

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Kot LLC
d/b/a Cigarettes and More,

Respondent.

Docket No. C-13-1266
FDA Docket No. FDA-2013-H-1071

Decision No. CR2985

Date: November 6, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Kot LLC d/b/a Cigarettes and More, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. Respondent did not 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 \$500.

CTP began this case by serving the 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 cigarettes to a minor, failed to verify that a cigarette purchaser was 18 years of age or older, and utilized a self-service display to offer tobacco products for sale, 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 \$500.

On September 12, 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 proposed 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 has not filed an answer within the time provided by regulation, nor has it requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the [C]omplaint 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 Cigarettes and More, an establishment that sells tobacco products and is located at 7150 Leetsdale Drive, #202, Denver, Colorado 80224. Complaint ¶ 3.
- On January 4, 2013, an FDA-commissioned inspector observed a violation of 21 C.F.R. Part 1140 at Respondent’s establishment. The inspector observed a violation of 21 C.F.R. § 1140.16(c) due to “a customer-accessible display of cigarette tobacco on the main sales floor of the establishment.” Complaint ¶ 10.
- On January 17, 2013, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from January 4, 2013. The letter explained that the observations constituted a violation of a regulation found at 21 C.F.R. § 1140.16(c), and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violation, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 10.
- Anna Abdulmanova, Respondent’s owner, responded to the Warning Letter with a January 21, 2013 letter of her own. Ms. Abdulmanova “stated that

the establishment was purchased shortly before the inspection, . . . the new owners had believed that the establishment was in compliance with all applicable tobacco regulations[,] . . . [and] the establishment planned to move all tobacco products to behind the counters to ensure face-to-face sales.” Complaint ¶ 11.

- On March 28, 2013, at approximately 10:32 AM MT, FDA-commissioned inspectors documented additional violations of 21 C.F.R. Part 1140 at Respondent’s establishment. The inspectors documented a violation of 21 C.F.R. § 1140.14(a) when “a person younger than 18 years of age was able to purchase a package of Camel Blue cigarettes . . . [.]” The inspectors also documented a violation of 21 C.F.R. § 1140.14(b)(1) when “the minor’s identification was not verified before the sale” Complaint ¶ 1.
- CTP issued a Notice of Compliance Check Inspection to Cigarettes and More on April 1, 2013, due to the March 28, 2013 inspection. The Notice of Compliance Check Inspection specifically informed Respondent that “a minor was able to . . . purchase a regulated tobacco product at approximately 10:32 AM” on March 28, 2013. Complaint ¶ 2.

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. 13,229 (Mar. 10, 2010). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing a purchaser’s date of birth, that no cigarette purchaser is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Finally, the regulations prohibit the use of self-service displays as a method of sale of cigarettes and smokeless tobacco, 21 C.F.R. § 1140.16(c), except where the establishment does not permit any person younger than 18 years of age to be present or enter at any time, 21 C.F.R. § 1140.16(c)(2)(ii).

Taking the above alleged facts as true, Respondent had three violations of regulations contained in 21 C.F.R. Part 1140 within a three-month period. Specifically, Respondent had a violation on January 4, 2013, and two violations on March 28, 2013. Respondent violated the prohibition on the use of self-service displays as a method of selling cigarettes or smokeless tobacco on January 4, 2013. 21 C.F.R. § 1140.16(c). Respondent’s actions on March 28, 2013, violated the prohibition against selling cigarettes to persons younger than 18 years of age,

