

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Petitioner,

v.

Shailesh Tilvawala d/b/a Sam's Newsstand,

Respondent.

CRD Docket No. C-12-992

FDA Docket No. FDA-2012-H-0741

Decision No. CR2596

Date: August 21, 2012

INITIAL DECISION AND DEFAULT JUDGMENT

I enter a default judgment against Respondent, Shailesh Tilvawala d/b/a Sam's Newsstand. The Center for Tobacco Products (CTP) filed an administrative complaint against Respondent that alleges facts and legal authority that are sufficient to justify the imposition of a civil money penalty of \$250. Respondent did not timely answer the complaint nor did he request an extension of time within which to file an answer.

CTP began this case by serving a complaint on Respondent and by 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 verify the age of a person purchasing tobacco products, violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$250.

On July 18, 2012, CTP served the complaint on Respondent by United Parcel Service, as is provided for by 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 in which to file answer. CTP warned Respondent that, if it failed to take one of these actions within 30 day, the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering it to pay the full amount of the proposed penalty. Respondent did not file an answer 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 decide whether a default judgment is appropriate here, and I conclude that it is merited based on the allegations of the administrative complaint and Respondent's failure to answer them.

For purposes of this decision I assume that the following facts alleged in the complaint are true. Specifically:

- Respondent owns an establishment that sells tobacco products and which does business as Sam's Newsstand. The business is located at the southwest corner of the intersection of 15th Street and John F. Kennedy Boulevard, Philadelphia, Pennsylvania, 19102.
- On June 13, 2011, an FDA-commissioned inspector made observations at Respondent's place of business that included: sale of cigarettes or smokeless tobacco to a minor under the age of 18; and failure by him to identify by means of photographic identification, containing the bearer's date of birth, that no person purchasing cigarettes or smokeless tobacco was younger than 18 years of age.
- On September 15, 2011, CTP issued a Warning Letter to Respondent that recited the June 13, 2011 observations. The letter informed Respondent that the observed facts constituted violations of regulations at 21 CFR §§ 1140.14(a) and (b)(1) that prohibited sales of tobacco products to individuals under the age of 18 and that required verification of age of purchasers of tobacco products. It advised him that failure to correct the violations could result in the imposition of a civil money penalty or other regulatory action by FDA.
- The Warning Letter was delivered to Respondent. Respondent replied to the letter by telephone on September 23, 2011. In that call he promised to check the photographic identification of anyone under the age of 27 years.
- On March 8, 2012, at about 2:32 p.m., an inspector observed a minor under the age of 18 buy a package of Newport Box Cigarettes at Respondent's place of business.

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 violations of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R § 1140(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 tobacco products to individuals younger than age 18 on two occasions, on June 13, 2011 and on March 8, 2012. On the first occasion Respondent failed to verify the age of the purchaser. These actions and omissions by Respondent constitute a violation of law for which a civil money penalty is merited. Therefore, 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