

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,

Complainant,

v.

OM SAI Krishna, Inc. d/b/a Quick Stop,

Respondent.

Docket No. C-12-787  
FDA Docket No. FDA-2012-H-0557

Decision No. CR2586

Date: August 15, 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, 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 Erie, Pennsylvania that sells tobacco products. Complaint ¶ 2. CTP conducted two inspections of Respondent's establishment and documented violations on both occasions. Complaint ¶ 8. During the first inspection on June 29, 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); [and] fail[ed] to verify by means of photographic identification, containing the bearer's date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age, as required by 21 C.F.R. § 1140.14(b)(1).

#### Complaint ¶ 10.

After the first inspection, on September 29, 2011, CTP issued a warning letter to Respondent specifying the violations that the inspector observed. Complaint ¶ 10. The letter warned Respondent that a failure to correct the violations could result in the imposition of civil money penalties and that it was Respondent's responsibility to ensure compliance with the law. In an October 3, 2011 letter, Harshna Patel, who identified herself as Respondent's owner, stated to CTP that all of Respondent's employees were trained to comply with FDA regulations and that she installed a camera system to monitor Respondent's employees. Complaint ¶ 11.

During a follow-up inspection, an FDA-commissioned inspector documented that "a person younger than 18 years of age was able to purchase a package of Newport Box 100s cigarettes on February 13, 2012, at approximately 4:24 PM" and that the minor's photographic identification was not verified before the sale. Complaint ¶ 9.

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the Complaint on June 20, 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 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 against Respondent. 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).

Accepting the facts alleged in the Complaint as true, I find that those facts establish Respondent’s liability under the Act. *See* 21 U.S.C. §§ 333(f)(9), 387c(a)(7)(B), 387f(d); 21 C.F.R. §§ 1140.1(b), 1140.14. I also find that CTP’s request to impose a \$500 civil money penalty is permissible. *See* 21 C.F.R. § 17.2.

Therefore, Respondent is directed to pay a civil money penalty in the amount of \$500.00. This initial decision becomes final and binding upon both parties within 30 days of the date of its issuance. 21 C.F.R. § 17.11(b).

It is so ordered.

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/s/  
Scott Anderson  
Administrative Law Judge