

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Frey Enterprises, Inc.
d/b/a KNJ Gas Mart,

Respondent.

Docket No. C-13-753
FDA Docket No. FDA-2013-H-0539

Decision No. CR2848

Date: July 2, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Frey Enterprises, Inc. d/b/a KNJ Gas 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 that Respondent 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's staff unlawfully sold regulated tobacco products to a minor or minors on two separate occasions and, prior to one of these transactions, failed to verify that the tobacco purchaser

was of sufficient age, 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 May 13, 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, an 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 any 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 KNJ Gas Mart, an establishment that sells tobacco products and is located at 308 North Main Street, Dupon, Illinois 62239.
- On January 27, 2012, an FDA-commissioned inspector observed two violations of regulations found at 21 C.F.R. Part 1140 while inspecting Respondent's establishment. First, Respondent violated 21 C.F.R. § 1140.14(a) when Respondent's staff sold tobacco products to a minor. Specifically, a person younger than 18 years of age was able to purchase a package of "Newport Box 100s" cigarettes on January 27, 2012, at approximately 12:21 PM CST. Second, during this same transaction, Respondent's staff violated 21 C.F.R. § 1140.14(b)(1) when Respondent's staff failed to verify, by means of photographic identification containing the bearer's date of birth, that the tobacco purchaser was 18 years of age or older.

- On February 23, 2012, CTP issued a Warning Letter to Respondent¹ detailing the inspector's observations from January 27, 2012. In addition to describing the violations, the letter advised Respondent that the FDA may initiate a civil money penalty action or take other regulatory action against Respondent if Respondent failed to correct the violations. The letter also stated that it was Respondent's responsibility to comply with the law.
- On March 4, 2012, Suzanne Frey responded, in writing, to CTP's Warning Letter on behalf of Respondent. Ms. Frey stated that the establishment's employees were retrained to verify the identification of all minors and to refrain from selling tobacco products to any individual under the age of 18.
- On December 20, 2012, FDA-commissioned inspectors documented an additional violation during a subsequent inspection of Respondent's establishment. Specifically, at 4:50 PM CST, Respondent's staff sold a package of "Newport Box" cigarettes to a person younger than 18 years of age.

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 cigarettes or smokeless tobacco is younger than 18 years of age.

Here, Respondent's staff sold cigarettes or smokeless tobacco to a minor or minors on two separate occasions, January 27, 2012, and December 20, 2012. In addition, prior to the January 27, 2012 transaction, Respondent's staff did not verify, by checking the tobacco purchaser's photographic identification, that the tobacco purchaser was 18 years or age or older as required by the regulations.

¹ In paragraph 3 of the Complaint, CTP alleges that "[KNJ Gas Mart] also operates as a Phillips 66 gas station."

