

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Pamela Antonetty
d/b/a Bodega 24,

Respondent.

Docket No. C-13-1159
FDA Docket No. FDA-2013-H-0952

Decision No. CR3001

Date: November 21, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, Pamela Antonetty d/b/a Bodega 24, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$10,000. Respondent failed to answer the Complaint, despite the fact that I granted her two extensions of time within which to do so. Therefore, I enter a default judgment against Respondent and assess a civil money penalty of \$10,000.

CTP began this case by serving the Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent impermissibly sold cigarettes to minors, failed to verify that cigarette purchasers were 18 years of age or older, and sold individual cigarettes, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations,

Cigarettes and Smokeless Tobacco, 21 C.F.R. Part 1140 (2012). CTP seeks a civil money penalty of \$10,000.

On August 19, 2013, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. In the Complaint and accompanying cover letter, CTP explained that within 30 days, Respondent should pay the proposed penalty, file an answer, or request an extension of time within which to file an answer. CTP warned Respondent that if it failed to take one of these actions within 30 days, an Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty.

On September 16, 2013, Respondent requested an extension of time within which to file an answer. In a September 24, 2013 Order, I granted Respondent until September 30, 2013, to file an answer and informed her that no further extension would be granted. Yet, on October 1, 2013, Respondent again requested an extension of time within which to file an answer, arguing that she sought to settle this matter with CTP but would not be able to do so before the deadline for filing an answer. In an October 24, 2013 Order, I again granted Respondent additional time within which to file an answer and ordered Respondent to file her answer no later than October 31, 2013. I specifically warned Respondent that I would not grant further extensions under any circumstances and that if she failed to file an answer by October 31, 2013, I would issue a default judgment in this case.

Respondent has not filed an answer within the ample time I have provided her. Pursuant to 21 C.F.R. § 17.11(a), I am required to “assume the facts alleged in the [C]omplaint to be true” and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Bodega 24, an establishment that sells tobacco products and is located at 154 High Street, Holyoke, Massachusetts 01040. Complaint ¶ 3.
- On April 27, 2011, an FDA-commissioned inspector observed two violations of 21 C.F.R. Part 1140 at Respondent’s establishment. The inspector observed a violation of 21 C.F.R. § 1140.14(a) due to a “[s]ale of cigarettes or smokeless tobacco to a person younger than 18 years of age . . . [.]” The inspector also observed a violation of 21 C.F.R. § 1140.14(b)(1) due to Respondent’s “[f]ailure 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” Complaint ¶ 12.

- On July 14, 2011, CTP issued a Warning Letter to Respondent regarding the inspector’s observations from April 27, 2011. The letter explained that the observations constituted violations of regulations found at 21 C.F.R. § 1140.14(a) and (b)(1), and that the named violations were not necessarily intended to be an exhaustive list of all violations at the establishment. The Warning Letter went on to state that if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent is responsible for complying with the law. Complaint ¶ 12.
- Pamela Antonetty, Respondent’s owner, replied to the Warning Letter on July 27, 2011. “Ms. Antonetty stated that any employee working behind the counter would be thoroughly trained on how to properly read identifications [and she] would require . . . employees to request photographic identification from any person under 27 years of age who purchased tobacco products.” Complaint ¶ 13.
- During a two-part inspection conducted on February 25, 2012, and February 27, 2012, FDA-commissioned inspectors documented three additional violations of 21 C.F.R. Part 1140 at Respondent’s establishment. The inspectors documented a violation of 21 C.F.R. § 1140.14(a) on February 25, 2012, when “a person younger than 18 years of age was able to purchase a package of Marlboro 100's cigarettes . . . at approximately 12:48 PM ET[.]” The inspectors documented a violation of 21 C.F.R. § 1140.14(b)(1) at the same time when “the minor's identification was not verified before the sale” Finally, the inspectors documented a violation of 21 C.F.R. § 1140.14(d) during the course of the two-part inspection because the establishment “[sold] individual cigarettes.”¹ Complaint ¶ 10.

¹ Section 1140.14(d) prohibits retailers from “*break[ing] or otherwise open[ing] any cigarette or smokeless tobacco package* to sell or distribute individual cigarettes . . . [.]” (emphasis added). Although CTP does not allege each of the elements of a violation of 21 C.F.R. § 1140.14(d), because Respondent did not answer the complaint, I will infer that each element of the violation was present.

- CTP initiated a civil money penalty action, C-12-946, against Respondent on July 11, 2012, that concluded when the Administrative Law Judge issued a default judgment against Respondent on August 31, 2012. Respondent subsequently paid the \$2,000 civil money penalty on November 14, 2012. Complaint ¶¶ 10-11.
- On October 31, 2012, FDA-commissioned inspectors documented two more violations of 21 C.F.R. Part 1140 at Respondent's establishment. The inspectors documented a violation of 21 C.F.R. § 1140.14(a) when "a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes . . . at approximately 2:21 PM ET[.]" The inspectors documented a violation of 21 C.F.R. § 1140.14(b)(1) when "the minor's identification was not verified before the sale" Complaint ¶ 1.

These facts establish that Respondent is liable under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Secretary issued the regulations at 21 C.F.R. Part 1140 under section 906(d) of the Act. 21 U.S.C. § 387(a); 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,229 (Mar. 10, 2010). The regulations prohibit the sale of cigarettes to any person younger than 18 years of age. 21 C.F.R. § 1140.14(a). The regulations also require retailers to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Finally, the regulations prohibit retailers from opening packages of cigarettes in order to sell individual cigarettes. 21 C.F.R. § 1140.14(d).

Taking the above alleged facts as true, Respondent had seven violations of regulations contained in 21 C.F.R. Part 1140 within an eighteen-month period. Specifically, Respondent had two violations on April 27, 2011, two violations on February 25, 2012, one violation during the course of a two-part inspection on February 25, 2012, and February 27, 2012, and two violations on October 31, 2012. Respondent's actions on April 27, 2011, February 25, 2012, and on October 31, 2012, violated the prohibition against selling cigarettes to persons younger than 18 years of age. 21 C.F.R. § 1140.14(a). Respondent's actions on April 27, 2011, February 25, 2012, and on October 31, 2012, also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age. 21 C.F.R. § 1140.14(b)(1). Finally, Respondent's actions during a two-part inspection conducted on February 25, 2012, and February 27, 2012, also violated the prohibition against opening a package of cigarettes in order to sell individual

cigarettes. 21 C.F.R. § 1140.14(d). Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

The regulations require me to impose a civil money penalty in an amount that is either the maximum provided for by law or the amount sought in the Complaint, whichever is smaller. 21 C.F.R. § 17.11(a)(1)-(2). The regulations currently allow a maximum penalty of \$10,000 for a seventh violation within an eighteen-month period, 21 C.F.R. § 17.2, and CTP has requested a fine of that amount. Therefore, I find that a civil money penalty of \$10,000 is warranted and so order one imposed.

/s/

Steven T. Kessel
Administrative Law Judge