

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

IM Woodmoor, Inc. / Imran Uddin
d/b/a Woodmoor Shell,

Respondent.

Docket No. C-15-1056
(FDA No. FDA-2015-H-0232)

Decision No. CR3726

Date: March 25, 2015

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, IM Woodmoor, Inc./Imran Uddin d/b/a Woodmoor Shell, that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$2,000. Respondent did not answer the Complaint, nor did Respondent request an extension of time within which to file an answer. Therefore, I enter a default judgment against Respondent and assess a civil money penalty of \$2,000.

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 a minor, 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. pt. 1140 (2013). CTP seeks a civil money penalty of \$2,000.

On January 29, 2015, 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.

Respondent has not filed an answer within the time provided by regulation, nor has it requested an extension. 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 Woodmoor Shell, an establishment that sells tobacco products and is located at 10144 Colesville Road, Silver Spring, Maryland 20901. Complaint ¶ 3.
- CTP previously issued a warning letter to Respondent Woodmoor Shell on October 17, 2013, citing a violation on August 21, 2013, and stating that failure to correct the violations may result in a civil money penalty action. Complaint ¶ 10.
- On May 27, 2014, CTP initiated a previous civil money penalty action, CRD Docket Number 14-1172, FDA Docket Number FDA-2014-H-0677 against Respondent for three violations of 21 C.F.R. Part 1140 within a 24-month period. CTP alleged those violations to have occurred on October 17, 2013, and January 4, 2014. Complaint ¶ 10.
- The previous action concluded when Imran Udin, Respondent’s authorized representative, settled the claims on Respondent’s behalf. On July 9, 2014, Mr. Udin signed an Acknowledgement Form in which he “admit[ed] that the violations...occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he understood that the violations may be counted in determining the total number of violations for purposes of future actions.” The Administrative Law Judge closed the case on July 31, 2014. Complaint ¶ 11.
- At approximately 11:17 a.m. on August 15, 2014, at Respondent’s business establishment, 10144 Colesville Road, Silver Springs, Maryland 20901, FDA-commissioned inspectors documented that a person younger than 18 years of age was able to purchase a package of Newport Box cigarettes. Complaint ¶ 1.

These facts establish Respondent Woodmoor Shell'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). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes to any person younger than 18 years of age.

Taking the above alleged facts as true, Respondent violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), on August 15, 2014. Therefore, Respondent's actions constitute violations of law that merit a civil money penalty.

CTP has requested a fine of \$2,000, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil money penalty of \$2,000 is warranted and so order one imposed.

 /s/
Steven T. Kessel
Administrative Law Judge