

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Jean Gervais d/b/a Papi's Mini Market,

Respondent.

Docket No. C-12-973
FDA Docket No. FDA-2012-H-0718

Decision No. CR2605

Date: August 31, 2012

INITIAL DECISION AND DEFAULT JUDGMENT

I enter a default judgment against Respondent, Jean Gervais d/b/a Papi's Mini Market. 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 \$500. 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 \$500.

On June 29, 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 days, 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 Papi's Mini Market. The business is located at 4201 Germantown Avenue, Philadelphia, PA, 19140.
- On June 30, 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 22, 2011, CTP issued a Warning Letter to Respondent that recited the June 30, 2011, observations. The letter informed Respondent that the observed facts constituted violations of regulations at 21 C.F.R. §§ 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 did not reply to it.
- On February 23, 2012, at about 2:30 p.m., an inspector observed a minor under the age of 18 buy a package of Newport Non-Menthol Box Cigarettes at Respondent's place of business.
- On February 29, 2012, an inspector observed Respondent or its employee sell individual (unpacked) cigarettes.

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(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. Under 21 C.F.R. § 1140.14(d), a retailer may not sell individual cigarettes.

Here, Respondent sold tobacco products to individuals younger than age 18 on two occasions, on June 30, 2011, and February 23, 2012. On June 30, 2011, Respondent failed to verify the age of the purchaser. On February 29, 2012, Respondent sold unpackaged cigarettes. 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 \$500 is permissible under 21 C.F.R. § 17.2.

/s/
Steven T. Kessel
Administrative Law Judge