

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Smoke & More, Inc.,

Respondent.

Docket No. C-13-351  
FDA Docket No. FDA-2013-H-0121

Decision No. CR2756

Date: April 17, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an administrative complaint against Respondent, Smoke & More, Inc., that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. 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 assess a civil money penalty of \$500.

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 maintained a self-service display in a facility that permits minors to enter and sold cigarettes in a package containing fewer than twenty cigarettes, 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. The complaint further alleges that Respondent impermissibly received in interstate commerce and

delivered or proffered for delivery “clove” cigarettes, also in violation of the Act. CTP seeks a civil monetary penalty of \$500 for these violations.

On March 7, 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 take one of these actions within 30 days, the Administrative Law Judge could issue an initial decision ordering Respondent to pay the full amount of the proposed penalty, pursuant to 21 C.F.R. § 17.11.

Respondent has not filed an answer within the time provided by regulation or timely requested an extension. 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 a default judgment and impose a civil monetary penalty. Accordingly, I must determine whether the allegations in the complaint establish violations of the Act.

Specifically, CTP alleges that:

- Respondent owns Smoke & More, an establishment that sells tobacco products and is located at 808 72<sup>nd</sup> Street East, Tacoma, Washington 98404. Complaint ¶ 2.
- On March 22, 2012, an FDA-commissioned inspector observed that Respondent had a self-service display in a non-exempt establishment. Complaint ¶ 11.
- “[O]n May 31, 2012, CTP issued a Warning Letter to Smoke & More.” Complaint ¶ 11. The letter informed Respondent of the violation the FDA-commissioned inspector had observed on March 22, 2012, and that the failure to correct violations could result in the imposition of a civil money penalty or other regulatory action. Complaint ¶ 11. Moreover, CTP informed Respondent that the warning letter was not intended to provide an exhaustive list of violations and that Respondent maintained the responsibility to ensure that it complied with the law. Complaint ¶ 11.
- Pursuant to a two-part inspection conducted on August 11, and 23, 2012, FDA-commissioned inspectors noted two violations: (1) “[s]elling a cigarette package that contains fewer than 20 cigarettes”; and (2) “[r]eceiving in interstate commerce and delivering or proffering for delivery ‘clove’ flavored cigarettes.” Complaint ¶ 1.a.-b.

Taking these facts as true, I must find pursuant to 21 C.F.R. § 17.11(a) 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, codified at 21 U.S.C. § 387f(d). 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). Those regulations generally prohibit the use of self-service displays and other “‘impersonal’ modes of sale” and require that a retailer sell tobacco products “only in a direct, face-to-face exchange between the retailer and the consumer.” 21 C.F.R. § 1140.16(c). The regulations also generally prohibit the sale of “any cigarette package that contains fewer than 20 cigarettes.” 21 C.F.R. § 1140.16(b). The Act further prohibits “[t]he receipt in interstate commerce of any . . . tobacco product . . . that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.” 21 U.S.C. § 331(c). A tobacco product is deemed “adulterated” if it fails to meet entirely the “tobacco product standard established under section 387g.” 21 U.S.C. § 387b(5). That section, in turn, prohibits cigarettes from containing, “as a constituent . . . or additive, an artificial or natural flavor . . . or an herb or spice, including . . . clove . . . .” 21 U.S.C. § 387g(a)(1)(A).

Here, Respondent first misbranded a tobacco product when it maintained a self-service display, in violation of 21 C.F.R. § 1140.16(c). Respondent also misbranded a tobacco product when it sold packages of fewer than 20 cigarettes, in violation of 21 C.F.R. § 1140.16(b). Finally, Respondent violated 21 U.S.C. § 331(c) and § 387g(a)(1)(A) when it received in interstate commerce and delivered or proffered for delivery “clove” cigarettes. Respondent’s actions constitute violations of law for which a civil money penalty is merited. *See* 21 U.S.C. § 333f(9)(A).

The regulations require the imposition of a civil money penalty in the amount that is either the maximum provided for by law or the amount sought in the complaint, whichever is smaller. 21 C.F.R. § 17.11(a). Respondent has committed its second regulatory violation within a 12-month period, the maximum penalty for which is \$250. 21 C.F.R. § 17.2. Respondent has also committed an additional statutory violation for which it may be fined up to \$15,000. 21 U.S.C. § 333f(9)(A). CTP, through its Complaint, requested a civil money penalty in the amount of \$250 for the two regulatory violations and \$250 for the separate statutory violation. Therefore, I impose a civil money penalty in the amount of \$500.

/s/

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Steven T. Kessel  
Administrative Law Judge