

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

T & B Holdings, LLC d/b/a Shell,

Respondent.

Docket No. C-14-161
FDA Docket No. FDA-2013-H-1381

Decision No. CR3074

Date: January 10, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) initiated the above-captioned matter when it filed an Administrative Complaint for Civil Money Penalties (Complaint) with the Departmental Appeals Board, Civil Remedies Division (CRD) and the Food and Drug Administration's (FDA) Division of Dockets Management. CTP seeks to impose civil money penalties under the Federal Food, Drug, and Cosmetic Act (Act) and the Act's implementing regulations.

The Complaint alleges the following facts. Respondent owns an establishment that sells tobacco products and is located at 2180 East Broadway Road, Tempe, Arizona 85282. Complaint ¶ 3. CTP conducted two inspections of the establishment. Complaint ¶ 9. During an inspection of Respondent's establishment, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Grizzly Long Cut Premium Mint smokeless tobacco on January 28, 2013, at approximately 9:34 AM." Complaint ¶ 10.

On February 14, 2013, CTP issued a warning letter to Respondent specifying the violations that the inspector observed. The letter warned Respondent that if it failed to correct the violations, civil money penalties could be imposed on it and that it was Respondent's responsibility to ensure compliance with the law. Complaint ¶ 10.

On February 20, 2013, Rizvi Islam, Respondent's District Manager, responded by telephone to the warning letter on Respondent's behalf. "Mr. Islam stated that the clerk checked the identification . . . [and] that the establishment would give written notice to the clerk and fire the clerk who sold the tobacco product to the minor if the clerk sold to another minor in the future." Complaint ¶ 11.

During a subsequent inspection, FDA-commissioned inspectors documented that "a person younger than 18 years of age was able to purchase a package of Marlboro 100's on May 30, 2013, at approximately 9:34 AM." Complaint ¶ 1.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on November 14, 2013, via United Parcel Service. CTP charged Respondent with violating 21 C.F.R. § 1140.14(a) (sale of tobacco products to a minor). Complaint ¶¶ 1, 10. CTP asked the CRD to impose a \$250 civil money penalty based on two alleged violations of the regulations in a 12-month period. Complaint ¶ 13.

The Complaint provided detailed instructions related to filing an answer and requesting an extension of time to file an answer. Complaint ¶¶ 14-18, 20-22. The Complaint stated that failure to file an answer could result in the imposition of a civil money penalty against Respondent. Complaint ¶ 19. Further, after CTP filed the Complaint, CRD sent Respondent an Initial Order informing Respondent of the requirement to file an answer to avoid a default judgment. CRD sent a form answer along with the Initial Order that Respondent could fill out and file with CRD. Respondent neither filed an answer nor requested an extension of time within the 30-day time period prescribed in 21 C.F.R. § 17.9.

If a respondent does not file an answer within 30 days of a properly served complaint, the regulations provide that:

[T]he presiding officer shall assume the facts alleged in the complaint to be true, and, if such facts establish liability under the relevant statute, the presiding officer shall issue an initial decision within 30 days of the time the answer was due, imposing:

- (1) The maximum amount of penalties provided for by law for the violations alleged; or
- (2) The amount asked for in the complaint, whichever amount is smaller.

