

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Pester Marketing Company
d/b/a Alta Convenience,

Respondent.

Docket No. C-13-101
FDA Docket No. FDA-2012-H-1122

Decision No. CR2680

Date: January 2, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an administrative complaint against Respondent, Pester Marketing Company d/b/a Alta Convenience, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$2000. 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 assess a civil money penalty of \$2000.

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), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. Part 1140 (2012). CTP seeks a civil money penalty of \$2000.

On November 21, 2012, CTP served a 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 has not filed an answer within the time provided by regulation, nor has it timely requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the complaint to be true” and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its complaint:

- Respondent owns Alta Convenience, an establishment that sells tobacco products and is located at 2900 South Wadsworth Boulevard, Denver CO 80227. Complaint ¶ 2.
- Previously, this establishment did business under the name 1st Stop. *Id.*
- On July 1, 2011, an FDA-commissioned inspector observed two violations of the regulations. The inspector observed a violation of the regulation prohibiting the sale of cigarettes or smokeless tobacco to a person younger than 18 years of age at the establishment. The inspector also observed a violation of the regulation requiring the verification, by photo identification containing the bearer’s date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age. Complaint ¶ 11.
- On October 13, 2011, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from July 1, 2011. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and 14(b)(1), and that these regulations prohibit the sale of tobacco products to individuals under the age of 18 and require retailers to verify the photo identification of cigarette and smokeless tobacco purchasers under the age of 27. The Warning Letter went on to state that failure to correct the violations could result in the imposition of a civil money penalty or other regulatory action by the FDA and that Respondent is responsible for complying with the law. *Id.*

- On October 17, 2011, Margaret Gallegos contacted CTP on behalf of Respondent in response to the Warning Letter. Ms. Gallegos conveyed her belief that Respondent no longer employed the individual responsible for the violations. She further stated that the store had a policy to “card” any tobacco product purchaser under the age of 40 and a policy prohibiting sales of tobacco products to anyone under the age of 18. Complaint ¶ 12.
- On November 25, 2011, CTP sent a letter to Ms. Gallegos acknowledging the receipt of the establishment’s response and reiterating Respondent’s continuing obligation to comply with the Act and its implementing regulations. *Id.*
- During an inspection conducted on January 29 and February 5, 2012, an FDA-commissioned inspector documented two further violations of the regulations. The inspector observed a violation of the regulation prohibiting the sale of cigarettes or smokeless tobacco to a person younger than 18 years of age at the establishment. The inspector also observed a violation of the regulation requiring the verification, by photo identification containing the bearer’s date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age. Complaint ¶ 9.
- As a result, CTP initiated a CMP action on April 18, 2012, Docket Number C-12-578, FDA 2012-H-0375, against Pester Marketing Company d/b/a 1st Stop, for violations of 21 C.F.R. Part 1140. Specifically, CTP initiated the action for violations of 21 C.F.R. 1140.14(a) and 14(b)(1). *Id.*
- The CMP action concluded on June 4, 2012, as a result of Pester Marketing Company d/b/a 1st Stop, having paid a penalty. CTP issued a Request for Case Closure to Respondent on May 31, 2012. Complaint ¶ 10.
- On July 3, 2012, an FDA-commissioned inspector again documented a violation of the regulations by Respondent for selling tobacco products to a minor. Specifically, a person younger than 18 years of age purchased a package of Camel Blue cigarettes from Respondent at approximately 5:52 PM MT. Complaint ¶ 1.

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 distributed or offered for sale in any state 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). The Secretary issued the regulations at 21 C.F.R. § Part 1140 under section 906(d) of the Act. 21 U.S.C. 387(a); 21 U.S.C. § 387f(d)(1); 75 Fed. Reg.

