

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Whistlin' Jack Lodge, Inc.,

Respondent.

Docket No. C-15-625
FDA Docket No. FDA-2014-H-2149

Decision No. CR3595

Date: January 23, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Whistlin' Jack Lodge, Inc., alleging facts and legal authority sufficient to justify imposing a \$2,000 civil money penalty. 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 \$2,000.

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's staff unlawfully sold cigarettes to a minor and failed to verify that a cigarette purchaser was of sufficient age, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, found at 21 C.F.R. pt. 1140. CTP seeks a civil money penalty of \$2,000.

On December 11, 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 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 issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty. 21 C.F.R. § 17.11.

Respondent has not filed an answer within the time provided by regulation, nor has it requested an extension. Therefore, pursuant to 21 C.F.R. § 17.11(a), I am required to issue an initial decision by default if the Complaint is sufficient to justify a penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

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

- Respondent owns Whistlin' Jack Lodge, an establishment that sells tobacco products and is located at 20800 State Route 410, Naches, Washington 98937. Complaint ¶ 3.
- CTP previously initiated a civil money penalty action, CRD Docket Number C-14-752, FDA Docket Number FDA-2014-H-0262, against Respondent for two violations of 21 C.F.R. pt. 1140 within a 12-month period. Specifically, Respondent violated 21 C.F.R. § 1140.14(a) on March 10, 2013 and September 9, 2013 by selling tobacco products to a minor. Complaint ¶ 10; March 10, 2014 Complaint ¶¶ 1, 10.
- The previous civil money penalty action concluded when Doug Williams, Respondent's authorized representative, settled the action with CTP on Respondent's behalf. On March 20, 2014, Mr. Williams signed an Acknowledgment Form in which he "admitt[ed] that the violations . . . occurred, waiv[ed] Respondent's ability to contest the violations in the future, and stat[ed] that he understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions against Respondent." The Administrative Law Judge closed the case on May 14, 2014. Complaint ¶ 11.
- During a subsequent inspection of Respondent's establishment conducted on June 17, 2014, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . at approximately 2:20 PM[.]" The inspectors also noted that "the minor's identification was not verified before the sale" 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 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 regulations prohibit the sale of cigarettes or smokeless tobacco to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photographic identification containing the purchaser's date of birth, that no purchaser of cigarettes or smokeless tobacco is younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1).

Here, Respondent had four violations of regulations found at 21 C.F.R. pt. 1140 within a 24-month period. Respondent acknowledged that two violations occurred when its representative settled the previous civil money penalty action. Then, on June 17, 2014, Respondent sold cigarettes to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a). During that same transaction, Respondent failed to verify, by means of photographic identification containing the bearer's date of birth, that the cigarette purchaser was 18 years of age or older, in violation of 21 C.F.R. § 1140.14(b)(1). Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$2,000, which is a permissible fine for four violations of the regulations found at 21 C.F.R. pt. 1140. 21 C.F.R. § 17.2. I thus find that a civil money penalty of \$2,000 is warranted and so order one imposed.

/s/
Steven T. Kessel
Administrative Law Judge