Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

New Hop Poh Kitchen LLC,

Respondent.

Docket No. C-13-516 FDA Docket No. FDA-2013-H-0277

Decision No. CR2767

Date: April 29, 2013

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, New Hop Poh Kitchen LLC, alleging facts and legal authority sufficient to justify the imposition of a civil money penalty of \$2,000. Respondent did not timely 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 order that Respondent pay a civil money penalty in the amount of \$2,000.

CTP began this case by serving a 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 individual cigarettes in its establishment, impermissibly sold cigarettes to a minor in the establishment, and failed to appropriately verify the age of a person purchasing cigarettes, thereby violating the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations found at 21 C.F.R. Part 1140. CTP seeks a civil money penalty of \$2,000.

On March 15, 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 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, the 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 did not take one of the required actions within the time provided by regulation.

I am required to issue a default judgment if the Complaint is sufficient to justify a penalty, and the Respondent fails to answer timely or to request an extension. 21 C.F.R. § 17.11(a). For that reason, I must decide whether a default judgment is appropriate here, and I conclude that it is merited based on the allegations of the Complaint and Respondent's failure to answer them.

For purposes of this decision, I assume the facts alleged in the Complaint are true. 21 C.F.R. § 17.11(a). Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns New Hop Poh Kitchen, a business that sells tobacco products and is located at 49 Central Avenue, Orange, New Jersey -07050.
- On April 17, 2012, an FDA-commissioned inspector observed a violation at Respondent's establishment for selling individual cigarettes.
- On July 19, 2012, CTP issued a Warning Letter to New Hop Poh Kitchen regarding the inspector's observations from April 17, 2012. The letter stated that Respondent violated 21 C.F.R. § 1140.14(d) by selling individual cigarettes in the establishment. The letter also advised Respondent that if it failed to correct the violation, the FDA may impose a civil money penalty or take other regulatory action.
- On July 27, 2012, Chen Xiu Juan, site manager of Respondent's
 establishment, responded, in writing, to CTP's Warning Letter on behalf of
 Respondent. He stated that all tobacco products would be removed
 immediately from the establishment and that tobacco products no longer
 would be sold at the establishment.
- On October 23, 2012, CTP acknowledged, in writing, receipt of the establishment's response and reminded Respondent of its continuing obligation to be in compliance with the law.

On December 17, 2012, FDA-commissioned inspectors documented additional violations during a subsequent inspection of the establishment. Specifically, a person younger than 18 years of age was able to purchase two individual "Newport" cigarettes at approximately 4:21 p.m. Additionally, the minor's identification was not verified, by means of photographic identification containing the bearer's date of birth, before this sale.

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 sold or distributed 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). Under 21 C.F.R. § 1140.14(a), no retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), a retailer must verify, by means of photo identification containing the bearer's date of birth, that no person purchasing cigarettes or smokeless tobacco is younger than 18 years of age. Under 21 C.F.R. § 1140.14 (d), no retailer may break or otherwise open any cigarette package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size of 20 cigarettes. *See also* 21 C.F.R. § 1140.16(b).

Here, Respondent sold individual cigarettes in violation of the foregoing regulations on two separate occasions, April 17, 2012, and December 17, 2012. In addition, Respondent sold cigarettes to a minor on December 17, 2012, and did not appropriately check the photographic identification of the cigarette purchaser prior to the transaction. Respondent's actions and omissions on two separate occasions at the same retail outlet constitute violations of law for which a civil money penalty is merited. Accordingly, I find that a civil money penalty of \$2,000 is permissible under 21 C.F.R. § 17.2.

/s/ Steven T. Kessel

Administrative Law Judge