

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Smokes 4 Less #7 Inc.
d/b/a Smokes 4 Less,

Respondent.

Docket No. C-13-630
FDA Docket No. FDA-2013-H-0407

Decision No. CR2801

Date: May 29, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Smokes 4 Less #7 Inc. d/b/a Smokes 4 Less, 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 order that Respondent pay a civil money penalty in the amount of \$250.

CTP began this case by serving a 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 sold regulated tobacco products using a self-service display in a non-exempt facility, thereby

violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$250.

On April 12, 2013, CTP served the Complaint on Respondent by United Parcel Service (UPS), 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 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, the 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 did not file an answer within the time provided by regulation.

I am required to issue a default judgment if the complaint is sufficient to justify a penalty, and the Respondent fails to answer timely or to request an extension. 21 C.F.R. § 17.11(a). For that reason, I must decide whether a default judgment is appropriate here, and I conclude that it is merited based on the allegations of the Complaint and Respondent's failure to answer them.

For purposes of this decision, I assume that the following facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically:

- Respondent owns Smokes 4 Less, a business that sells tobacco products and is located at 19112 Freeport Street NW, Elk River, Minnesota 55330.
- On March 9, 2012, an FDA-commissioned inspector observed a violation while inspecting Respondent's establishment. Specifically, Respondent violated 21 C.F.R. § 1140.16(c) by using a self-service display in a non-exempt facility.
- On May 10, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from March 9, 2012. In addition to describing the violation, the letter advised Respondent that the FDA may initiate a civil money penalty action or take other regulatory action against Respondent if Respondent failed to correct the violation. The letter also stated that Respondent is responsible for complying with the law.
- On May 21, 2012, Mike Wazwaz, manager of Respondent's establishment, responded, by telephone, to the Warning Letter on behalf of Respondent. Mr. Wazwaz stated that all cigarettes are kept behind the counter and that no regulated tobacco products are accessible by self-service.

- On August 15 and September 6, 2012, FDA-commissioned inspectors documented an additional violation during a subsequent inspection of the establishment. Specifically, the establishment had multiple self-service displays containing smokeless tobacco and cigarette tobacco products. In addition, Mr. Wazwaz stated that the establishment permits minors to enter when accompanied by a parent.

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 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). Under 21 C.F.R. § 1140.16(c)(1) and (c)(2)(ii), a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer unless the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time. Self-service displays are a method of sale not permitted under 21 C.F.R. § 1140.16(c)(1).

Here, Respondent sold smokeless tobacco and cigarette tobacco products at its business establishment in a manner other than a direct, face-to-face exchange with its customer on three separate dates: March 9, August 15 and September 6, 2012. Specifically, Respondent allowed customers to select tobacco products from displays and to bring them to its cashier for purchase. On those dates, Respondent's establishment was not exempt from the requirement that tobacco products be sold only via a direct, face-to-face exchange because minors were permitted to enter if accompanied by a parent. These actions by Respondent constitute violations of law for which a civil money penalty is merited. Therefore, I find that a civil money penalty of \$250 is permissible under 21 C.F.R. § 17.2 and enter a default judgment against Respondent with an order that Respondent pay a civil money penalty in that amount.

/s/

Steven T. Kessel
Administrative Law Judge