

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Cedar Junction LLC,

Respondent.

Docket No. C-13-374
FDA Docket No. FDA-2013-H-0130

Decision No. CR2731

Date: March 25, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Cedar Junction LLC, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. Respondent did not timely answer the Complaint, nor did Respondent request an extension of time within which to file an answer. Therefore, I enter a default judgment against Respondent and order that Respondent pay a civil money penalty in the amount of \$250.

CTP began this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent impermissibly sold tobacco products to a minor and failed to appropriately verify the age of a person purchasing tobacco products, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$250.

On February 8, 2013, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. In the Complaint and accompanying cover letter, CTP explained that, within 30 days, Respondent should pay the penalty, file an answer, or request an extension of time within which to file an answer. CTP warned Respondent that, if it failed to take one of these actions within 30 days, the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty. Respondent did not take one of the required actions within the time provided by regulation.

I am required to issue a default judgment if the Complaint is sufficient to justify a penalty, and the Respondent fails to answer timely or to request an extension. 21 C.F.R. § 17.11(a). For that reason, I must decide whether a default judgment is appropriate here, and I conclude that it is merited based on the allegations of the Complaint and Respondent's failure to answer them.

For purposes of this decision, I assume the facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Cedar Junction, a business that sells tobacco products and is located at 662 Highway Y, Eldon, Missouri 65206. This establishment also serves as a Sinclair gas station.
- On April 27, 2012, an FDA-commissioned inspector observed violations while inspecting Respondent's establishment. These violations included Respondent's sale of tobacco products to a person younger than 18 years of age and Respondent's failure to verify, by means of photographic identification containing the bearer's date of birth, the age of a person purchasing tobacco products.
- On June 14, 2012, CTP issued a Warning Letter to Cedar Junction/Sinclair regarding the inspector's observations from April 27, 2012. The letter stated that Respondent's sale of tobacco products to a minor violated regulations found at 21 C.F.R. § 1140.14(a), and Respondent's failure to verify the age of a tobacco purchaser, by means of photographic identification containing the bearer's date of birth, violated regulations found at 21 C.F.R. § 1140.14(b)(1). The letter also advised Respondent that failure to correct the violations could result in the imposition of a civil money penalty or other regulatory action by FDA.

- On December 10, 2012, FDA commissioned inspectors documented an additional violation during a subsequent inspection of the establishment. At approximately 12:48 P.M. CT, a person under the age of 18 was able to purchase a package of “Grizzly Long Cut Premium Wintergreen” smokeless tobacco.

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). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), a retailer must verify, by means of photo identification containing the bearer’s date of birth, that no person purchasing the tobacco product is younger than 18 years of age.

Here, Respondent sold cigarettes or smokeless tobacco to a minor in violation of the foregoing regulations on two separate occasions, April 27, 2012, and December 10, 2012. In addition, Respondent did not appropriately check the photographic identification of a tobacco purchaser prior to the April 27, 2012, transaction. CTP alleges that the April 27, 2012 violations occurred at Cedar Junction/Sinclair. Although the Complaint does not state that Cedar Junction/Sinclair is also known as or is a prior name of Cedar Junction, I infer that the two names refer to the same retail outlet. Therefore, Respondent’s actions and omissions on two separate occasions at the same retail outlet constitute violations of law for which a civil money penalty is merited. Accordingly, I find that a civil money penalty of \$250 is permissible under 21 C.F.R. § 17.2.

/s/
Steven T. Kessel
Administrative Law Judge