

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division**

Center for Tobacco Products,

Complainant

v.

Edwards Oil, Inc.
d/b/a Lucky Seven A-1 Corner 23 / BP,

Respondent

FDA Docket No. FDA-2015-H-4327
CRD Docket No. T-17-398

Decision No. TB2701

Date: May 9, 2018

DECISION

Found:

- 1) Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a)¹ and 1140.14(b)(1) as charged in the complaint; and
- 2) Respondent committed three (3) violations in a 24-month period as set forth hereinabove.
- 3) Respondent is hereby assessed a civil penalty in the amount of \$500.

Glossary:

ALJ	administrative law judge ²
CMP	civil money penalty
CTP/Complainant	Center for Tobacco Products
DJ	Default Judgment
FDCA	Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9)

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

² See 5 C.F.R. § 930.204.

DN	UPS Delivery Notification
FDA	Food and Drug Administration
HHS	Dept. of Health and Human Services
OSC	Order to Show Cause
POS	UPS Proof of Service
SOP	Service of Process
Respondent	Edwards Oil, Inc. d/b/a Lucky Seven A-1 Corner 23 / BP
TCA	The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009)

I. JURISDICTION

I have jurisdiction to hear this case pursuant to my appointment by the Secretary of Health and Human Services and my authority under the Administrative Procedure Act (5 U.S.C. §§ 554-556), 5 U.S.C.A. § 3106, 21 U.S.C. § 333(f)(5), 5 C.F.R. §§ 930.201 *et seq.* and 21 C.F.R. Part 17.³

II. PROCEDURAL BACKGROUND

The Center for Tobacco Products (CTP/Complainant) issued a Complaint dated November 30, 2015, alleging that FDA documented three (3) violations within a 24-month period. Edwards Oil, Inc. d/b/a Lucky Seven A-1 Corner 23 / BP (Respondent or Lucky Seven A-1 Corner 23 / BP) was served with process on December 3, 2015 by United Parcel Service. Respondent filed an Answer dated December 31, 2015 in which it admitted the allegations in the complaint but contended that CTP counted “multiple penalties for the same violation.”

³ See also *Butz v. Economou*, 438 U.S. 478 at 513, 98 S.Ct. 2894, 57 L.Ed.2d 895 (1978); *Marshall v. Jerrico, Inc.*, 446 U.S. 238 (1980); *Federal Maritime Com’n v. South Carolina State Ports Authority*, 535 U.S. 743, 744 (2002).

On May 3, 2016, the parties submitted Stipulations of Fact in which Respondent again admitted to the violations and indicated it did not intend to contest the facts alleged in the complaint. *See* Stipulation of Fact, Docket (Dkt.) No. 10. Respondent also stipulated that it has the financial means to pay \$500 if liability is assessed in this matter, and the payment of \$500 will not constitute a financial hardship for Respondent. *Id.* The parties agreed the sole remaining issue in this matter is a purely legal question related to CTP's method of counting violations. *See* Joint Motion to Stay Proceedings, Dkt. No. 9.

On September 14, 2016, Respondent filed a Motion to Stay Proceedings pending the United States Court of Appeals for the District of Columbia Circuit's decision in *Orton Motor, Inc. v. U.S. Dep't of Health and Human Serv.*, No. 16-1299 (D.C. Cir. filed Aug. 24, 2016), *aff'd*, 884 F.3d 1205 (D.C. Cir. 2018). On October 4, 2016, I granted Respondent's Motion and stayed the proceedings pending the resolution of *Orton*. Order on Respondent's Motion to Stay Proceedings, Dkt. No 19. On March 20, 2018, the Court of Appeals upheld CTP's methodology for counting violations of the tobacco regulations. *Orton Motor, Inc. v. U.S. Dep't of Health and Human Serv.*, 884 F.3d 1205 (D.C. Cir. 2018).

The pending issue regarding CTP's method of counting violations is resolved, and this matter is now ready for decision (21 C.F.R. § 17.45(c)).

III. BURDEN OF PROOF

CTP as the petitioning party has the burden of proof (21 C.F.R. § 17.33).

IV. LAW

21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a) and 1140.14(b)(1).

V. ISSUE

Did Respondent violate 21 U.S.C. § 331, specifically 21 C.F.R. §§ 1140.14(a) and 1140.14(b)(1) as alleged in the complaint?

VI. ALLEGATIONS

A. Agency's recitation of facts

CTP alleged that Respondent owned an establishment, doing business under the name Lucky Seven A-1 Corner 23 / BP, located at 1501 East Howard Street, Hibbing, Minnesota 55746. Respondent's establishment received tobacco products in interstate commerce and held them for sale after shipment in interstate commerce.

CTP's complaint alleged that on August 14, 2014, CTP issued a Warning Letter to Respondent, alleging that Respondent committed the following violations:

- a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a).
Specifically, a person younger than 18 years of age was able to purchase tobacco products on July 21, 2014; and
- b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(b)(1). Specifically, the minor's identification was not verified before the sale, as detailed above, on July 21, 2014.

Because no opportunity for a hearing was provided before the Warning Letter was issued, Respondent had a right to challenge the allegations in the Warning Letter in the instant case. *See Orton Motor, Inc. v. U.S. Dep't of Health and Human Serv.*, 884 F.3d 1205, 1215 (D.C. Cir. 2018).

Further, during an inspection of Lucky Seven A-1 Corner 23 / BP conducted on August 13, 2015, an FDA-commissioned inspector documented the following violations:

- a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a). Specifically, a person younger than 18 years of age was able to purchase a package of Marlboro cigarettes on August 13, 2015, at approximately 11:21 AM; and
- b. Failing to verify the age of a person purchasing tobacco products by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(b)(1). Specifically, the minor's identification was not verified before the sale, as detailed above, on August 13, 2015, at approximately 11:21 AM.

B. Respondent's recitation of facts

In its Answer, Respondent admitted the allegations in the complaint.

Therefore, as I will detail later, the violations described in the Complaint counts as three (3) violations for purposes of computing the civil money penalty in the instant case. *See Guidance for Industry*, at 13-15.

I find and conclude Respondent committed three (3) violations of 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a) and 21 C.F.R. § 1140.14(b)(1) within a 24-month period as set forth in the Complaint.

VII. FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

The “relevant statute” in this case is actually a combination of statutes and regulations: The Family Smoking Prevention and Tobacco Control Act, Pub. L. No.

111-31, 123 Stat. 1776 (2009) (TCA), amended the Food, Drug, and Cosmetic Act (21 U.S.C.A. Chap. 9) (FDCA) and created a new subchapter of that Act that dealt exclusively with tobacco products, (21 U.S.C. §§ 387-387u), and it also modified other parts of the FDCA explicitly to include tobacco products among the regulated products whose misbranding can give rise to civil, and in some cases criminal, liability. The 2009 amendments to the FDCA contained within the TCA also charged the Secretary of Health and Human Services with, among other things, creating regulations to govern tobacco sales. The Secretary's regulations on tobacco products appear in Part 1140 of title 21, Code of Federal Regulations.

Under the FDCA, “[a] tobacco product shall be deemed to be misbranded if, in the case of any tobacco product sold or offered for sale in any State, it is sold or distributed in violation of regulations prescribed under section 387f(d).” 21 U.S.C. § 387c(a)(7)(B) (2012). Section 387 a-1 directed FDA to re-issue, with some modifications, regulations previously passed in 1996. 21 U.S.C. § 387 a-1(a)(2012). These regulations were passed pursuant to section 387f(d), which authorizes FDA to promulgate regulations on the sale and distribution of tobacco products; 75 Fed. Reg. 13,225 (March 19, 2010), codified at 21 C.F.R. Part 1140 (2015); 21 U.S.C. § 387f(d)(1) (2012). Accordingly, 21 C.F.R. § 1140.1(b) provides that “failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.”

Under 21 U.S.C. § 331(k), “[t]he alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with

respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded” is a prohibited act under 21 U.S.C. § 331. Thus, when a Retailer such as Respondent misbrands a tobacco product by violating a requirement of 21 C.F.R. Part 1140, that misbranding in turn violates the FDCA, specifically 21 U.S.C. § 331(k). FDA may seek a civil money penalty from “any person who violates a requirement of this chapter which relates to tobacco products.” 21 U.S.C. § 333(f)(9)(A) (2012). Penalties are set by 21 U.S.C. § 333 note and 21 C.F.R. § 17.2. Under current FDA policy, the first time FDA finds violations of 21 C.F.R. Part 1140 at an establishment, FDA only counts one violation regardless of the number of specific regulatory requirements that were actually violated, but if FDA finds violations on subsequent occasions, it will count violations of specific regulatory requirements individually in computing any civil money penalty sought. This policy is set forth in detail, with examples to illustrate, at *U.S. Food & Drug Admin., Guidance for Industry and FDA Staff, Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers, Responses to Frequently Asked Questions (Revised) (2016)*, available at <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM447310.pdf> [hereinafter *Guidance for Industry*], at 13-14. So, for instance, if a retailer sells a tobacco product on a particular occasion to a minor without checking for photographic identification, in violation of 21 C.F.R. §§ 1140.14(a) and (b)(1), this will count as two separate violations for purposes of computing the civil money penalty,

unless it is the first time violations were observed at that particular establishment. This policy of counting violations has been determined by the HHS Departmental Appeals Board (Board) to be consistent with the language of the FDCA and its implementing regulations, *see CTP v. Orton Motor Company*, Departmental Appeals Board Decision number 2717 of June 30, 2016. The Board's decision was upheld on appeal. *See Orton Motor, Inc. v. U.S. Dep't of Health and Human Serv.*, 884 F.3d 1205 (D.C. Cir. 2018).

VIII. LIABILITY

When a retailer such as Respondent is found to have “misbranded” a tobacco product in interstate commerce, it can be liable to pay a CMP. 21 U.S.C. §§ 331, 333.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a) in that a person younger than 18 years of age was able to purchase tobacco products on July 21, 2014 and August 13, 2015.

I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(b)(1) on those same dates in that Respondent also violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco product purchasers are younger than 18 years of age.

The conduct set forth above on July 21, 2014 and August 13, 2015 counts as three (3) violations under FDA policy for purposes of computing the civil money penalty. *See Guidance for Industry*, at 13-15.

IX. PENALTY

There being liability under the relevant statute, I must now determine the amount of penalty to impose. My discretion regarding a penalty is constrained by regulation. I must impose either the maximum amount permitted by law or the amount requested by the Center, whichever is lower. 21 C.F.R. § 17.11(a)(1), (a)(2).

In terms of specific punishments available, the legislation that provides the basis for assessing civil monetary penalties divides retailers into two categories: those that have “an approved training program” and those that do not. Retailers with an approved program face no more than a warning letter for their first violation; retailers without such a program begin paying monetary penalties with their first. TCA § 103(q)(2), 123 Stat. 1839, *codified at* 21 U.S.C. § 333 note. *See* 21 C.F.R. § 17.2. The FDA has informed the regulated public that “at this time, and until FDA issues regulations setting the standards for an approved training program, all applicable CMPs will proceed under the reduced penalty schedule.” FDA Regulatory Enforcement Manual, Aug 2015, ¶ 5-8-1. Because of this reasonable exercise of discretion, the starting point for punishments and the rate at which they mount are clear – the lower and slower schedules.

X. MITIGATION

It is incumbent upon Respondent to present any factors that could result in mitigation of CTP’s proposed penalty. Specifically, it is Respondent’s burden to provide mitigating evidence. Respondent has not presented any mitigating factors for me to consider. Additionally, Respondent stipulated that it has the financial means to pay the

civil money penalty, and the payment will not constitute a financial hardship. *See* Stipulation of Fact, Dkt. No. 10.

XI. CONCLUSION

Respondent committed three (3) violations in a 24-month period and so, Respondent is liable for a civil money penalty of \$500. *See* 21 C.F.R. § 17.2.

WHEREFORE, evidence having read and considered it be and is hereby ORDERED as follows:

- a. I find Respondent has been served with process herein and is subject to this forum;
- b. I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(a) on July 21, 2014 and August 13, 2015, in that a person younger than 18 years of age was able to purchase tobacco products as set forth in the complaint;
- c. I find and conclude that the evidentiary facts, by a preponderance of the evidence standard, support a finding Respondent violated 21 U.S.C. § 331, specifically 21 C.F.R. § 1140.14(b)(1) on July 21, 2014 and August 13, 2015, in that Respondent failed to verify, by means of photo identification containing a purchaser's date of birth, that no cigarette purchasers are younger than 18 years of age;
- d. I find and conclude Respondent committed three (3) violations of the regulations within a 24-month period; and
- e. I assess a monetary penalty in the amount of \$500.

_____/s/_____
Richard C. Goodwin
U.S. Administrative Law Judge