

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products
(FDA No. FDA-2012-H-0817),

Complainant

v.

Falin Zhang, d/b/a Happy House

Docket No. C-12-1058

Decision No. CR2623

Date: September 21, 2012

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving a complaint on Respondent, Falin Zhang d/b/a Happy House, at 700 West Allegheny Ave., Philadelphia, PA 19133, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Happy House impermissibly sold tobacco products to a minor and failed to verify the age of a person purchasing tobacco products, 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 Happy House a \$500 civil money penalty.

As provided for in 21 C.F.R. sections 17.5 and 17.7, on August 3, 2012, CTP served the complaint on Respondent Happy House 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 Happy House 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, 700 West Allegheny Avenue, Philadelphia, PA, on August 23, 2011, an FDA-commissioned inspector observed the sale of cigarettes or smokeless tobacco to a person younger than 18 years of age;
- At Respondent's business establishment, 700 West Allegheny Avenue, Philadelphia, PA, on August 23, 2011, 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;
- In a warning letter dated November 10, 2011, the CTP informed Respondent Happy House of the inspector's August 23, 2011 observations and that such actions violate federal law, 21 C.F.R. §§ 1140.14(a) and 1140.14(b). The letter further warned that Respondent Happy House's failure to correct its violation[s] could result in a civil money penalty or other regulatory action;
- At approximately 3:42 p.m. on March 30, 2012, at Respondent's business establishment, 700 West Allegheny Avenue, Philadelphia, PA, an FDA-commissioned inspector observed the sale of Newport Box cigarettes to a person younger than 18 years of age;
- At approximately 3:42 p.m. on March 30, 2012, at Respondent's business establishment, 700 West Allegheny Avenue, Philadelphia, PA, 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.

These facts establish Respondent Happy House'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.

A \$500 civil money penalty is permissible under 21 C.F.R. section 17.2.

