

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Zanco, L.L.C.
d/b/a Shell,

Respondent.

Docket No. C-13-1092
FDA Docket No. FDA-2013-H-0912

Decision No. CR2956

Date: October 22, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Zanco, L.L.C. d/b/a Shell, 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's staff unlawfully

sold cigarettes to a minor, failed to verify that the tobacco purchaser was of sufficient age prior to this transaction, and impermissibly used a self-service display of regulated tobacco products 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 August 20, 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 timely take one of these actions the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision by default ordering Respondent to pay the full amount of the proposed penalty. Respondent did not take any of the required actions within the time provided by regulation.

I am required to issue an initial decision by default if the Complaint is sufficient to justify a penalty, and the Respondent fails to timely answer 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. I conclude that it is 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 Shell, an establishment that sells tobacco products and is located at 56 Lathrop Road, Plainfield, Connecticut 06374. Complaint ¶ 2.
- On July 28, 2012, during an inspection of Respondent's establishment, an FDA-commissioned inspector observed that Respondent's staff sold cigarettes to a minor. "Specifically, a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes . . . at approximately 2:29 PM ET" During that same transaction, the inspector also observed that Respondent's staff "[f]ail[ed] to verify the age of a person purchasing tobacco products[,] by means of photographic identification containing the bearer's date of birth[,] . . . before the sale . . . [on] July 28, 2012" Complaint ¶ 9.
- On October 18, 2012, CTP issued a Warning Letter to Respondent detailing the inspector's observations from July 28, 2012. The letter explained that the inspector's observations constituted violations of 21 C.F.R.

§ 1140.14(a) and (b)(1). 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 and stated that it was Respondent's responsibility to comply with the law. Complaint ¶ 9.

- On October 19, 2012, delivery records show that the Warning Letter was received by "Shawn," but the FDA did not receive a response to the Warning Letter. Complaint ¶ 10.
- On January 22, 2013, and January 29, 2013, FDA-commissioned inspectors conducted a two-part inspection of Respondent's establishment. On those dates, the inspectors documented that "the establishment, which [was] a convenience store open to the public, ha[d] a display of loose cigarette tobacco and smokeless tobacco that [was] accessible to the public," in violation of 21 C.F.R. § 1140.16(c). 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). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes 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 purchaser of cigarettes is younger than 18 years of age. Under 21 C.F.R. § 1140.16(c)(1), a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. The regulations prohibit retailers from using self-service displays as a method of sale for cigarettes and smokeless tobacco. 21 C.F.R. § 1140.16(c)(1). However, self-service displays of regulated tobacco products are permitted if located in facilities where the retailer ensures 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)(2)(ii).

Here, Respondent violated 21 C.F.R. § 1140.14(a) on July 28, 2012, when its staff sold cigarettes to a minor. Respondent also violated 21 C.F.R. § 1140.14(b)(1) when its staff did not verify, by checking the tobacco purchaser's photographic identification, that the tobacco purchaser was 18 years of age or older prior to this transaction. Additionally, on January 22, 2013 and January 29, 2013, Respondent's establishment contained a self-service display of loose cigarette and smokeless tobacco. On those dates, Respondent's establishment functioned as a convenience store that was open to the public. Therefore, Respondent violated 21 C.F.R. § 1140.16(c) because it impermissibly used a self-service display for regulated tobacco products in a facility that did not prohibit minors from entering.

