

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

Mei Juan You
d/b/a Hunan Garden,

Respondent.

Docket No. C-15-2617
FDA Docket No. FDA-2015-H-1753

Decision No. CR4727

Date: November 8, 2016

INITIAL DECISION

I sustain the determination of the Centers for Tobacco Products of the United States Food and Drug Administration (CTP) to impose a civil money penalty of \$11,000 against Respondent, Mei Juan You, d/b/a Hunan Garden. The preponderance of the evidence establishes that Respondent sold tobacco products to minors, failed to verify the purchaser's identification, and sold individual cigarettes during a forty-eight month period in violation of 21 C.F.R. §§ 1140.14(a), 1140.14(b)(1), and 1140.14(d). These actions were violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 387c(a)(7)(B).

I. Procedural History

Respondent requested a hearing in order to challenge CTP's determination to impose an \$11,000 civil money penalty against her. CTP filed a brief plus ten proposed exhibits that are identified as CTP Ex. 1 - CTP Ex. 10. Respondent filed neither exhibits nor a brief, but requested an in-person hearing in order to cross-examine CTP's witnesses.

I convened an in-person hearing on February 8, 2016. Respondent had advised me that she could not speak English, so I obtained an interpreter of Mandarin Chinese for that hearing. However, at the hearing, Respondent also averred that she could not read English. I therefore adjourned the hearing in order to translate all of CTP's proposed exhibits into Mandarin Chinese.

I reconvened the hearing on September 14, 2016 after having the exhibits translated. At this hearing Respondent appeared with an individual who identified himself as Mr. Chen. Mr. Chen was uncertain as to whether he would represent Respondent. He subsequently advised me that he was not Respondent's representative. Therefore, I consider Respondent to have appeared pro se. At the September 14, 2016 hearing Respondent did not object to the admission of any of CTP's proposed exhibits and declined to cross-examine CTP's witnesses. I received into evidence CTP Ex. 1 - CTP Ex. 10.

Neither party filed a post-hearing brief.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues are whether:

1. Respondent violated regulations governing the sale of tobacco products to minors;
2. A civil money penalty of \$11,000 is reasonable.

B. Findings of Fact and Conclusions of Law

There is no dispute in this case that Respondent is a business that sells tobacco products to the general public.

CTP determined to impose a civil money penalty against Respondent pursuant to the authority conferred by the Federal Food, Drug, and Cosmetic Act (Act) and implementing regulations at Part 21 of the Code of Federal Regulations (C.F.R.).

The Act prohibits the misbranding of tobacco products while they are held for sale after shipment in interstate commerce. 21 U.S.C. § 331(k). FDA and its agency, CTP, may seek civil money penalties from any person who violates the Act's requirements as they relate to the sale of tobacco products. 21 U.S.C. § 331(f)(9). The sale of tobacco products to an individual who is under the age of 18 and the failure to verify the photographic identification of an individual who is not over the age of 26 are violations of implementing regulations. 21 C.F.R. §§ 1140.14(a), (b)(1). Additionally, the sale of "single cigarettes" – cigarettes that are sold individually from an open package of cigarettes – is a violation of 21 C.F.R. § 1140.14(d).

The alleged violations that are at issue here are not the first instance in which Respondent was charged with violating law and regulations concerning the sale of tobacco products. CTP filed a previous administrative complaint against Respondent on October 14, 2014, alleging that Respondent: on June 14, 2014 unlawfully sold tobacco products to a minor and failed to verify the minor purchaser's age by means of photographic identification; and on December 9, 2013 unlawfully sold a single cigarette to a minor and failed to verify the minor's age on that date. CTP Ex. 1. On November 9, 2014, Respondent admitted to the allegations in the October 14, 2014 complaint and waived her right to contest those violations in the future. These previous allegations of noncompliance are administratively final and are not subject to challenge by Respondent.

What remains at issue are additional allegations of noncompliance made by CTP. CTP alleges that on February 8, 2015, Respondent sold tobacco products consisting of three single cigarettes to a minor and that Respondent failed to check the minor's identification on that date. These allegations, if true, constitute three additional violations of law: unlawful sale of tobacco products to a minor in violation of 42 C.F.R. § 1140.14(a); failure to check the identification of an underage purchaser in violation of 42 C.F.R. § 1140.14(b); and unlawful sale of single cigarettes from an opened package in violation of 42 C.F.R. § 1140.14(d).

The evidence relied on by CTP consists of the testimony of an inspector, Tonya Ahmed, plus a photograph of three individual cigarettes. CTP Ex. 4; CTP Ex. 5. Ms. Ahmed testified that she accompanied a minor to Petitioner's facility on February 8, 2015. There, she personally observed a clerk sell three individual Newport cigarettes to the minor. CTP Ex. 4 at 2-3. Ms. Ahmed averred that she subsequently photographed the cigarettes purchased by the minor and that CTP Ex. 5 is an accurate photograph of those cigarettes. *Id.*; CTP Ex. 5.

On its face this evidence is more than sufficient to prove that Respondent violated the law on February 8, 2015. Respondent offered nothing by way of rebuttal.

