

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Yara Market Inc.
d/b/a Downtown Market,

Respondent.

Docket No. C-14-297
FDA Docket No. FDA-2013-H-1503

Decision No. CR3115

Date: February 11, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Yara Market Inc. d/b/a Downtown Market, 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 utilized self-service displays of regulated tobacco products, 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 December 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 Downtown Market, an establishment that sells tobacco products and is located at 228 East Main Street, Anoka, Minnesota 55303. Complaint ¶ 2.
- On January 8, 2013, an FDA-commissioned inspector observed a violation of 21 C.F.R. § 1140.16(c) at Respondent’s establishment because “the establishment . . . ha[d] self-service displays that include[d] smokeless tobacco and cigarette tobacco in customer accessible part [sic] of the establishment, [and] [wa]s open to persons of all ages.” Complaint ¶ 9.
- On January 24, 2013, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from January 8, 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 ¶ 9.

- FDA received no response to the Warning Letter from Respondent, though United Parcel Service records demonstrate that an individual named “Yara” received the Warning Letter on January 25, 2013. Complaint ¶ 10.
- On June 17, 2013, an FDA-commissioned inspector documented an additional violation of 21 C.F.R. § 1140.16(c) at Respondent’s establishment where “the establishment . . . ha[d] self-service displays that include[d] smokeless tobacco and cigarette tobacco in customer accessible parts of the establishment, [and] [wa]s open to persons of all ages.” 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. 13,229 (Mar. 10, 2010). The regulations prohibit the use of self-service displays of cigarettes or smokeless tobacco, 21 C.F.R. § 1140.16(c)(1), except where no person younger than 18 years of age is present in or allowed to enter the establishment at any time, 21 C.F.R. § 1140.16(c)(2)(ii).

Taking the above alleged facts as true, Respondent had two violations of regulations contained in 21 C.F.R. Part 1140 within a six-month period. Specifically, Respondent violated 21 C.F.R. § 1140.16(c) on January 8, 2013, and June 17, 2013, by utilizing self-service displays of tobacco products. Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

The regulations require me to impose a civil money penalty in an amount that is either the maximum provided for by law or the amount sought in the Complaint, whichever is smaller. 21 C.F.R. § 17.11(a)(1)-(2). The regulations currently allow a maximum penalty of \$250 for a second violation within a six-month period, 21 C.F.R. § 17.2, and CTP has requested a fine of that amount. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge