

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Lakeview Foods, Inc.  
d/b/a Lakeview Food & Liquors,

Respondent.

Docket No. C-13-314  
FDA Docket No. FDA-2013-H-0084

Decision No. CR2721

Date: March 13, 2013

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Lakeview Foods, Inc. d/b/a Lakeview Food & Liquors, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$250. 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 order that Respondent pay a civil money penalty in the amount of \$250.

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 impermissibly sold tobacco products to a minor and used a self-service display in a non-exempt facility, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its

implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$250.

On January 28, 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, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty. Respondent did not take one of the required actions within the time provided by regulation.

I am required to issue a default judgment if the Complaint is sufficient to justify a penalty, and the Respondent fails to answer timely or to request an extension. 21 C.F.R. § 17.11(a). For that reason, I must decide whether a default judgment is appropriate here, and I conclude that it is merited based on the allegations of the Complaint and Respondent's failure to answer them.

For purposes of this decision, I assume the facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Lakeview Food & Liquors, a business that sells tobacco products and is located at 4106 North Sheridan Road, Chicago, Illinois 60613.
- On September 6, 2011, an FDA-commissioned inspector observed a violation at Respondent's establishment, namely, Respondent sold cigarettes or smokeless tobacco to a person younger than 18 years of age.
- On December 8, 2011, CTP issued a Warning Letter to Respondent regarding the inspector's observations from September 6, 2011. The letter stated that the observations constituted a violation of regulations found at 21 C.F.R. § 1140.14(a) and that these regulations prohibit the sale of cigarettes or smokeless tobacco to a person younger than 18 years of age. The letter also advised Respondent that failure to correct the violations could result in the imposition of a civil money penalty or other regulatory action by FDA and that it was Respondent's responsibility to ensure compliance with the law.
- On August 16, 2012, FDA commissioned inspectors again documented a violation during a subsequent inspection of the establishment. Specifically,

a display of “Skoal” smokeless tobacco was directly accessible to customers. Since Respondent’s establishment is a convenience store that is open to the general public, thus not qualifying as a facility where minors are not permitted to enter at any time, the inspectors documented a violation for Respondent’s use of a self-service display in a non-exempt facility.

These facts establish 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. 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). 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), a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include self-service displays. However, 21 C.F.R. 1140.16(c)(2)(ii) permits facilities to use self-service displays but only if the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

Here, Respondent sold tobacco products to a minor in violation of the foregoing regulations on September 6, 2011. Most recently, on August 16, 2012, Respondent used a self-service display of smokeless tobacco in an establishment that does not restrict minors from entering. Respondent’s actions constitute violations of law for which a civil money penalty is merited. Accordingly, I find that a civil money penalty of \$250 is permissible under 21 C.F.R. § 17.2.

/s/

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Steven T. Kessel  
Administrative Law Judge