

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division**

Center for Tobacco Products,
(FDA No. FDA-2017-H-4684)

Complainant

v.

Seja, Inc.
d/b/a 7-Eleven Store 32605A,

Respondent.

Docket No. T-17-5673

Decision No. TB2743

Date: May 22, 2018

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty (CMP) against Respondent, Seja, Inc. d/b/a 7-Eleven Store 32605A, located at 8674 Maitland Summit Boulevard, Orlando, Florida 32810, for two 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, within a 12-month period. Specifically, CTP alleges that Respondent violated the Act by impermissibly selling cigarettes to minors on two separate occasions. For the reasons discussed below, I find in favor of CTP and impose a \$279 CMP against Respondent.

I. Procedural History

CTP began this matter by serving an administrative complaint, seeking a \$279 CMP, on Respondent at 8674 Maitland Summit Boulevard, Orlando, Florida 32810, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. In its answer, Respondent denied the allegations and requested a hearing.

On September 22, 2017, I issued an Acknowledgment and Pre-Hearing Order (APHO) setting forth case procedures and exchange deadlines. On February 14, 2018, CTP filed its pre-hearing exchange, which included an Informal Brief of Complainant, and 21 exhibits (CTP Exs. 1-21). The 21 exhibits included the direct testimony, in the form of declarations, for three witnesses – Senior Regulatory Counsel Laurie Sternberg, Inspector Jose Ceballos, and Inspector Rolando Banasco. Respondent did not file a pre-hearing exchange.

On March 27, 2018, I scheduled this matter for a prehearing conference. The prehearing conference was scheduled for April 26, 2018 at 11:00 AM (Eastern). Both parties were notified of the time and date. The prehearing conference was held as scheduled on April 26, 2018. Representatives for CTP appeared on the call, however, Respondent failed to appear.

On April 26, 2018, I issued an Order requiring Respondent to show cause for its failure to appear at the prehearing conference. Respondent was warned that failure to respond to the Order could result in sanctions, including the issuance of a decision finding Respondent liable for the violations in the complaint and imposing a civil money penalty. Respondent was given until May 7, 2018 to show cause. To date, Respondent has not responded to the April 26, 2018 Order.

Pursuant to 21 C.F.R. § 17.35(e), I am authorized to impose sanctions and issue an initial decision imposing penalties and assessments if a party fails to defend an action. Any sanction I impose must reasonably relate to the severity and nature of the failure or misconduct. 21 C.F.R. § 17.35(b). Here, Respondent did not file a pre-hearing exchange as ordered by my September 22, 2017 APHO, it failed to appear at the prehearing conference, and it did not respond to my April 26, 2018 Order. Based on Respondent's repeated failure to defend this action, I find sanctions are appropriate. Accordingly, I find Respondent is liable for the violations alleged in the complaint and impose the \$279 CMP sought by CTP.

II. Decision

CTP determined to impose a civil money penalty against Respondent pursuant to the authority conferred by the Act and implementing regulations at Part 21 of the Code of Federal Regulations. 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). FDA and its agency, CTP, may seek civil money penalties from any person who violates the Act's requirements as they relate to the sale of tobacco products. 21 U.S.C. § 331(f)(9). The sale of cigarettes to an individual who is under the age of 18 is a violation of implementing regulations. 21 C.F.R. §§ 1140.14(a)(1).

In its complaint, CTP alleges that Respondent committed two violations of the Act and its implementing regulations within a 12-month period. Specifically, CTP alleges:

- At approximately 5:27 p.m. on September 29, 2016, at Respondent's business establishment, 8674 Maitland Summit Boulevard, Orlando, Florida 32810, an FDA-commissioned inspector documented Respondent's staff selling a package of Marlboro Gold Pack cigarettes to a person younger than 18 years of age;
- In a warning letter dated October 20, 2016, CTP informed Respondent of the inspector's September 29, 2016 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;
- At approximately 11:36 p.m. on June 9, 2017, at Respondent's business establishment, 8674 Maitland Summit Boulevard, Orlando, Florida 32810, an FDA-commissioned inspector documented Respondent's staff selling a package of Newport Box cigarettes to a person younger than 18 years of age.

Based on Respondent's failure to defend its action, I find these facts are true and establish Respondent's liability under the Act. Under 21 C.F.R. § 17.2, a \$279 civil money penalty is permissible for two violations of the regulations found at 21 C.F.R. pt. 1140. Respondent has not provided any mitigating circumstances for me to consider, therefore, I find \$279 is an appropriate penalty.

III. Conclusion

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$279 against Respondent, Seja, Inc. d/b/a 7-Eleven Store 32605A, for two 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, within a twelve-month period.

_____/s/
Margaret G. Brakebusch
Administrative Law Judge