

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Dollar Haven LLC,

Respondent.

Docket No. C-13-783
FDA Docket No. FDA-2013-H-0584

Decision No. CR2850

Date: July 9, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Dollar Haven LLC, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$2,000. 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 impermissibly offered individual cigarettes for sale in its establishment, unlawfully sold regulated tobacco products to minors and, prior to these transactions, failed to verify that the tobacco purchasers were of sufficient age, 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 \$2,000.

On May 21, 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 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 did not take one of the required actions 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 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 Dollar Haven LLC, a business that sells tobacco products and is located at 111 Derby Avenue, New Haven, Connecticut 06511.
- On June 26, 2012, an FDA-commissioned inspector observed two violations of regulations found at 21 C.F.R. Part 1140 while inspecting Respondent's establishment. Specifically, Respondent violated 21 C.F.R. § 1140.14(a) when, at approximately 10:20 AM, Respondent's staff sold a package of Newport Box 100s cigarettes to a person younger than 18 years of age. During this same transaction, Respondent's staff failed to verify, by means of photographic identification containing the bearer's date of birth, the age of the tobacco purchaser as required by 21 C.F.R. § 1140.14(b)(1).
- On September 6, 2012, CTP issued a Warning Letter to Dollar Haven LLC regarding the inspector's observations from June 26, 2012. In addition to describing the violations, 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 violations. The letter also stated that it was Respondent's responsibility to comply with the law.

- On September 25, 2012, Janett Quintero, manager of Respondent's establishment, responded, by telephone, to CTP's Warning Letter on behalf of Respondent. She stated that "the clerk who committed the violation no longer works at the register." She also stated that she had spoken with the staff about checking the identification of customers purchasing tobacco products.
- On November 20, 2012, CTP acknowledged, in writing, receipt of the establishment's response and reminded Respondent of its continuing obligation to be in compliance with the law.
- On January 3 and 9, 2013, FDA-commissioned inspectors documented additional violations during a subsequent inspection of the establishment. Specifically, a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes at approximately 12:54 PM on January 3, 2013. Prior to this transaction, Respondent's staff did not verify that the tobacco purchaser was 18 years of age or older by checking the purchaser's photographic identification. The inspectors also observed that Respondent's establishment offered individual cigarettes for sale in violation of 21 C.F.R. § 1140.14(d).

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. § 1140.14(a), no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), a retailer must verify, by means of photo identification containing the bearer's date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age. Under 21 C.F.R. § 1140.14 (d), no retailer may break or otherwise open any cigarette package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size of 20 cigarettes. *See also* 21 C.F.R. § 1140.16(b).

Here, Respondent's staff sold cigarettes or smokeless tobacco to a minor or minors on two separate occasions, June 26, 2012, and January 3, 2013. Prior to those transactions, Respondent's staff did not verify that the tobacco purchasers were 18 years of age or older by checking their photographic identification as required by the regulations. In addition, during a two-part inspection on January 3 and 9, 2013, FDA-commissioned inspectors documented Respondent's establishment offering individual cigarettes for sale in violation of the foregoing regulations. Respondent's actions and omissions on two occasions at the same retail outlet constitute violations of law for which a civil money penalty is merited.

