

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Creekside Markets, Inc.
d/b/a Creekside Market 3,

Respondent.

Docket No. C-13-391
FDA Docket No. FDA-2013-H-0139

Decision No. CR2730

Date: March 25, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Creekside Markets, Inc. d/b/a Creekside Market 3, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. 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 \$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 a self-service display in a non-exempt facility and failed to ensure that all violative self-service displays, advertising, labeling, and other items were removed or brought into compliance with regulations, 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 February 11, 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 Creekside Market 3, an establishment that sells tobacco products and is located at 4050 Erwin Highway, Afton, TN 37616. Complaint ¶ 2.
- On January 4, 2012, an FDA-commissioned inspector observed a violation of 21 C.F.R. § 1140.16(c)(1), a regulation requiring cigarettes and smokeless tobacco to be sold exclusively in direct, face-to-face exchanges in facilities that fail to ensure that no person younger than 18 years of age is present or permitted to enter at any time, at Respondent’s establishment. The inspector also observed a violation of 21 C.F.R. § 1140.14(e), a regulation requiring retailers to ensure that all violative self-service displays, advertising, labeling, and other items in their establishments are removed or brought into compliance with the requirements of 21 C.F.R. Part 1140. Complaint ¶ 9.
- On February 2, 2012, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from January 4, 2012. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.16(c)(1) and 21 C.F.R. § 1140.14(e), 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

failure to correct the violations could result in the imposition of a civil money penalty or other regulatory action by the FDA and that Respondent is responsible for complying with the law. *Id.*

- FDA received no response to the Warning Letter from Respondent, though United Parcel Service records demonstrate that an individual named “Johnson” received the Warning Letter on February 3, 2012. Complaint ¶ 10.
- During a two part inspection conducted on May 3, 2012, and June 8, 2012, FDA commissioned inspectors observed an additional violation at Respondent’s establishment. Inspectors documented a violation of 21 C.F.R. § 1140.16(c) where Respondent “[had] a self-service display of smokeless tobacco products on the checkout counter next to the cash register and [did] not restrict entry [into the establishment] to persons 18 years of age or older.” 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 require retailers who sell cigarettes or smokeless tobacco to do so exclusively in direct, face-to-face exchanges, where the retailers fail to ensure that no person younger than 18 years of age is present or permitted to enter at any time. 21 C.F.R. § 1140.16(c)(1), (c)(2)(ii). The regulations also require retailers to ensure that all violative self-service displays, advertising, labeling, and other items in their establishments are removed or brought into compliance with the requirements of 21 C.F.R. Part 1140. 21 C.F.R. § 1140.14(e).

Taking the above alleged facts as true, Respondent had three violations of regulations contained in 21 C.F.R. Part 1140 within a seven month period. Specifically, Respondent had two violations on January 4, 2012, and a violation observed during a two-part inspection on May 3, 2012, and June 8, 2012. Respondent’s actions violated 21 C.F.R. § 1140.16(c)(1) and 21 C.F.R. § 1140.14(e). Therefore, Respondent’s actions constitute violations of law for which a civil money penalty is merited.

The regulations require the imposition of a civil money penalty in the 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 \$500 for three violations within a seven month period. 21 C.F.R. § 17.2. CTP, however, has requested a fine in the amount of \$250. Therefore, I find that a civil money penalty of \$250 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge