

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2013-H-0498)

Complainant

v.

Pranay Corporation
d/b/a Smoke For Less,

Respondent.

Docket No. C-13-696

Decision No. CR2843

Date: June 25, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving a complaint on Respondent, Pranay Corporation d/b/a Smoke For Less, at 1026 Weiland Road, Buffalo Grove, Illinois 60089, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Smoke For Less impermissibly sold tobacco products to a minor and utilized a self-service display to sell tobacco products 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 a \$250 civil money penalty against Respondent Smoke For Less.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on May 9, 2013, CTP served the complaint on Respondent Smoke For Less 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 Smoke For Less has neither filed an answer within the time prescribed, nor requested an extension of time within which to file an answer. 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, 1026 Weiland Road, Buffalo Grove, Illinois 60089, on March 26, 2012, an FDA-commissioned inspector observed Respondent's staff sell cigarettes or smokeless tobacco to a person younger than 18 years of age;
- In a warning letter issued May 10, 2012, CTP informed Respondent of the inspector's March 26, 2012 observations, and that such actions violate federal law, 21 C.F.R. § 1140.14(a). The letter further warned that if Respondent failed to correct its violation, a civil money penalty or other regulatory action could result;
- During a two-part inspection conducted on December 4, 2012, and December 6, 2012, at Respondent's business establishment, 1026 Weiland Road, Buffalo Grove, Illinois 60089, an FDA-commissioned inspector observed a self-service display of roll-your-own cigarette tobacco on the establishment's wall, across from the checkout counter. Further, the inspector observed a person younger than 18 years of age enter the establishment, and the establishment's owner confirmed that persons younger than 18 years of age are allowed to enter the establishment as a matter of course.

These facts establish the liability of Respondent Smoke For Less 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). The Secretary issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. 387(a); *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). 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. § 1140.16(c), retailers are prohibited from using self-service displays to sell cigarettes or smokeless tobacco, unless the facility is one in which persons younger than 18 years of age are not permitted to enter at any time, 21 C.F.R. § 1140.16(c)(2)(ii).

A \$250 civil money penalty is permissible under 21 C.F.R. § 17.2.

Order

For these reasons, I enter default judgment in the amount of \$250 against Respondent Pranay Corporation d/b/a Smoke For Less. Pursuant to 21 C.F.R. section 17.11 (b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

 /s/
Carolyn Cozad Hughes
Administrative Law Judge