Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Han Holding Inc. d/b/a Super H Convenience Store,

Respondent.

Docket No. C-13-321 FDA Docket No. FDA-2013-H-0090

Decision No. CR2727

Date: March 21, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Han Holding Inc. d/b/a Super H Convenience Store, 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 5, 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 Super H Convenience Store, a business that sells tobacco products and is located at 11901 Business Park Drive, Waldorf, Maryland 20601.
- On June 18, 2012, 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 a person purchasing tobacco products.
- On August 16, 2012, CTP issued a Warning Letter to Super H Convenience Store regarding the inspector's observations from June 18, 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 November 29, 2012, FDA commissioned inspectors documented additional violations during a subsequent inspection of the establishment. At approximately 2:07 P.M. ET, 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, June 18, 2012, and November 29, 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