Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Amin BaBakr, d/b/a Happy Mart

Respondent.

Docket No. C-13-241 FDA Docket No. FDA-2013-H-0015

Decision No. CR2709

Date: February 19, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products ("CTP") filed an Administrative Complaint ("Complaint") against Respondent, Amin BaBakr d/b/a Happy Mart, 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 Respondent to 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, 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 January 7, 2013, CTP served the Complaint on Respondent by United Parcel Service ("UPS"), 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 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 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 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 Happy Mart, a business that sells tobacco products and is located at 1200 North Division Street, Forrest City, Arkansas 72335.
- On December 4, 2011, an FDA-commissioned inspector made observations at Respondent's place of business that included a violation for selling cigarettes or smokeless tobacco to a person younger than 18 years of age.
- On January 26, 2012, CTP issued a Warning Letter to Respondent regarding the inspector's observations from December 4, 2011. The letter explained that the observations constituted violations of regulations at 21 C.F.R. § 1140.14(a) and that these regulations prohibit the sale of cigarettes or smokeless tobacco to any person younger than 18 years of age. The Warning Letter advised Respondent that failure to correct the violation could result in the imposition of a civil money penalty or other regulatory action by FDA.
- The Warning Letter was delivered to Respondent by UPS. It was received on January 27, 2012, by "Ahmad." Respondent did not reply to the Warning Letter.
- On May 29, 2012, at approximately 11:19 A.M., an FDA-commissioned inspector once again made observations at Respondent's place of business.

The inspector observed a person younger than the age of 18 buy a package of "Marlboro Gold Pack 100's" 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 § 1140.1(b). Those regulations prohibit, in part, the sale of cigarettes or smokeless tobacco to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a).

Here, Respondent sold tobacco products to individuals younger than 18 years of age on two occasions, specifically, December 4, 2011, and May 29, 2012. Respondent's actions constitute violations 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