

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Al Zama LLC
d/b/a Smoker's Discount World,

Respondent.

Docket No. T-16-1181
FDA Docket No. FDA-2016-R-1897

Decision No. TB937

Date: March 20, 2017

INITIAL DECISION

The Center for Tobacco Products (“CTP”) seeks to impose a No-Tobacco-Sale Order (“NTSO”) for a period of thirty (30) calendar days against Respondent, Al Zama LLC d/b/a Smoker’s Discount World located at 351 Boston Post Road, Suite 9, North Windham, Connecticut 06256 for five repeated violations of 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. Specifically, CTP alleges Respondent violated the Act by impermissibly selling tobacco products to minors and unlawfully utilizing a self-service display of cigarette tobacco in a non-exempt facility.

I. Procedural History

CTP began this matter on July 7, 2016, by serving an administrative complaint (“Complaint”) on Respondent, at 351 Boston Post Road, Suite 9, North Windham, Connecticut 06256 as provided for in 21 C.F.R. §§ 17.5 and 17.7. Respondent timely answered the Complaint on July 19, 2016. In its answer (“Respondent’s Answer”), Respondent denied the allegations. On August 25, 2016, I issued an Acknowledgement and Prehearing Order (“APHO”) that set deadlines for the parties to file their pre-hearing exchanges. On October 27, 2016, the parties filed a Joint Status Report to inform me that their attempt to settle the matter was unsuccessful. CTP filed its pre-hearing exchange on November 18, 2016. CTP’s exchange consists of a brief and twenty proposed exhibits that are identified as CTP Ex. 1- CTP Ex. 20. Respondent failed to file its pre-hearing exchange by the December 9, 2016 deadline.

On December 22, 2016, I ordered the parties to submit a joint status report by January 3, 2017, informing me as to whether they wished to proceed to a hearing. On January 3, 2017, the parties filed a Joint Status Report to inform me that Respondent did not intend to file a pre-hearing exchange and that the parties wished to proceed to a hearing.

On January 24, 2017, I scheduled this matter for a pre-hearing conference. On February 7, 2017, CTP filed a Motion to Exclude Evidence Not Exchanged in accordance with the Acknowledgement and Pre-Hearing Order issued on August 25, 2016. The prehearing conference was held as scheduled on February 13, 2017 at 10:00 AM Eastern Time. Representatives for both parties appeared on the conference call. During the conference, the Respondent’s attorney represented that Respondent was not opposed to CTP’s motion and did not intend to file a pre-hearing exchange. The parties agreed that an administrative hearing was not required in this case and consented to a decision based on the administrative record. Accordingly, I am issuing a decision on the record in this case. I receive CTP’s Informal Brief and CTP Ex. 1- CTP Ex. 20 into the record. I also receive Respondent’s Answer into the record.

II. Analysis

A. Issues

The issues are whether:

1. The Respondent committed five repeated violations of FDA’s tobacco regulations over a 36-month period;

2. Whether an NTSO of 30 consecutive days' duration is reasonable.

B. Findings of Fact and Conclusions of Law

There is no dispute in this case that Respondent does business as Smoker's Discount World, located at 351 Boston Post Road, Suite 9, North Windham, Connecticut 06256. Respondent's business includes the sale of tobacco products to the general public.

a. Violations

CTP determined to impose a NTSO against Respondent pursuant to the authority conferred by the Federal Food, Drug, and Cosmetic Act (Act) and implementing regulations at Part 21 of the Code of Federal Regulations (C.F.R.). The Act prohibits the misbranding of tobacco products while they are held for sale after shipment in interstate commerce. 21 U.S.C. § 331(k). The sale of tobacco products to an individual who is under the age of 18 and the use of self-service displays to sell tobacco products, except in a facility in which no person younger than 18 years of age is permitted to enter at any time, are violations of implementing regulations. 21 C.F.R. § 1140.14(a)(1)¹ and §1140.16(c).

The alleged violations that are at issue here are not the first instance in which Respondent was charged with violating the laws and regulations concerning the sale of tobacco products. CTP alleges that the original violation in this case occurred on June 25, 2013, when the Respondent had displays or devices on its premises that provided customers direct access to tobacco products in violation of 21 C.F.R. § 1140.16(c). Complaint at 5. CTP alleges that on November 19, 2013, the Respondent unlawfully sold tobacco products to minors in violation of 21 C.F.R. § 1140.14(a) and continued to have displays or devices on its premises that provided customers direct access to tobacco products in violation of 21 C.F.R. § 1140.16(c). *Id.* The Respondent denies these allegations. Respondent's Answer. On July 11, 2014, an Initial Decision and Default Judgment in the amount of \$500 issued against the Respondent. CTP Ex. 2. Thus, these previous allegations of noncompliance are administratively final and are not subject to challenge by Respondent.

CTP also alleges that the Respondent continued to violate the Act on September 3, 2014, when the Respondent unlawfully sold tobacco products to minors in

¹ On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

violation of 21 C.F.R. § 1140.14(a) and continued to have displays or devices on its premises that provided customers direct access to tobacco products in violation of 21 C.F.R. § 1140.16(c). *Id.* The Respondent denies these allegations.

Respondent's Answer. However, on June 3, 2015, the Respondent signed an Acknowledgement Form acknowledging that the September 3, 2014 violations occurred and waiving its right to contest these violations in the future. CTP Ex. 4. Thus, these previous allegations of noncompliance are administratively final and are not subject to challenge by Respondent.

What remains at issue are additional allegations of noncompliance made by CTP. CTP alleges that the Respondent committed the most recent violation on August 19, 2015. CTP alleges that on that date, at approximately 10:29 AM, a person under the age of 18 year of age was able to purchase a package of Rave cigarette tobacco contained in a self-service display at Respondent's business in violation of 21 C.F.R. § 1140.16(a) and § 1140.16(c). Complaint at 4.

To support these allegations, CTP submitted evidence including the declaration of Inspector Bryan Champagne, the inspector's narrative report of the alleged incident, and a photograph of the Rave tobacco product allegedly purchased on August 19, 2015. CTP Exs. 6, 9, and 11. In his declaration, Inspector Champagne states that he accompanied a minor to Respondent's facility on August 19, 2015. CTP Ex. 6. While there, he personally observed "several aisles containing self-service displays on the main sales floor." *Id.* Inspector Champagne states that he "had a clear unobstructed view of the minor and the sales counter" and observed the minor taking "a package of Rave cigarette tobacco from the self-service display directly to the sales counter" where the minor "purchased the package from an employee at the establishment." *Id.* Inspector Champagne stated that he processed the tobacco product in accordance with procedure, placed the product in a bag, and took a photograph of the tobacco product. *Id.*; CTP Ex. 11.

On its face this evidence is more than sufficient to prove that Respondent violated the law on August 19, 2015. Respondent offered nothing by way of rebuttal. As a result, I find that the facts as outlined above establish Respondent Al Zama LLC d/b/a Smoker's Discount World's liability under the Act.

b. No Tobacco Sale Order

CTP proposes to impose a NTSO for a period of thirty (30) calendar days against Respondent based on the fact that Respondent committed seven violations (two original and five repeat violations) of law in the period commencing June 25, 2013, and running through August 19, 2015. The proposed penalty is the maximum allowed by law. 21 C.F.R. § 17.2.

Remedies may consist of civil money penalties and NTSOs. NTSOs are authorized at 21 U.S.C. § 333(f)(8). The section allows for the imposition of an NTSO against a person who has committed “repeated violations” of restrictions on the sale of tobacco products. The term “repeated violations” is defined to mean “at least 5 violations of particular requirements over a 36-month period at a particular retail outlet” 21 U.S.C. § 333.

The Act establishes factors that must be considered in deciding on the length of an NTSO, but it does not specify NTSO time periods:

In determining the . . . period to be covered by a no-tobacco-sale order, the Secretary shall take into account the nature, circumstances, extent, and gravity of the . . . violations and, with respect to the violator, . . . , effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require

21 U.S.C. § 333(f)(5)(B).

To support the request for an NTSO for a period of thirty (30) calendar days in this matter, CTP refers to policy guidelines that establish maximum NTSO durations. Informal Brief of Complainant at 10-11. For a first NTSO, CTP recommends that the maximum duration be 30 calendar days. *See* CTP, U.S. FDA., U.S. Dep’t of Health & Human Servs., Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with an Order (August 2015)². CTP’s policy is to, in general, seek the maximum duration for an NTSO established by the guidelines. It explains its rationale for establishing these recommended maximum NTSO durations as follows:

First, if there are grounds for imposing an NTSO, the retailer has already engaged in repeated violations of the law and regulations restricting the sale and distribution of tobacco products, and therefore has a prior history of violations. Second, the restrictions codified at Part 1140 [of the regulations] are intended to protect the public health, especially children and adolescents, and FDA therefore considers repeated violations of these restrictions to be very serious. Nearly 9 out of 10 adult smokers smoked their first cigarette by age 18 (87 percent). If the current trajectory of smoking rates continues, 5.6 million children alive today will die prematurely as a result of smoking. Third, FDA believes that imposing

² Determination of the Period Covered by a No-Tobacco Sale Order and Compliance With an Order: Guidance for Tobacco Retailers is available at: <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf>.

NTSOs where the periods of time gradually increase, starting with a maximum of 30 days and then a maximum of 6 months before issuing an order permanently prohibiting the sale of tobacco products, strikes an appropriate balance between considerations related to the number, extent, and gravity of the violations on one hand, and the retailer's ability to do business on the other hand. The increasing periods of time for which FDA intends to impose NTOS are also consistent with the scheme of increasing [civil money penalties]

Id.

I find CTP's guidelines to be reasonable when read in the context of the Act's language and purpose. The guidelines are not regulations and therefore not binding as a matter of law. However, I find them persuasive and accord CTP deference in view of its expertise in administering the Act and implementing regulations.

While I am mindful that an NTOS may have a profound effect on a retailer's business and even on that retailer's ability to stay in business, the Respondent has not presented any arguments or evidence of the impact an NTOS would have on its business. Additionally, the Respondent's continued failure to abide by the laws and regulations governing the sale of tobacco products indicate that the imposition of an NTOS may be the only way to deter Respondent from continuing to engage in unlawful sales of tobacco products.

The facts of this case establish that Respondent is a repeated violator of law. Between June 25, 2013 and August 19, 2015, Respondent utilized displays or devices on its premises that provided customers direct access to tobacco products on four occasions. On three of these occasions Respondent also allowed minors to purchase tobacco products from these self-service displays. Thus, Respondent committed a total of five repeated violations of regulations governing tobacco sales in a period of less than 36 months. CTP imposed civil money penalties against Respondent twice, but those civil money penalties did not deter Respondent from continuing to sell tobacco products to minor purchasers.

Order

For these reasons, I enter a No Sale Tobacco Order for a period of thirty (30) calendar days against Respondent Al Zama LLC d/b/a Smoker's Discount World. 21 C.F.R. § 17.45.

/s/

Margaret G. Brakebusch
Administrative Law Judge