

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Center for Tobacco Products,  
(FDA No. FDA-2018-R-1430)

Complainant,

v.

1701 Express, Inc.  
d/b/a Citgo,

Respondent.

Docket No. T-18-1877

Decision No. TB4019

Date: June 27, 2019

**INITIAL DECISION**

I impose a No-Tobacco-Sale Order (NTSO) against Respondent, 1701 Express, Inc. d/b/a Citgo, for a period of 30 consecutive calendar days based on Respondent's repeated violations of federal tobacco regulations over a period of 36 months.

**I. Background**

I held an in-person hearing in this case, by telephone, on February 14, 2019. At the hearing, I received into evidence exhibits offered by the Center for Tobacco Products (CTP) that it identified as CTP Exhibit (Ex.) 1-CTP Ex. 14. Transcript (Tr.) 5-6. I received into evidence exhibits offered by Respondent that it identified as R. Ex. 1-R. Ex. 10. Tr. 5.

## II. Issues, Findings of Fact and Conclusions of Law

### A. Issues

The issues presently before me are whether Respondent committed violations of federal tobacco regulations and whether an NTSO of 30 consecutive calendar days' duration is a reasonable remedy.

### B. Findings of Fact and Conclusions of Law

CTP asserts that I should impose an NTSO 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). The Food and Drug Administration (FDA) and its agency, CTP, may seek the imposition of remedies against 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).<sup>1</sup>

Remedies may consist of civil money penalties and NTSOs. NTSOs are authorized at 21 U.S.C. § 333(f)(8). The section allows for the imposition of an NTSO against a person who has committed "repeated violations" of restrictions on the sale of tobacco products. The term "repeated violations" is defined to mean "at least 5 violations of particular requirements over a 36-month period at a particular retail outlet . . . ." 21 U.S.C. § 333 note.

The Act establishes factors that must be considered in deciding on the length of an NTSO, but it does not identify specific NTSO time periods:

In determining the . . . period to be covered by a no-tobacco-sale order, the Secretary shall take into account the nature, circumstances, extent, and gravity of the . . . violations and, with respect to the violator, . . . 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 . . . .

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<sup>1</sup> On August 8, 2016, the citations to certain tobacco violations changed. For more information see: <https://federalregister.gov/a/2016-10685>.

21 U.S.C. § 333(f)(5)(B); *see also Kat Party Store, Inc. d/b/a Mr. Grocer Liquor Store*, DAB TB509, at 2 (2016).

CTP developed policy guidelines that establish maximum NTSO durations. For a first NTSO, CTP recommends that the maximum duration be 30 calendar days. *See Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with an Order: Guidance for Tobacco Retailers*, at 4 (Aug. 2015) available at <http://www.fda.gov/media/93328/download>. CTP's policy is to, in general, seek the maximum duration for an NTSO established by the guidelines. It explains its rationale for establishing these recommended maximum NTSO durations as follows:

First, if there are grounds for imposing an NTSO, the retailer has already engaged in repeated violations of the law and regulations restricting the sale and distribution of tobacco products, and therefore has a prior history of violations. Second, the restrictions codified in part 1140 [of the regulations] are intended to protect the public health, especially children and adolescents, and FDA therefore considers repeated violations of these restrictions to be very serious. Nearly 9 out of 10 adult daily smokers smoked their first cigarette by age 18 (87 percent). If the current trajectory of smoking rates continues, 5.6 million children alive today will die prematurely as a result of smoking. Third, FDA believes that imposing NTSOs where the periods of time gradually increase, starting with a maximum of 30 days and then a maximum of 6 months before issuing an order permanently prohibiting the sale of tobacco products, strikes an appropriate balance between considerations related to the number, extent, and gravity of the violations on one hand, and the retailer's ability to continue to do business on the other hand. The increasing periods of time for which FDA intends to impose NTSOs are also consistent with the scheme of increasing [civil money penalties] . . . .

*Id.* (citations omitted).

CTP's guidelines are not written as regulations and are not, therefore, binding as a matter of law. But, they are persuasive, and I accord CTP deference in view of its expertise in administering the Act and implementing regulations. I find especially persuasive the guidelines' reliance on statistics showing the terrible consequences of smoking on our population and the strong linkage between tobacco addiction and commencement of smoking at an early age.

I am mindful also that an NTSO may have a profound effect on a retailer's business and even on that retailer's ability to stay in business. However, this

remedy is reserved only for the most egregious offenders – individuals and entities that have repeatedly violated the law despite the imposition against them of escalating civil money penalties – and is necessary if for no other reason than to protect the public against these offenders’ inability to comply with law and regulations governing tobacco sales. Generally speaking, the need to protect the public outweighs the adverse effects that an NTSO may have on an individual retailer’s business, especially in light of the fact that imposition of this remedy is reserved only for those retailers who demonstrate indifference to the requirements of law.

Respondent is a repeated violator of law and regulations governing the sale of tobacco products to minors. Respondent admitted to multiple violations occurring between March 15, 2015 and January 14, 2017. These violations include: unlawfully selling tobacco products to a minor on March 15, 2015; two additional unlawful sales on March 26, 2016 and January 14, 2017; failing to verify a purchaser’s age by means of photographic identification on March 15, 2015; and two additional failures to verify age by means of photographic identification on March 26, 2016 and January 14, 2017. CTP Exs. 1-4. These admitted violations are administratively final and may not be challenged by Respondent.

The sale of tobacco products that triggered this case occurred on September 28, 2017. On this occasion, an inspector, Hiram Harris, accompanied a minor purchaser to Respondent’s establishment. CTP Ex. 5, at ¶ 7. Mr. Harris testified that he verified that the minor possessed identification establishing her age to be less than 18 years and that she had no tobacco products in her possession prior to entering Respondent’s establishment. *Id.* He testified that he entered the establishment after the minor entered and observed one of Respondent’s employees selling a package of cigarettes to her. *Id.* at ¶ 8. He averred that he did not see the employee check the minor’s identification. *Id.* As corroboration for Mr. Harris’ testimony, CTP offered photographs of the cigarettes that the minor allegedly purchased. CTP Ex. 9; CTP Ex. 10.

Respondent does not deny selling cigarettes to the minor purchaser. It contends, however, that the purchaser misrepresented her age to Respondent’s employee, thus duping the employee into making a prohibited sale. As proof for this assertion Respondent offered an excerpt of an audio tape that allegedly records the transaction at issue. R. Ex. 9.

I find Respondent’s evidence to be unpersuasive. The tape excerpt records the employee asking someone whether he/she is 18, followed by a brief period of silence, and the employee’s verbal statement: “you good.” R. Ex. 9 at 9:14:38-9:15:01. There is nothing on the tape proving that the minor purchaser affirmatively represented her age to be 18. Moreover, even if the minor had done

so, that did not relieve the employee of his duty to request the purchaser's identification and to verify the purchaser's age from the identification. Had the clerk done so the purchaser's actual age (16 in this case) would have been evident. *See* CTP Ex. 6.

I find Mr. Harris' testimony to be credible and I find that, coupled with the photographic evidence offered by CTP, his testimony establishes that Respondent violated tobacco sales regulations on September 28, 2017. The unlawful sale on that date coupled with the failure by Respondent's employee to verify the purchaser's age amount to two more repeated violations in addition to the four previous and administratively final repeated violations. The evidence establishes that Respondent committed at least six repeated violations of tobacco sales regulations during the period beginning March 15, 2015 (original violations) and continuing through September 28, 2017.

I find imposition of an NTSO of 30 consecutive calendar days against Respondent to be reasonable. It is evident that multiple civil money penalties have not deterred Respondent from continuing to sell tobacco products in violation of law. I impose the remedy because something other than a civil money penalty plainly is needed here. Moreover, I do so because, if for no other reason, the public needs to be insulated from Respondent's business practices for a reasonable period of time.

Respondent argues that an NTSO should not be imposed against it because, it asserts, Mr. Harris was less than credible in his testimony and the minor affirmatively misrepresented her age when she asked to purchase cigarettes from Respondent's employee. These arguments serve as no basis to mitigate the remedy. As I have found, Mr. Harris' testimony is credible. Respondent offered no persuasive evidence to rebut it. Moreover, Respondent did not prove that the minor purchaser misrepresented her age and, as I have explained, Respondent's employee was legally required to verify the minor's age simply by requesting that she show identification to him. Indeed, his failure to do so constitutes a violation of the tobacco sale regulations.

\_\_\_\_\_/s/\_\_\_\_\_  
Steven T. Kessel  
Administrative Law Judge