

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1254)

Complainant,

v.

Sullivan Road Quik Mart, Inc. / Dexter and Bernadine Stalls
d/b/a Sullivan Road Quik Mart / Exxon,

Respondent.

Docket No. C-14-1771

Decision No. CR3436

Date: October 28, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Sullivan Road Quik Mart, Inc. / Dexter and Bernadine Stalls d/b/a Sullivan Road Quik Mart / Exxon, 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 individual cigarettes, and 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. pt. 1140 (2013). CTP seeks a civil money penalty of \$250.

On September 2, 2014, 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 Sullivan Road Quik Mart /Exxon, an establishment that sells tobacco products located at 711 Sullivan Road, Statesville, North Carolina 28677. Complaint ¶ 3.
- On December 13, 2013, during an inspection of Respondent’s establishment, an FDA-commissioned inspector observed the sale of individual cigarettes. Complaint ¶ 10.
- On February 12, 2014, CTP issued a Warning Letter informing Respondent of the inspector's December 13, 2013 observation. Based on UPS records, the Warning Letter was received by “Stalls” on February 14, 2014. The letter explained that the observation constituted a violation of regulations found at 21 C.F.R. § 1140.14(d), and that the named violation was not necessarily intended to be an exhaustive list of all violations at the establishment. The letter further warned that Respondent's failure to correct its violation could result in a civil money penalty or other regulatory action. Complaint ¶ 10.
- Lack of a response to the February 12, 2014 Warning Letter prompted CTP to send another letter to Respondent on April 7, 2014. The letter indicated that “CTP had not received a response to the Warning Letter and remind[ed] Sullivan Road Quik Mark of its continuing obligation to be in compliance with the Act and its implementing regulations.” Complaint ¶ 10.
- In an April 14, 2014 letter, Bernadine Stalls submitted a response to the Warning Letter on behalf of Respondent. In the letter “Ms. Stall stated that the establishment no longer allows any open packages of cigarettes behind the counter and no single cigarettes are sold at the establishment anymore.” Complaint ¶ 11.

- During a subsequent inspection of Respondent's establishment conducted on May 29, 2014, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of L&M Menthol cigarettes . . . at approximate 10:44 PM." Complaint ¶ 1.

These facts establish Respondent Sullivan Road Quik Mart / Exxon 's liability 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). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010).

The regulations prohibit the sale or distribution of individual cigarettes. 21 C.F.R. § 1140.14(d). Additionally, 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.

Taking the above alleged facts as true, Respondent violated the prohibition of (i) sale or distribution of individual cigarettes, 21 C.F.R. § 1140.14(d), on February 12, 2014; and (ii) against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on May 29, 2014. Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$250, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge