age. Under 21 C.F.R. § 1140.16(c), retailers may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer and refrain from using a self-service display in a non-exempt facility.

A \$5,591 civil money penalty is permissible under 21 C.F.R. § 17.2.

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

