

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Alena LLC
d/b/a Camelback Smoke Shop,

Respondent.

Docket No. C-13-1263
FDA Docket No. FDA-2013-H-1069

Decision No. CR2989

Date: November 8, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Alena LLC d/b/a Camelback Smoke Shop, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. 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 \$250.

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 minors and failed to verify that a cigarette purchaser was 18 years of age or older, 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 \$250.

On September 18, 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 Camelback Smoke Shop, an establishment that sells tobacco products and is located at 650 East Camelback Road, Phoenix, Arizona 85012. Complaint ¶ 3.
- On December 4, 2012, at approximately 11:42 AM, an FDA-commissioned inspector observed two violations of 21 C.F.R. Part 1140 at Respondent’s establishment. The inspector observed 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 Marlboro 100’s cigarettes . . . [.]” The inspector also observed a violation of 21 C.F.R. § 1140.14(b)(1) when “the minor’s identification was not verified before the sale” Complaint ¶ 10.
- CTP issued a Notice of Compliance Check Inspection to Camelback Smoke Shop on December 5, 2012, due to the December 4, 2012 inspection. The Notice of Compliance Check Inspection specifically informed Respondent that “a minor was able to . . . purchase a regulated tobacco product at approximately 11:42 AM” on December 4, 2012. Complaint ¶ 10.
- On January 3, 2013, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from December 4, 2012. 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 the named violations were 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 violations, 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.

- Mike Iskhakov responded to the Warning Letter for Respondent in a January 21, 2013 email. “Mr. Iskhakov . . . stated that although all employees alleged that they had not sold the tobacco product to the minor, the establishment would take extra care to ensure that all employees would check the identification of tobacco purchasers who appear to be under the age of 27.” Complaint ¶ 11.
- On March 14, 2013, at approximately 11:44 AM, FDA-commissioned inspectors documented an additional violation 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 Marlboro 100’s cigarettes” Complaint ¶ 1.
- CTP issued a Notice of Compliance Check Inspection to Camelback Smoke Shop on March 18, 2013, due to the March 14, 2013 inspection. The Notice of Compliance Check Inspection specifically informed Respondent that “a minor was able to . . . purchase a regulated tobacco product at approximately 11:44 AM” on March 14, 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 purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

Taking the above alleged facts as true, Respondent had three violations of regulations contained in 21 C.F.R. Part 1140 within a four-month period. Specifically, Respondent had two violations on December 4, 2012, and a violation on March 14, 2013. Respondent’s actions on both occasions violated the prohibition against selling cigarettes to persons younger than 18 years of age. 21 C.F.R. § 1140.14(a). Respondent’s actions on December 4, 2012, also violated the requirement that retailers verify, by means of photo identification containing a

