

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Zimfa Incorporated
d/b/a Albany Avenue Shell,

Respondent.

Docket No. C-14-753
FDA Docket No. FDA-2014-H-0266

Decision No. CR3218
Date: May 5, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Zimfa Incorporated d/b/a Albany Avenue Shell (Respondent), which alleges facts and legal authority sufficient to justify imposing a \$5,000 civil money penalty.

CTP initiated this case by serving a Complaint on Respondent and filing a copy of the Complaint with the Civil Remedies Division (CRD) and the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent's staff unlawfully sold regulated tobacco products to minors on three occasions, and during each transaction, Respondent's staff failed to verify that the cigarette purchasers were of sufficient age, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), codified at 21 U.S.C. §§ 301 – 399d, and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$5,000.

On March 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 must take one of the following three actions: 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 ordering Respondent to pay the full amount of the proposed penalty. 21 C.F.R. § 17.11.

Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the complaint to be true, and, if such facts establish liability under [the Act],” issue an initial decision and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns Albany Avenue Shell, an establishment that sells tobacco products and is located at 949 Albany Avenue, Hartford, Connecticut 06112. Complaint ¶ 3.
- On August 19, 2013, CTP initiated a civil money penalty action against Respondent for three violations of 21 C.F.R. Part 1140 within a 24-month period. Complaint ¶ 10. Specifically, on February 27, 2012, an FDA-commissioned inspector observed that Respondent “[sold] tobacco products to a minor . . . [and] the minor’s identification was not verified before the sale . . . on February 27, 2012, at approximately 11:08 AM EST.” August 19, 2013 Complaint ¶ 10.
- During a subsequent two-part inspection conducted on January 29, 2013 and January 31, 2013, FDA-commissioned inspectors documented violations of 21 C.F.R. Part 1140 when “a person younger than 18 years of age was able to purchase a package of Maverick Box cigarettes on January 29, 2013, at approximately 1:01 PM EST; and . . . the minor’s identification was not verified before the sale, as detailed above, on January 29, 2013, at approximately 1:01 PM EST.” August 19, 2013 Complaint ¶ 1.
- “Syed I. Bokharl identified himself as being authorized to settle claims on behalf of Zimfa Incorporated d/b/a Albany Avenue Shell” and settled CRD Docket Number C-13-1147. The CRD closed the case on October 18, 2013. Complaint ¶ 11.
- During an additional two-part inspection, FDA-commissioned inspectors documented a violation of 21 C.F.R. § 1140.14(a) and (b)(1) at

Respondent's establishment. Specifically, the inspectors observed that "a person younger than 18 years of age was able to purchase a package of Marlboro 100's cigarettes on October 28, 2013 . . . at approximately 10:49 AM; and . . . the minor's identification was not verified before the sale, as detailed above, on October 28, 2013, at approximately 10:49 AM." Complaint ¶ 1.

I find that these facts, which I must assume are true, establish that Respondent is liable under the Act. *See* 21 C.F.R. § 17.11(a). 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, codified at 21 U.S.C. § 387f(d). *See* 21 U.S.C. § 387(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). Retailers are required to verify, by means of photo 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 committed six violations of 21 C.F.R. Part 1140 within a 36-month period. Respondent violated 21 C.F.R. § 1140.14(a) on February 27, 2012, January 29, 2013, and October 28, 2013, when its staff sold regulated tobacco products to minors. On those same dates, Respondent also violated 21 C.F.R. 1140.14(b)(1) when its staff failed to verify the purchasers' ages by means of photographic identification containing the purchasers' date of birth. Therefore, Respondent's actions and omissions constitute violations of law that merit a civil money penalty. The regulations allow for a civil money penalty in the amount of \$10,000 for six violations in a 36-month period. 21 C.F.R. § 17.2. However, CTP has only requested \$5,000. Accordingly, I find that a civil money penalty in the amount of \$5,000 is permissible and order it imposed. 21 C.F.R. § 17.2.

/s/
Steven T. Kessel
Administrative Law Judge