

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2017-R-6670)

Complainant

v.

George's Grocery USA, LLC
d/b/a George's USA,

Respondent.

Docket No. T-18-522

Decision No. TB2777

Date: June 5, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

I hereby impose a No-Tobacco-Sale Order (NTSO) against Respondent, George's Grocery USA, LLC d/b/a George's USA (Respondent), for a consecutive six-month period, for seven repeated violations of federal tobacco regulations over a period of 36 months.

I. Background

The Center for Tobacco Products ("Complainant" or "CTP") seeks to impose an NTSO, for a consecutive six-month period, against Respondent, located at 2509 Main Street, Bridgeport, Connecticut 06606, for seven repeated 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 or 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 sold individual cigarettes, thereby violating the Act, and its implementing regulations at 21 C.F.R. pt. 1140.

The complaint likewise alleges that Complainant previously initiated an NTSO action against Respondent, in which, Respondent admitted to eight repeated¹ violations of the Act within a 36-month period, and was subject to an NTSO for an agreed upon time period. Therefore, Complainant now seeks a second NTSO against Respondent for a consecutive six-month period.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on December 4, 2017, Complainant served the complaint on Respondent George's USA by United Parcel Service. On January 4, 2018, Respondent filed an answer denying the allegations. On January 11, 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 February 20, 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 March 23, 2018, Complainant filed a Motion to Compel Discovery stating that it served its Request for Production of Documents on Respondent on February 15, 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 March 26, 2018 letter issued by my direction, Respondent was given until April 10, 2018 to file a response to Complainant's Motion to Compel Discovery.

On April 10, 2018, Respondent filed a response but did not provide an explanation for failing to provide Complainant with the requested documents, and did not address Complainant's Motion to Compel Discovery. Accordingly, in an order dated April 10, 2018, I granted Complainant's Motion to Compel Discovery and ordered Respondent to comply with Complainant's Request for Production of Documents by April 25, 2018. Respondent was warned that a 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.²

On May 1, 2018, Complainant filed a Motion to Impose Sanctions indicating that Respondent had not complied with my April 10, 2018 order. In a May 2, 2018 letter issued by my direction, Respondent was given until May 14, 2018 to file a response to

¹ Complainant is not counting two of the prior repeated violations in the current NTSO action because they fall outside the specified 36-month period.

² The April 10, 2018 Order inadvertently referenced imposition of "a civil money penalty." It should have correctly referenced imposition of "a no-sale-tobacco order."

Complainant's Motion to Impose Sanctions. To date, Respondent has not responded to Complainant's Motion to Impose Sanctions or the May 2, 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 three separate judicial directions. Specifically, Respondent failed to comply with the deadline set forth in the APHO for responding to a discovery request, the order granting Complainant's motion to compel discovery issued on April 10, 2018, and the letter sent by my direction on May 2, 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:

- On May 12, 2014, Complainant initiated the first civil money penalty (CMP) action, CRD Docket Number C-14-1057, FDA Docket Number FDA-2014-H-0579, against Respondent for four³ violations of 21 C.F.R. pt. 1140 within a 24-month period. Complainant alleged those violations⁴ to have occurred at Respondent's business establishment, 2509 Main Street, Bridgeport, Connecticut 06606, on June 11, 2013, October 7, 2013, and October 9, 2013;
- The first CMP action concluded when Respondent admitted the allegations contained in the Complaint issued by Complainant, and agreed to pay a monetary penalty in settlement of that claim. Further, "Respondent expressly waived its right to contest such violations in subsequent actions";
- On December 9, 2014, Complainant initiated the second CMP action, CRD Docket Number C-15-605, FDA Docket Number FDA-2014-H-2131, against Respondent for seven violations of 21 C.F.R. pt. 1140 within a 48-month period. Complainant alleged those violations to have occurred at Respondent's business establishment, 2509 Main Street, Bridgeport, Connecticut 06606, on June 11, 2013, October 7, 2013, October 9, 2013, and August 19, 2014;

³ Two violations were documented on June 11, 2013, two on October 7, 2017, and one on October 9, 2013. 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.

⁴ Respondent's original violations occurred on June 11, 2013 (selling tobacco products to a minor and failing to verify identification) and on October 9, 2013 (selling individual cigarettes).

- The second CMP action concluded when an Initial Decision and Default Judgment was entered by an Administrative Law Judge finding Respondent liable for the violations;
- On September 14, 2015, Complainant initiated the third CMP action, CRD Docket Number C-15-4064, FDA Docket Number FDA-2015-H-3290, against Respondent for eight violations of 21 C.F.R. pt. 1140 within a 48-month period. CTP alleged those violations to have occurred at Respondent's business establishment, 2509 Main Street, Bridgeport, Connecticut 06606, on June 11, 2013, October 7, 2013, October 9, 2013, August 19, 2014, and May 6, 2015;
- The third CMP action concluded when an Initial Decision and Default Judgment was entered by an Administrative Law Judge finding Respondent liable for the violations;
- Complainant initiated the first NTSO action, CRD Docket Number T-17-2950, FDA Docket Number FDA-2017-R-1621, against Respondent for eight repeated violations⁵ of 21 C.F.R. pt. 1140 within a 36-month period. Complainant alleged those violations to have occurred at Respondent's business establishment, 2509 Main Street, Bridgeport, Connecticut 06606, on June 11, 2013, October 7, 2013, October 9, 2013, August 19, 2014, May 6, 2015, and August 16, 2016;
- The first NTSO action concluded when Respondent admitted all of the allegations in the complaint, agreed to an NTSO, and an Administrative Law Judge issued an NTSO for the agreed-upon time period. Further, "Respondent expressly waived its right to contest such violations in subsequent actions";
- On August 1, 2017, at Respondent's business establishment, 2509 Main Street, Bridgeport, Connecticut 06606, an FDA-commissioned inspector observed open packages of Newport cigarettes and Marlboro cigarettes. The owner confirmed that individual cigarettes were available for individual purchase.

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,

⁵ CTP did not count repeated violations from Respondent's first CMP in the current NTSO case because they fall outside the 36-month period.

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)⁶, 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. § 1140.14(a)(4), no retailer may break or otherwise open any cigarette package to sell or distribute individual cigarettes.

Under 21 U.S.C. § 333(f)(8), a No-Tobacco-Sale Order is permissible for seven repeated violations of the regulations found at 21 C.F.R. pt. 1140. The maximum period of time for the second No-Tobacco-Sale Order received by a retailer is six months. *See* Pub. L. 111-31, div. A, title I, § 103(q)(1)(A), June 22, 2009, 123 Stat. 1838, 1839; Food & Drug Admin., Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers at 5-6, *available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM252955.pdf> (last updated Dec. 15, 2016); *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/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf> (last updated August 2015).

Order

For these reasons, I enter default judgment against Respondent George's Grocery USA, LLC d/b/a George's USA, in the form of a No-Tobacco-Sale Order, for a consecutive six-month period. During this period of time, Respondent shall stop selling cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and covered tobacco products regulated under the Federal Food, Drug, and Cosmetic Act. 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/
Catherine Ravinski
Administrative Law Judge

⁶ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.