

UNITED STATES OF AMERICA  
BEFORE THE DEPARTMENTAL APPEALS BOARD  
CIVIL REMEDIES DIVISION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

---

In the Case of: )  
 )  
Center for Tobacco Products, )  
 )  
Complainant, )  
 )  
v. )  
 )  
HR Puff N Stuff LLC )  
d/b/a HR Puff N Stuff, )  
 )  
Respondent. )

---

**ADMINISTRATIVE COMPLAINT  
FOR NO-TOBACCO-SALE ORDER**

FDA Docket No. FDA-2017-R-0766  
CRD Docket No. T-17-2343

**INTRODUCTION**

1. The Center for Tobacco Products (“CTP”), Food and Drug Administration (“FDA”), United States Department of Health and Human Services, requests that the Administrative Law Judge (“ALJ”) impose a no-tobacco-sale order (“NTSO”) for a 30 consecutive calendar day period on HR Puff N Stuff LLC, d/b/a HR Puff N Stuff (“Respondent”) for repeatedly violating particular FDA tobacco regulations promulgated under Section 906(d) of the Federal Food, Drug, and Cosmetic Act (“Act”) (21 U.S.C. § 387f(d)), which are codified in 21 C.F.R. Part 1140. As shown in the following table<sup>1</sup> and described in more detail below, Respondent committed six repeated violations of particular FDA’s tobacco

---

<sup>1</sup> As explained in the Previous Case History section of this Complaint, CTP previously filed two civil money penalty (“CMP”) cases against Respondent. The table identifies Respondent’s original violations of FDA’s regulations in 21 C.F.R. Part 1140 and Respondent’s repeated violations of those particular regulations that occurred within a specified 36-month period after the original violations.

regulations within the 36-month period that included March 27, 2014 to May 24, 2016:

Charged Violation <sup>2, 3</sup>	Violative Inspection Dates				Number of Repeated Violations
	10/16/2012	03/27/2014	07/21/2015	05/24/2016	
Selling cigarettes / smokeless tobacco to a minor, 21 C.F.R. § 1140.14(a) / 21 C.F.R. § 1140.14(a)(1)	OV	X	X	X	3
Failing to verify ID for cigarettes / smokeless tobacco sale, 21 C.F.R. § 1140.14(b)(1) / 21 C.F.R. § 1140.14(a)(2)(i)	OV	X	X	X	3
<u>FDA Action</u>	Warning Letter Sent 10/29/2012	First CMP Initiated 10/08/2014 FDA-2014-H-1517 CRD C-15-24	Second CMP Initiated 11/06/2015 FDA-2015-H-4010	Current Complaint	<b>Total: 6 Repeated Violations</b>

### LEGAL AUTHORITY

- The Act provides for an NTSO prohibiting the sale of tobacco products at a retail outlet against any person who commits repeated violations of requirements promulgated under Section 906(d) of the Act (21 U.S.C. § 387f(d)). 21 U.S.C. § 333(f)(8). The regulations at 21 C.F.R. Part 1140 (hereafter, "Part 1140

<sup>2</sup> "OV" indicates an original violation. "X" indicates a repeated violation of a particular requirement.

<sup>3</sup> As of August 8, 2016, the effective date of FDA's Final Rule Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, available at <https://federalregister.gov/a/2016-10685>, the citations to certain FDA tobacco regulations have changed, although the text of those regulations has remained substantively the same. To account for the change in citation form, this chart and complaint will include references to the original and new citations indicated as Original (pre-August 8, 2016) Citation / New (post August 7, 2016) Citation. CTP counts as a "repeated violation" an action that violates the same textual regulation, regardless of whether the specific citation for such violation has changed.

regulations”) were issued under Section 906(d) of the Act (21 U.S.C. § 387f(d)). 75 Fed. Reg. 13,225 (Mar. 19, 2010). The term “repeated violations” in 21 U.S.C. § 333(f)(8) is defined as “at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation.” See Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, § 103(q)(1)(A), 123 Stat. 1776, 1838 (2009).

3. CTP has provided public notice that retailers who have committed five or more repeated violations of particular Part 1140 regulations within a 36-month period may be subject to an NTSO for a period provided in the following table:

<b>Number of NTSOs received by Retailer</b>	<b>Maximum Period of Time for NTSO</b>
First NTSO	30 Calendar Days
Second NTSO	6 Months
Third (and subsequent) NTSO	Permanent NTSO

See CTP, U.S. FDA., U.S. Dep’t of Health & Human Servs., Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance with an Order (August 2015), *available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM460155.pdf>.

4. FDA has documented repeated violations of 21 C.F.R. Part 1140 at Respondent’s establishment, as detailed below.

### **CURRENT ALLEGATIONS**

5. Respondent owns an establishment that does business under the name HR Puff N Stuff and is located at 231 East Main Street, Gas City, IN 46933.

6. An FDA-commissioned inspector conducted an inspection at Respondent's establishment on May 24, 2016. During that inspection, Respondent committed the following violations:
  - a. Selling cigarettes or smokeless tobacco to a minor, in violation of 21 C.F.R. § 1140.14(a) / 1140.14(a)(1). Specifically, a person younger than 18 years of age was able to purchase a package of Marlboro 100's cigarettes on May 24, 2016, at approximately 5:05 PM; and
  - b. Failing to verify the age of a person purchasing cigarettes or smokeless tobacco by means of photographic identification containing the bearer's date of birth, as required by 21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i). Specifically, the minor's identification was not verified before the sale, as detailed above, on May 24, 2016, at approximately 5:05 PM.
7. On May 27, 2016, CTP issued a Notice of Compliance Check Inspection to Respondent's establishment stating that an inspection had been conducted on May 24, 2016, and that during this inspection, a minor was able to enter the establishment and purchase a regulated tobacco product at approximately 5:05 PM. This Notice stated that other potential violations of federal tobacco law may have been observed, and further stated that if, after review, CTP determined that there was a violation of federal law, the establishment may receive further notification from FDA.

#### **PREVIOUS CASE HISTORY**

8. Respondent has been the subject of two prior CMP actions based on its violations of the Part 1140 regulations.

9. CTP initiated its first CMP action against Respondent<sup>4</sup> on October 8, 2014, alleging that Respondent sold cigarettes or smokeless tobacco to a minor (21 C.F.R. § 1140.14(a) / 1140.14(a)(1)), and failed to verify the age of a person purchasing cigarettes or smokeless tobacco by means of photographic identification containing the bearer's date of birth (21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i)) on October 16, 2012 and March 27, 2014. See Compl., FDA Docket Number FDA-2014-H-1517, CRD Docket Number C-15-24. ("First CMP Action"). The First CMP action was closed after HR Puff N Stuff LLC / Harold V. Hileman and Richard Alvarado, d/b/a HR Puff N Stuff admitted all of the allegations in the Complaint and paid the agreed upon penalty. In acknowledging that the alleged violations occurred, Respondent expressly waived its right to contest such violations in subsequent actions. See First CMP Action, Attachment to Notice of Settlement Agreement.
10. On November 6, 2015, CTP initiated its second CMP action against Respondent, alleging that, in addition to the violations alleged in the First CMP Action, Respondent sold cigarettes or smokeless tobacco to a minor (21 C.F.R. § 1140.14(a) / 1140.14(a)(1)), and failed to verify the age of a person purchasing cigarettes or smokeless tobacco by means of photographic identification containing the bearer's date of birth (21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i)) on July 21, 2015. See Compl., FDA Docket Number FDA-2015-H-4010 ("Second

---

<sup>4</sup> In the first CMP action, CTP identified Respondent as HR Puff N Stuff LLC / Harold V. Hileman and Richard Alvarado d/b/a HR Puff N Stuff. CTP subsequently identified licensing evidence, from the Indiana Secretary of State website, showing that HR Puff N Stuff LLC owns the establishment that does business as HR Puff N Stuff located at 231 East Main Street, Gas City, IN 46933. Harold V. Hileman and Richard Alvarado have been identified to CTP as "co-owners" of this establishment by telephone. Accordingly, CTP has named HR Puff N Stuff LLC as the Respondent in all cases subsequent to the initial CMP Case.

CMP Action”), attached at Exhibit 1. The Second CMP action was closed pursuant to settlement after HR Puff N Stuff LLC, d/b/a HR Puff N Stuff admitted all of the allegations in the Complaint and paid the agreed upon penalty. In acknowledging that the alleged violations occurred, Respondent expressly waived its right to contest such violations in subsequent actions. See Second CMP Action, Attachment to Notice of Settlement Agreement, attached at Exhibit 2.

### **EVIDENCE SUPPORTING CURRENT REQUEST FOR NTSO**

11. With its most recent sale to a minor (21 C.F.R. § 1140.14(a) / 1140.14(a)(1)) and failure to verify identification (21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i)) on May 24, 2016, see paragraph 6 of this Complaint, Respondent committed the following six repeated violations of regulations that it originally violated on October 16, 2012, in the 36-month period that included March 27, 2014 to May 24, 2016:
  - a. Three repeated violations of selling cigarettes or smokeless tobacco to a minor, in violation of 21 C.F.R. § 1140.14(a) / 1140.14(a)(1), on March 27, 2014, July 21, 2015, and May 24, 2016; and
  - b. Three repeated violations of failing to verify the age of a person purchasing cigarettes or smokeless tobacco by means of photographic identification containing the bearer’s date of birth, in violation of 21 C.F.R. § 1140.14(b)(1) / 1140.14(a)(2)(i), on March 27, 2014, July 21, 2015, and May 24, 2016.

Accordingly, Respondent has committed a total of six repeated violations of particular requirements in 21 C.F.R. Part 1140 within a 36-month period and is subject to an NTSO. See 21 U.S.C. § 333(f)(8).

### **OPTIONS FOR RESPONDING TO COMPLAINT**

12. Respondent must respond to this Complaint. The cover letter provides information on options for responding. Respondent has the right to request a hearing by filing an Answer within 30 days after service of the Complaint. 21 C.F.R. § 17.9. The Answer will be deemed to be a request for a hearing, unless the Answer states otherwise. Failure to file an Answer within 30 days after service of the Complaint may result in a default order. 21 C.F.R. § 17.11. The Answer must be filed with the Departmental Appeals Board, Civil Remedies Division, 330 Independence Ave., S.W., Cohen Building, Room G-644 (MS 6132), ATTN: FDA NTSO, Washington, D.C. 20201. The Answer must include both the FDA Docket Number and CRD Docket Number, which are found at the top of this document.
13. Respondent has the right, but is not required, to retain counsel for representation.

**REQUEST FOR RELIEF**

14. CTP respectfully requests that the ALJ impose a no-tobacco-sale order preventing Respondent from selling cigarettes, cigarette tobacco, roll-your own tobacco, smokeless tobacco, and covered tobacco products for a 30 consecutive calendar day period.

DATED: February 15, 2017

Respectfully submitted,

/s/

\_\_\_\_\_  
**James H. Smith**

Attorney for Complainant  
Center for Tobacco Products  
United States Food and Drug Administration  
White Oak Bldg. 32, Room 4374  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002  
Telephone: 301.796.8718  
Fax: 301.847.8618  
Email: [james.smith@fda.hhs.gov](mailto:james.smith@fda.hhs.gov)