

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant,

v.

Pramukh Corporation d/b/a 7-Eleven #24057,

Respondent.

Docket No. C-12-474
FDA Docket No. FDA-2012-H-0305

Decision No. CR2549

Date: June 11, 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 Civil Remedies Division 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 Independence, Missouri that sells tobacco products. CTP conducted two inspections of the establishment since May of 2011. During a May 25, 2011 inspection, an FDA-commissioned inspector observed that Respondent "[sold] cigarettes or smokeless tobacco to a person younger than 18 years of age, in violation of 21 C.F.R. § 1140.14(a)." (Compl. ¶ 10.)

On September 1, 2011, CTP issued a warning letter to Respondent specifying the violation that the inspector observed. The letter warned Respondent that a failure to

correct violations could result in the imposition of civil money penalties and that it was Respondent's responsibility to ensure compliance with the law. (Compl. ¶ 10.) The CTP did not receive a response to the warning letter. (Compl. ¶ 11.)

During a two-part inspection on December 5 and 22, 2011, an FDA-commissioned inspector observed that "a person younger than 18 years of age was able to purchase a package of Decade Red cigarettes on December 5, 2011, at approximately 7:08 PM Central Standard Time." (Compl. ¶ 9.) CTP charged Respondent with violating 21 C.F.R. § 1140.14(a) (sale of tobacco products to a minor). *Id.* CTP asked to impose a \$250 civil money penalty based on two alleged violations of the regulations in a 12-month period. (Compl. ¶ 13.)

In compliance with 21 C.F.R. §§ 17.5 and 17.7, CTP served Respondent with the complaint on April 11, 2012, via United Parcel Service. 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. § 1140.14. I also find that CTP's request to impose a \$250 civil money penalty is permissible. *See* 75 Fed. Reg. 73,951, 73,954 (Nov. 30, 2010) (to be codified at 21 C.F.R. § 17.2).

