

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2015-H-1193)

Complainant

v.

Phero and Anna, Inc.
d/b/a Lone Star Market 2,

Respondent.

Docket No. C-15-2023

Decision No. CR4737

Date: November 21, 2016

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Phero and Anna, Inc. d/b/a Lone Star Market 2, located at 5758 Greenwood Drive, Corpus Christi, Texas 78417, for five violations of 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, within a thirty-six month period. Specifically, CTP alleges that Lone Star Market 2 violated the Act by impermissibly selling tobacco products to minors, on three separate occasions, and failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, on three separate occasions.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$5,000 civil money penalty on Respondent Lone Star Market 2, at 5758 Greenwood Drive, Corpus Christi, Texas 78417, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. Respondent timely answered CTP's complaint. In its answer, Respondent denied the allegations. On June 3, 2015, I issued an Acknowledgement and Prehearing Order (APHO) that set deadlines for the parties to file their pre-hearing exchanges.

CTP filed its pre-hearing exchange on May 10, 2016. CTP's pre-hearing exchange included the declarations of two witnesses. Respondent filed its pre-hearing exchange on May 31, 2016. Respondent provided the declarations of four witnesses.

On August 2, 2016, I held a pre-hearing conference in this case. Following the pre-hearing conference, I issued an Order that scheduled the hearing for September 22, 2016. That Order noted that during the pre-hearing conference, Respondent's counsel indicated that he wanted to cross examine one of CTP's witnesses, Inspector Juan Garcia. The Order further noted that CTP indicated that it did not want to cross examine any of Respondent's witnesses.

On August 9, 2016, Respondent filed a Motion for Summary Decision and to Strike Inspector Garcia's testimony. CTP filed a response on August 24, 2016. I issued an Order on August 25, 2016, denying Respondent's Motion.

On September 22, 2016, a hearing was held in this case. The purpose of the hearing was to allow Respondent to cross examine Inspector Juan F. Garcia.

On an October 12, 2016, I informed the parties that the Court had received the transcript of the hearing, and set the deadline for the parties' post-hearing brief submissions as November 14, 2016. Both parties filed post-hearing briefs.

Analysis

I. Violations

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. 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).

In its Complaint, CTP alleges that Respondent Lone Star Market 2 committed five violations of the Act and its implementing regulations within a thirty-six month period. Lone Star Market 2 filed an answer, and informal brief, that denied selling a tobacco product to a minor. Answer; Informal Brief of Respondent.

The matter currently before me involves one prior complaint. The prior complaint was settled by the parties and closed on October 20, 2014. In settling the complaint, the Respondent admitted the violations occurred, waived the ability to contest the violations in the future, and stated that it understood that the admitted to violations may be counted in determining the total number of violations for future enforcement actions. Complaint; Informal Brief of Complainant. The current Complaint involves two new violations: impermissibly selling cigarettes to a minor, and failing to verify, by means of photo identification containing a date of birth, that the purchaser was 18 years of age or older.

CTP's case against Respondent rests on the testimony of Mr. Garcia plus corroborating evidence. CTP Ex. 4. Mr. Garcia is an FDA-commissioned officer whose duties include determining whether retail outlets are unlawfully selling tobacco products to minors. *Id.* at 1-2. Mr. Garcia's inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.*

Mr. Garcia testified that he went to Respondent's place of business on November 9, 2014. CTP Ex. 4 at 2-3. Mr. Garcia further testified that on November 9, 2014, he confirmed that the minor was carrying her photographic identification, and that she did not have tobacco products in her possession. Mr. Garcia testified that the minor entered the establishment and went directly to the sales counter. Mr. Garcia explained that he stood in an area of the store with a clear view of the sales counter. Mr. Garcia stated that he saw the minor purchase a package of cigarettes from an employee of Respondent, and that the minor did not provide photographic identification to the employee, and that the employee did not provide the minor with a receipt after purchase. *Id.*

Mr. Garcia stated that after the purchase, the minor and he both exited the store and returned to his vehicle, where the minor immediately gave him the pack of cigarettes. The cigarettes were observed to be a package of Marlboro cigarettes. CTP Ex. 4 at 3. Mr. Garcia testified that he then labeled the cigarettes as

evidence, and took photographs of the package. *Id.* at 3, 12-13. Mr. Garcia testified that shortly after the inspection he recorded the inspection in the FDA's Tobacco Inspection Management System. *Id.* at 3.

Mr. Garcia's testimony plus the corroborating evidence consisting of photographs of the pack of cigarettes that he obtained from the minor on November 9, 2014, are proof that Respondent unlawfully sold a tobacco product to a minor, and failed to check the minor's identification before making the sale.

Throughout the case Respondent's counsel has asserted that there were other customers in the store at the time of the purchase and that the store owner, Mr. Loubani, personally knew Mr. Garcia. The inference being that because Mr. Loubani knew Mr. Garcia he would not have sold cigarettes to a minor in his presence. Respondent's counsel further argued at hearing that any testimony from Mr. Garcia should be stricken as hearsay. In addition to Mr. Loubani's testimony, Respondent offered the testimony of Ms. Grande, Mr. Gutierrez, and Ms. Young.

In its post-hearing brief, Respondent again asserts Mr. Garcia's testimony should be stricken as hearsay and that Mr. Loubani would not have sold cigarettes to Mr. Garcia as he knew him to be a tobacco inspector. Respondent further argues that Mr. Garcia's reliance on the minor's driver's license and birth certificate is misplaced and that additional effort should have been made to verify the veracity of these documents.

CTP's post-hearing brief asserts that Mr. Garcia's testimony should not be considered hearsay and that the witness statements submitted by Respondent were irrelevant to the issues at hand.

I find that although Inspector Garcia did not verify the birth certificate or driver's license with the state authorities, the method he used to verify their authenticity was sufficient. Mr. Garcia examined the documents and compared the photo on the license with the minor. Mr. Garcia testified that he was familiar with these types of documents. I find that his assumption of validity was reasonable – especially in the absence of any evidence to the contrary. I similarly find that Respondent's assertion that he knew Mr. Garcia and would not have sold cigarettes to a minor in his presence is unpersuasive. Mr. Garcia's testimony is that the minor entered the store without cigarettes. As a result, the only reasonable explanation that I can find for her emerging from the store with cigarettes is that she purchased them in the store. The evidence that she made such a purchase is supported by Mr. Garcia's testimony plus corroborating evidence. The witness statements submitted by Respondent indicating that Respondent has a policy in place against selling cigarettes to minors and that Respondent has not sold

cigarettes in the past is not sufficient to establish that the sale to a minor did not occur on November 9, 2014.

Respondent's request that Mr. Garcia's testimony be stricken as hearsay is denied. Under 21 C.F.R. Part 17, the Administrative Law Judge determines the admissibility of evidence and has discretion to apply the Federal Rules of Evidence when deemed appropriate. However, the Federal Rules of Evidence are not controlling in an administrative hearing. Mr. Garcia personally witnessed the sale and observed the minor enter Respondent's establishment without cigarettes and subsequently leave the store with cigarettes in hand. That testimony, plus the corroborating evidence, leads to the inference that the minor could only have obtained cigarettes by purchasing them at Respondent's business establishment.

I find that these facts establish Respondent Phero and Anna, Inc. d/b/a Lone Star Market 2's liability under the Act.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Lone Star Market 2 is liable for a civil money penalty not to exceed the amounts listed in FDA's civil money penalty regulations at 21 C.F.R. § 17.2. In its Complaint, CTP sought to impose the maximum penalty amount, \$5,000, against Respondent for five violations of the Act and its implementing regulations within a thirty-six month period. Complaint ¶ 13. In its Informal Brief, CTP continues to assert that a \$5,000 civil money penalty is appropriate. Informal Brief of Complainant at 9-11.

In both its Answer and its Informal Brief, Respondent denied any obligation to pay a civil money penalty because it did not violate the regulations. However, the parties previously agreed in a December 14, 2015, stipulation that Respondent had the ability to pay the \$5,000 civil money penalty.

I have found that Respondent committed five violations of the Act and its implementing regulations within a thirty-six month period. When determining the amount of a civil money penalty, I am required to take into account "the nature, circumstances, extent and gravity of the violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require." 21 U.S.C. § 303(f)(5)(B). Respondent has not provided any arguments with regards to the nature, circumstances, extent and gravity of the violations, any history of prior such violations, the degree of culpability, etc. Instead, Respondent's sole argument has been that it should not have to pay a civil money penalty because it did not commit the violations.

i. Nature, Circumstances, Extent and Gravity of the Violations

Time and again, Respondent Lone Star Market 2 has failed to comply with the Act and its implementing regulations. Over the course of the five violations discussed in this Complaint, Respondent has admitted to three violations, and I have found that Respondent committed the two most recent violations; specifically Respondent has committed: three violations of selling tobacco products to minors, and two violations for failing to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the civil money penalty amount should be set accordingly.

ii. Respondent's Ability to Pay And Effect on Ability to do Business

As noted above, Respondent previously stipulated that it has the ability to pay the \$5,000 civil money penalty.

iii. History of Prior Violations

The current action is the second civil money penalty action brought against Respondent since September 2, 2014 for violations of the Act and its implementing regulations. In the first civil money penalty action, CRD Docket Number C-14-1705, FDA Docket Number FDA-2014-H-1189, Respondent twice violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a), and violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(b)(1). Respondent settled the prior complaint with CTP for an undisclosed penalty amount.

I agree with CTP that “[t]hese repeat violations show an unwillingness or inability to sell tobacco products in accordance with federal tobacco regulations.” Informal Brief at 11. While Respondent has already paid a civil money penalty for its previous violations, its continued inability to comply with the federal tobacco regulations calls for a more severe penalty.

iv. Degree of Culpability

Respondent Lone Star Market 2 admitted to three violations. Based on my finding that Respondent committed the two most recent violations in the current complaint, I hold it fully culpable for all five violations of the Act and its implementing regulations.

