

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Oxxo Marketing Co.
d/b/a Texaco,

Respondent.

Docket No. C-13-971
FDA Docket No. FDA-2013-H-0807

Decision No. CR2906

Date: August 29, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Oxxo Marketing Co. d/b/a Texaco, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. 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 \$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 minors and failed to verify that a purchaser of cigarettes 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 \$500.

On July 10, 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 timely 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 Texaco, an establishment that sells tobacco products and is located at 2500 14th Street, Plano, Texas 75074. Complaint ¶ 3.
- On April 7, 2012, at approximately 1:50 PM CT, 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. § 1140.14(a) when “a person younger than 18 years of age was able to purchase a package of Marlboro Gold Pack cigarettes” Complaint ¶ 10.
- On June 28, 2012, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from April 7, 2012. The letter explained that the observations constituted a violation of a regulation found at 21 C.F.R. § 1140.14(a), and that the named violation was not necessarily the only violation at the establishment. The Warning Letter further stated that if Respondent failed to correct the violation, regulatory action by the FDA or a civil money penalty action could occur. Finally, the letter informed Respondent that it bore a responsibility to comply with the law. Complaint ¶ 10.

- Crystal Arredondo, a Shift Leader at Respondent's establishment, responded to the Warning Letter on Respondent's behalf with a letter dated November 5, 2012. In her letter, "Ms. Arredondo stated that corrective action was taken against the employee responsible for the violation . . . and that all employees have been instructed to request identification from all customers attempting to purchase cigarettes regardless of age." Complaint ¶ 11.
- On December 8, 2012, FDA-commissioned inspectors documented two 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 Marlboro Gold Pack cigarettes . . . at approximately 5:19 PM[.]" 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 Texaco on December 18, 2012, due to the minor's December 8, 2012 cigarette purchase. The Notice stated that the violation described was not necessarily the only violation reported. 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 purchasers of cigarettes 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 an eight-month period. Specifically, Respondent had a violation on April 7, 2012, and two violations on December 8, 2012. 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 8, 2012, also violated the

