

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Big Bear Tobacco, Inc
d/b/a Smokers Choice Smoke Shop,

Respondent.

Docket No. C-12-1070
FDA Docket No. FDA-2012-H-0827

Decision No. CR2644

Date: October 15, 2012

DECISION

The Center for Tobacco Products (CTP) began this matter by serving a complaint on Respondent, Big Bear Tobacco, Inc., d/b/a Smokers Choice Smoke Shop, at 7144 N. 35th Ave., Phoenix, AZ 85051, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Respondent Big Bear impermissibly sold tobacco products to a minor, failed to verify the age of a person purchasing tobacco products, and impermissibly used a self-service display in a non-exempt facility, violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations, 21 C.F.R. Part 1140. CTP seeks to impose against Respondent Big Bear a \$2,000 civil money penalty.

As provided for in 21 C.F.R. sections 17.5 and 17.7, on August 15, 2012, CTP served the complaint on Respondent Big Bear by United Parcel Service. 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 in which to file an answer. CTP warned Respondent that, if it failed to take one of these actions within 30 days, the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering it to pay the full amount of the proposed penalty.

Respondent Big Bear has not filed an answer within the time prescribed. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- At Respondent's business establishment, 1903 West Thunderbird Road, Phoenix, AZ, on September 12, 2011, an FDA-commissioned inspector observed that Big Bear failed to limit its tobacco sales to direct, face-to-face exchanges; the facility has in place a self-service display but does not ensure that no person under 18-years-of-age is present or permitted to enter the premises;
- In a warning letter dated January 12, 2012, the CTP informed Respondent of the inspector's September 12, 2011 observations and that such actions violate federal law, 21 C.F.R. § 1140.16(c). The letter further warned that Big Bear's failure to correct its violation[s] could result in a civil money penalty or other regulatory action;
- At Respondent's business establishment, 1903 West Thunderbird Road, Phoenix, AZ, on March 29, 2012, an FDA-commissioned inspector observed the sale of American Spirit Original Blend cigarette tobacco to a person younger than 18-years-of-age;
- At Respondent's business establishment, 1903 West Thunderbird Road, Phoenix, AZ, on March 29, 2012, an FDA-commissioned inspector observed staff's failure to verify prior to sale, by means of photo identification containing the bearer's birth date, the age of a person purchasing tobacco products;
- On March 29 and/or April 6, 2012, an FDA-commissioned inspector observed a minor near the facility's roll-your-own machine; a person younger than 18-years-of-age was able to enter the establishment, retrieve a tobacco product contained in the self-service display, and take that product to the cashier.

These facts establish Respondent Big Bear's liability 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. § 387f(d); *see* 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). Under 21 C.F.R. section 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. section 1140.14(b)(1), a retailer must verify, by means of photo identification containing the bearer's date of birth, that no

person purchasing the tobacco product is younger than 18-years-of-age. Under 21 C.F.R. § 1140.16(c), unless its self-service display is located in a facility where the retailer ensures that no person younger than 18-years-of-age is present, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between retailer and consumer.

A \$2,000 civil money penalty is permissible under 21 C.F.R. section 17.2.

Order

For these reasons, I enter default judgment in the amount of \$2,000 against Respondent Big Bear Tobacco d/b/a Smokers Choice Smoke Shop. Pursuant to 21 C.F.R. section 17.11(b), this order becomes final and binding upon both parties 30 days after the date issued.

/s/

Carolyn Cozad Hughes
Administrative Law Judge