

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-3496)

Complainant

v.

Village One Stop, Inc.
d/b/a Village One Stop,

Respondent.

Docket No. T-17-464

Decision No. TB1469

Date June 15, 2017

INITIAL DECISION

The Center for Tobacco Products (CTP) seeks to impose a civil money penalty against Respondent, Village One Stop, Inc. d/b/a Village One Stop, located at 143 Clark Avenue South, Kelliher, Minnesota 56650, for three 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 twenty-four month period. Specifically, CTP alleges that Respondent violated the Act by impermissibly selling tobacco products to minors, on two 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 two separate occasions.

Procedural History

CTP began this matter by serving an administrative complaint seeking a \$550 civil money penalty on Respondent, at 143 Clark Avenue South, Kelliher, Minnesota

56650, 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 admitted to all of the violations as alleged in the complaint.

CTP filed its pre-hearing exchange on April 24, 2017. CTP's pre-hearing exchange included the declarations of two witnesses. Respondent did not file a pre-hearing exchange.

On June 1, 2017, I held a pre-hearing conference in this case. I explained to the parties that the sole purpose of an administrative hearing under the applicable regulations is to afford the parties an opportunity for cross-examination of exchange witnesses. Respondent declined to cross examine either of CTP's witnesses, including Inspector Mark Baetsch, who conducted both of the inspections in this case. Respondent stated Inspector Baetsch did nothing wrong during the inspections and does not dispute the findings in the inspector's report.

During the prehearing conference, Respondent again admitted to all of the violations alleged in the complaint. However, Respondent objected to being charged with more than two violations. Respondent stated that it is excessive to charge it with more than one violation per inspection. Respondent believes it should only be liable for two violations as there were only two inspections conducted.

I advised the parties that the applicable regulations provide otherwise. I informed Respondent that in accordance with customary practice, CTP counts the violations at the initial inspection as a single violation, and all subsequent violations as separate individual violations.

I notified the parties that a hearing would not be required in this matter and I would make a decision based on the evidence of record. The parties had no objections to the exhibits in the record, and they are now received and admitted into evidence. I also informed the parties that the decision, along with the parties' appeal rights, would be issued and sent to the parties, who could then appeal the decision to the Departmental Appeals Board (Board) if desired.

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)(1), (a)(2)(i).

In its Complaint, CTP alleges that Respondent committed three violations of the Act and its implementing regulations within a twenty-four month period. Specifically, CTP alleges that Respondent sold tobacco products to a minor on January 12, 2016 and April 16, 2016. On those same dates, CTP also alleges that Respondent failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older.

The facts of this case are not in dispute. As stated above, Respondent admitted to all of the violations as alleged in the Complaint. Respondent's Answer. However, in its answer, Respondent stated it "would like to appeal the number of violations being associated with these offenses" and requested "these two events to be classified as two violations." *Id.* Respondent contends that it is "currently being charged with three violations for the two dates . . . [t]he civil money penalty for number of violations increases both in dollar amount and length of period." *Id.* Respondent reiterated its argument during the prehearing conference but did not offer any justification to support its argument.

I have given due consideration to Respondent's argument regarding the method by which CTP calculates the number of violations committed. Respondent essentially argues that CTP should be limited to charging retailers with only one violation per inspection. I disagree.

In *CTP v. Orton Motor Company*, DAB No. 2717 (2016), the Board held that CTP has the authority to increase the CMP amounts based on the total number violations and the time frame over which they occur.

Though the regulations provide a context for determining what constitutes an act of misbranding, they do not mandate how such acts are to be counted for purposes of calculating the applicable CMP amount. *Id.* at 11. This leaves CTP with discretion to make this determination so long as its approach is not inconsistent with the regulations. *Id.* The Board found nothing in the regulations that prohibit CTP from treating multiple acts of misbranding as violations for CMP purposes regardless of whether they occurred in the course of one or many inspections or transactions. *Id.* CTP may rationally determine that those retailers whose acts

violate multiple distinct requirements should be subject to increasing penalties in order to encourage more careful compliance with each of the different requirements. *Id* at 17.

Thus, CTP's method of calculating the number of violations is permissible under the applicable regulations. As a result, I find that the facts as outlined above establish Respondent Village One Stop, Inc. d/b/a Village One Stop's liable for three (3) violations under the Act.

II. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Village One Stop, Inc. d/b/a Village One Stop 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, \$550, against Respondent for three violations of the Act and its implementing regulations within a twenty-four month period. Complaint ¶ 1-2.

I have found that Respondent committed three violations of the Act and its implementing regulations within a twenty-four 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 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

Respondent has not presented any evidence that it does not have the ability to pay the \$550 Civil Money Penalty sought by CTP.

