

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Acme Markets, Inc.
d/b/a Acme,

Respondent.

Docket No. T-18-531
FDA Docket No. FDA-2017-H-6680

Decision No. TB2684

Date: May 1, 2018

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Acme Markets, Inc. d/b/a Acme, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$279. Respondent filed an Answer to the Complaint, however, during the hearing process, Respondent failed to comply with judicial directions, therefore, I strike Respondent's answer and issue this decision of default judgment.

I. Procedural History

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, 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. CTP seeks a civil money penalty of \$279.

Respondent timely filed an answer, in which, it denied the allegations in the Complaint and requested a hearing. However, Respondent did not specify which allegations it denies nor did it provide any defenses or reasons why it contends the penalty sought by CTP. Pursuant to 21 C.F.R. § 17.9, an answer must:

- (1) admit or deny each of the allegations of liability made in the complaint; allegations not specifically denied in an answer are deemed admitted;
- (2) state all defenses on which the respondent intends to rely;
- (3) state all reasons why the respondent contends that the penalties and assessments should be less than the requested amount; and
- (4) state the name, address, and telephone number of the respondent's counsel, if any.

21 C.F.R. § 17.9.

On December 28, 2017, I issued an Acknowledgment and Pre-hearing Order (APHO) that set out instructions regarding case procedure and filing deadlines. The APHO established a deadline of March 19, 2018 for all pre-hearing exchanges from CTP to Respondent, and a deadline of April 9, 2018 for all pre-hearing exchanges from Respondent to CTP. CTP timely filed its pre-hearing exchange. Respondent did not file a pre-hearing exchange.

On April 12, 2018, I issued an Order to Show Cause (OSC) requiring Respondent to show cause why I should not strike its answer and enter a default judgment in favor of CTP. Specifically, I ordered Respondent to provide an explanation for its failure to comply with regulatory requirements in filing its answer and its failure to file a pre-hearing exchange, by no later than April 23, 2018. To date, Respondent has not filed a response to my OSC.

Therefore, pursuant to 21 C.F.R. § 17.35, I strike Respondent's answer for failing to defend this action and failing to comply with judicial directions. Specifically, Respondent's answer did not meet the regulatory requirements set forth at 21 C.F.R. § 17.9, it did not file a pre-hearing exchange as ordered in the APHO, and it did not file a response to the OSC. This conduct is sufficiently egregious to warrant striking Respondent's answer and issuing an initial decision by default.

II. Default Decision

Striking Respondent's answer leaves the complaint unanswered. 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 Acme, an establishment that sells tobacco products and is located at 460 East Main Street, Middletown, Delaware 19709. Complaint ¶¶ 5-6.

- During an inspection of Respondent’s establishment on June 12, 2017, at approximately 6:17 PM, an FDA-commissioned inspector observed that “a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes . . . [.]” Complaint ¶ 9.
- On June 29, 2017, CTP issued a Warning Letter to Respondent regarding the inspector’s observation from June 12, 2017. The letter explained that the observation constituted a violation of regulation, 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 ¶ 10.
- During a subsequent inspection of Respondent’s establishment on November 4, 2017, at approximately 4:00 PM, an FDA-commissioned inspector documented that “a person younger than 18 years of age was able to purchase a package of Marlboro Gold Pack cigarettes . . . [.]” Complaint ¶ 7.

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 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); 81 Fed. Reg. 28,974, 28,975-76 (May 10, 2016). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a)(1).

Taking the above alleged facts as true, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), on June 12, 2017, and November 4, 2017. Therefore, Respondent’s actions constitute violations of law that merit a civil money penalty.

CTP has requested a civil money penalty of \$279, which is a permissible penalty under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$279 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge