

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2015-H-0222)

Complainant

v.

Grewal Corporation  
d/b/a 7-Eleven 22398,

Respondent.

Docket No. C-15-1034

Decision No. CR3733

Date: March 30, 2015

**INITIAL DECISION AND DEFAULT JUDGMENT**

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Grewal Corporation d/b/a 7-Eleven 22398, at 539 Pleasant Street, Holyoke, Massachusetts 01040, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that 7-Eleven 22398 impermissibly sold cigarettes to minors and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140. CTP seeks to impose a \$5,000 civil money penalty against Respondent 7-Eleven 22398.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on January 28, 2015, CTP served the complaint on Respondent 7-Eleven 22398 by United Parcel Service. 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 in 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 it to pay the full amount of the proposed penalty.

Respondent 7-Eleven 22398 has neither filed an answer within the time prescribed, nor requested an extension of time within which to file an answer. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- CTP previously issued a warning letter to 7-Eleven 22398 on January 3, 2013, citing a violation of 21 C.F.R. pt. 1140 on December 5, 2012, at Respondent's business establishment, 539 Pleasant Street, Holyoke, Massachusetts 01040.
- On March 28, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-14-834, FDA Docket Number FDA-2014-H-0360, against Respondent for three violations of 21 C.F.R. pt. 1140 within a twenty-four month period. CTP alleged those violations to have occurred on December 5, 2012, and October 22, 2013.
- The previous action concluded when Ms. Mohinder, Respondent's authorized representative, settled the claims on Respondent's behalf. On April 25, 2014, Ms. Mohinder signed an Acknowledgment Form in which she "admitted that the violations...occurred, waiv[ed] her ability to contest the violations in the future, and stat[ed] that she understood that the violations may be counted in determining the total number of violations for purposes of future enforcement actions." The Administrative Law Judge closed the case on May 5, 2014.
- At approximately 1:56 PM on July 29, 2014, at Respondent's business establishment, 539 Pleasant Street, Holyoke, Massachusetts 01040, an FDA-commissioned inspector observed Respondent's staff selling a package of Marlboro Gold Pack 100's cigarettes to a person younger than 18 years of age. The inspector also observed that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older;

These facts establish Respondent 7-Eleven 22398's liability 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. § 387f(d); *see* 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010). The regulations prohibit the sale of tobacco products to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a).

