

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Boram Enterprises Inc.,
d/b/a Village Market & Deli

Respondent.

Docket No. C-13-364
FDA Docket No. FDA-2013-H-0123

Decision No. CR2732

Date: March 26, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Boram Enterprises Inc. d/b/a Village Market & Deli, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. 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 \$500.

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 \$500.

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 Village Market & Deli, a business that sells tobacco products and is located at 811 Russell Avenue, Suite A, Gaithersburg, Maryland 20879.
- On November 8, 2011, an FDA-commissioned inspector observed violations while inspecting Respondent's establishment. These violations included Respondent's sale of cigarettes or smokeless tobacco 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 the person purchasing cigarettes or smokeless tobacco.
- On January 5, 2012, CTP issued a Warning Letter to Village Market & Deli regarding the inspector's observations from November 8, 2011. The letter stated that Respondent's sale of cigarettes or smokeless tobacco to a minor violated regulations found at 21 C.F.R. § 1140.14(a), and Respondent's failure to verify, by means of photographic identification containing the bearer's date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age 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 September 11, 2012, FDA commissioned inspectors documented additional violations during a subsequent inspection of the establishment. At approximately 2:23 P.M., a person under the age of 18 was able to purchase a package of “Newport Box” cigarettes. Additionally, the minor’s identification was not verified, by means of photographic identification containing the bearer’s date of birth, before this sale.

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, November 8, 2011, and September 11, 2012. In addition, Respondent did not appropriately check the photographic identification of the tobacco purchasers prior to these transactions. 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 \$500 is permissible under 21 C.F.R. § 17.2.

/s/
Steven T. Kessel
Administrative Law Judge