

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-3074)

Complainant

v.

Red Sea Service Station, Inc.
d/b/a ARCO AM/PM,

Respondent.

Docket No. T-17-4

Decision No. TB2369

Date: January 16, 2018

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Red Sea Service Station, Inc. d/b/a ARCO AM/PM, located at 3201 20th Avenue West, Seattle, Washington 98199, for two 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 twelve month period. Specifically, CTP alleges that Respondent violated the Act by impermissibly selling cigarettes to minors, on two separate occasions.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$275 civil money penalty on Respondent, at 3201 20th Avenue West, Seattle, Washington 98199, 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 November 16, 2016, I issued an Acknowledgment and Pre-Hearing Order (APHO).

On February 1, 2017, CTP filed a Motion to Compel Further Responses, indicating that Respondent had not produced all of the documents in its request for production of documents, except for a brief letter, receipts, and a sales log. *See* 21 C.F.R. § 17.23(a). In a letter issued by my direction, Respondent was given until February 17, 2017, to object to CTP's motion. Respondent did not file an objection to CTP's motion. On February 28, 2017, I issued an Order granting CTP's Motion to Compel Further Responses and extended the pre-hearing exchange deadlines for 30 days. On March 21, 2017, CTP filed an Updated Status Report, indicating that CTP had received certain documents from Respondent in response to CTP's Request for Production of Documents.

Respondent filed its pre-hearing exchange on December 5, 2016. Subsequently, on April 7, 2017, CTP filed its pre-hearing exchange. On June 15, 2017, I held a pre-hearing conference in this case.¹ During the pre-hearing conference, Respondent stated that it wanted to cross examine the inspector involved in the inspections of its establishment. Following the pre-hearing conference, I issued an Order Scheduling Telephone Hearing for August 23, 2017, noting that Respondent wished to cross examine Inspector Ilya Kluchnikov.

On August 23, 2017, a hearing was held in this case. The purpose of the hearing was to allow Respondent to cross examine Inspector Ilya Kluchnikov. During the hearing, CTP's exhibits 1 through 21 were admitted into the record without objection. Hearing Transcript at 7. On October 4, 2017, 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 3, 2017. On October 27, 2017, CTP filed a Notice of Waiver of Post-Hearing Brief, indicating that it did not intend to file a post-hearing brief. On November 1, 2017, Respondent filed a letter, which I will treat as a post-hearing brief.

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

¹ A previously scheduled pre-hearing conference for June 1, 2017 was rescheduled due to a religious holiday.

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 cigarettes to an individual who is under the age of 18 is a violation of implementing regulations. 21 C.F.R. § 1140.14(a)(1)².

In its Complaint, CTP alleges that Respondent committed two violations of the Act and its implementing regulations within a twelve month period. Respondent filed an answer along with a transaction report and an informal brief, denying that cigarettes were sold to a minor. Answer; Informal Brief of Respondent. Specifically, Respondent argues that no cigarettes were sold during the time period alleged by CTP and that CTP should provide a receipt. *Id.*

CTP's case against Respondent rests on the testimony of Mr. Kluchnikov plus corroborating evidence. CTP Exhibits (Exs.) 4, 5, 8, 15. Mr. Kluchnikov is an FDA-commissioned officer with the state of Washington whose duties include determining whether retail outlets are unlawfully selling tobacco products to minors. CTP Ex. 4 at 1-2. Mr. Kluchnikov's inspections entail accompanying minors who attempt to purchase tobacco products from retail establishments such as the one operated by Respondent. *Id.*

Mr. Kluchnikov's declaration states that he conducted inspections of Respondent's place of business on January 8, 2016 and March 19, 2016. CTP Ex. 4 at 2-4. On cross-examination, Mr. Kluchnikov testified that he observed the cashier scanning cigarettes for the minor. Hearing Transcript at 11. Mr. Kluchnikov further testified that he did not ask for a receipt because it is not a standard practice. *Id.* at 13. Additionally, Mr. Kluchnikov testified that:

I do a very thorough post-inspection review. I make sure to have the correct address. I review all of the documents. I fill out a statement based on where I am. The minor as well fills out a statement of where they are. I know that the location that I went to is the location that I went to at the end of the inspection.

Id. at 14.

The testimony of Mr. Kluchnikov plus the corroborating evidence consisting of photographs of the packs of cigarettes that were obtained from each minor on January 8, 2016 and March 19, 2016, are proof that Respondent unlawfully sold

² On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

cigarettes to minors. Throughout the case, Respondent has denied that the sale of cigarettes to minors occurred and has argued that there is insufficient proof because there are no receipts for the purchases. Answer; Informal Brief of Respondent.

I have considered Respondent's arguments, but find them unpersuasive. Respondent has continued to assert that the sale of cigarettes to minors never occurred. Although the transaction report submitted by Respondent does not show a sale of tobacco products during the approximate time frame alleged in CTP's complaint on March 19, 2016, this report alone is not sufficient to rebut the allegations. Additionally, there is no provision in the applicable regulations requiring proof of purchase in the form of a cash register receipt. The evidence of record sufficiently identifies the cashiers who made the sales to the minors, and the sworn testimony of the Inspector establishes to my satisfaction that the violations charged in this case in fact took place on the dates in question.

I find that the facts as outlined above establish Respondent Red Sea Service Station, Inc. d/b/a ARCO AM/PM's liability under the Act.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Red Sea Service Station, Inc. d/b/a ARCO AM/PM 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, \$275, against Respondent for two violations of the Act and its implementing regulations within a twelve month period. Complaint ¶ 1.

In both its Answer and its Post-Hearing Brief, Respondent denied any obligation to pay a civil money penalty because there is insufficient proof it violated the regulations.

I have found that Respondent committed two violations of the Act and its implementing regulations within a twelve 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. § 333(f)(5)(B).

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

I have found that Respondent committed two violations of selling cigarettes to minors. 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

Respondent has not presented any evidence that it does not have the ability to pay the \$275 Civil Money Penalty sought by CTP.

iii. History of Prior Violations

The current action is the first civil money penalty action brought against Respondent for violations of the Act and its implementing regulations. As noted above, Respondent has twice violated the prohibition against selling cigarettes to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1).

iv. Degree of Culpability

Based on my finding that Respondent committed the two violations in the Complaint, I hold it fully culpable for two violations of the Act and its implementing regulations.

v. Additional Mitigating Factors

Respondent has not presented any evidence to mitigate the civil money penalty amount. As such, I find no reason to mitigate the penalty amount.

vi. Penalty

Based on the foregoing reasoning, I find a penalty amount of \$275 to be appropriate under 21 U.S.C. §§ 333(f)(5)(B) and 333(f)(9).

Conclusion

Pursuant to 21 C.F.R. § 17.45, I enter judgment in the amount of \$275 against Respondent, Red Sea Service Station, Inc. d/b/a ARCO AM/PM, for two 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 twelve month period.

/s/

Catherine Ravinski
Administrative Law Judge