

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

J & H of Washington, Inc., d/b/a Young's Quick Stop #1,

Respondent.

Docket No. C-12-877
FDA Docket No. FDA-2012-H-0656

Decision No. CR2593

Date: August 17, 2012

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's 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 in Aberdeen, Washington that sells tobacco products. Complaint ¶ 2. CTP conducted two inspections of the establishment. Complaint ¶ 8. During the first inspection, on June 6, 2011, an FDA-commissioned inspector observed that Respondent sold cigarettes or smokeless tobacco products to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a). Complaint ¶ 10.

After the first inspection, on September 8, 2011, CTP issued a warning letter to Respondent specifying the violation that the inspector observed. The letter warned Respondent that a failure to correct the violations could result in the imposition of civil money penalties, that it was Respondent's responsibility to ensure compliance with the law, and that the letter was not intended as an exhaustive list of violations. Complaint ¶ 10. CTP did not receive a response to the warning letter. Complaint ¶ 11.

During a two-part follow-up inspection on February 23 and March 5, 2012, an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes on February 23, 2012, at approximately 10:56 AM PST." Complaint ¶ 9. In addition, the inspector observed that "the minor's identification was not verified before the sale, as detailed above, on February 23, 2012, at approximately 10:56 AM PST." Complaint ¶ 9.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on June 22, 2012, via United Parcel Service. CTP charged Respondent with violating 21 C.F.R. § 1140.14(a) (sale of tobacco products to a minor) and 21 C.F.R. § 1140.14(b)(1) (failure to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth). Complaint ¶¶ 1, 9, 10. CTP asked the CRD to impose a \$500.00 civil money penalty based on three alleged violations of the regulations in a 24-month period. Complaint ¶ 13.

Both the cover letter to the Complaint and the Complaint provided detailed instructions related to filing an answer and requesting an extension of time to file an answer. The letter and Complaint stated that failure to file an answer could result in the imposition of a civil money penalty. 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 the:

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.

21 C.F.R. § 17.11(a). Further, a failure to file a timely answer means that "respondent waives any right to a hearing and to contest the amount of penalties and assessments" imposed in the initial decision. 21 C.F.R. § 17.11(b).

