

Guidance for Industry

Tobacco Retailer Training Programs (Revised) *

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products**

June 2014

OMB control number: 0910-0745

Expiration Date: 08/31/2016

See additional PRA statement in Section VI of the guidance*

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*This is a revision to the first edition of this guidance, which issued in September 2013. Revisions are noted by date at the end of the guidance.

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Guidance for Industry¹

Tobacco Retailer Training Programs

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance document is intended to assist retailers in implementing training programs for employees to learn about and comply with the Federal laws and regulations restricting:

- Sale and distribution of, including youth access to, cigarettes and smokeless tobacco; and
- Advertising and promotion of cigarettes and smokeless tobacco.

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31; 123 Stat. 1776) does not require retailers to implement retailer training programs. However, the statute does provide for lower civil money penalties for violations of access, sale and distribution, and advertising and promotion restrictions promulgated under section 906(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, for retailers who have implemented a training program that complies with standards developed by FDA for such programs. FDA intends to promulgate regulations establishing standards for approved retailer training programs. In the interim, however, for retailers

¹ This guidance was prepared by the Office of Compliance and Enforcement and Office of Regulations in the Center for Tobacco Products at FDA.

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34 who wish to implement training programs, this guidance document explains:
35

- 36 1. Definitions;
- 37 2. Recommendations for elements to be included in a retailer training program;
- 38 3. Recommended hiring and management practices;
- 39 4. The civil money penalties that may be assessed against retailers for violations of
40 restrictions promulgated under section 906(d) of the FD&C Act, as amended by the
41 Tobacco Control Act; and
- 42 5. How the penalty structure differs for retailers with and without approved training
43 programs.
44

45 FDA’s guidance documents, including this guidance, do not establish legally enforceable
46 responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should
47 be viewed only as recommendations, unless specific regulatory or statutory requirements are
48 cited. The use of the word *should* in Agency guidances means that something is suggested or
49 recommended, but not required.
50

51 **II. BACKGROUND**

52

53 On June 22, 2009, the President signed the Tobacco Control Act into law. The Tobacco Control
54 Act grants FDA important authority to regulate the manufacture, marketing and distribution of
55 tobacco products to protect the public health generally and to reduce tobacco use by minors.
56

57 Section 906(d) of the FD&C Act, as amended by the Tobacco Control Act, states that “[t]he
58 Secretary may by regulation require restrictions on the sale and distribution of a tobacco product,
59 including restrictions on the access to, and the advertising and promotion of, the tobacco product,
60 if the Secretary determines that such regulation would be appropriate for the protection of the
61 public health.”
62

63 Section 102 of the Tobacco Control Act requires FDA to re-issue its 1996 final regulation
64 restricting the sale and distribution of cigarettes and smokeless tobacco products. The regulation
65 (codified as part 1140 (21 CFR part 1140)) is deemed to be issued under Chapter 9 of the FD&C
66 Act, as amended by the Tobacco Control Act. Part 1140 contains provisions designed to limit
67 young people’s access to cigarettes and smokeless tobacco products, as well as restrictions on
68 advertising and promotion of such tobacco products, to curb the appeal of these products to
69 minors (75 FR 13225; March 19, 2010).
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A. Provisions Regarding Sale and Distribution

The regulation imposes, among other things, the following restrictions on sale and distribution of, including youth access to, cigarettes and smokeless tobacco.²

Retailers of tobacco products MUST:

1. Not sell cigarettes or smokeless tobacco to persons younger than 18 years of age (21 CFR 1140.14(a)).
2. Verify the age of purchasers of cigarettes or smokeless tobacco who are under the age of 27 by means of photographic identification that contains the bearer's date of birth (21 CFR 1140.14(b)).
3. Only sell cigarettes or smokeless tobacco in direct, face-to-face transactions, with limited exceptions (21 CFR 1140.14(c), 1140.16(c)).
4. Not sell cigarettes and smokeless tobacco using vending machines or self-service displays unless they are located in a facility where the retailer ensures that persons younger than 18 years of age are not present or permitted to enter at any time (21 CFR 1140.16(c)).
5. Remove or bring into compliance all self-service displays, advertising, labeling and other items located in the retailer's establishment that do not comply with the requirements under 21 CFR 1140 (21 CFR 1140.14(e)).
6. Not break or otherwise open packages of cigarettes to sell or distribute single cigarettes or sell any package with less than 20 cigarettes (21 CFR 1140.14(d), 21 CFR 1140.16(b)).
7. Not break or otherwise open packages of smokeless tobacco to sell or distribute any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual use (21 CFR 1140.14(d)).
8. Not distribute free samples of tobacco products, except for samples of smokeless tobacco products in a qualified adult-only facility, as defined by the regulations (21 CFR 1140.16(d)).

B. Provisions Regarding Advertising and Promotion

The regulation imposes, among other things, the following restrictions on advertising and promotion of cigarettes and smokeless tobacco.³

² For the full text of the regulation, refer to 21 CFR part 1140.

³ On March 19, 2012, the United States Court of Appeals for the Sixth Circuit issued an Opinion and Judgment that, among other things, found 21 CFR 1140.32(a) and 21 CFR 1140.34(b) to be unconstitutional under the First Amendment. (See *Discount Tobacco, et al v. United States*, 674 F.3d 509 (6th Cir. 2012).) Therefore, FDA will not seek to enforce these provisions.

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109 Retailers of tobacco products MUST:

110

111 1. Notify the Agency 30 days prior to the use of advertising or labeling for cigarettes or
112 smokeless tobacco which the retailer intends to disseminate or cause to be disseminated
113 in a medium that is not listed in 21 CFR 1140.30(a)(1). The notice shall describe the
114 medium and discuss the extent to which the advertising or labeling may be seen by
115 persons younger than 18 years of age. The retailer shall send this notice to the U.S. Food
116 and Drug Administration, Center for Tobacco Products, Document Control Center,
117 Building 71, Room G335, Attn: Office of Compliance and Enforcement, 10903 New
118 Hampshire Avenue, Silver Spring, MD 20993 (21 CFR 1140.30(a)(2)).

119

120 2. Not sponsor any athletic, musical, artistic, or other social or cultural event, or any entry
121 or team in any event, in the brand name, logo, symbol, motto, selling message,
122 recognizable color or pattern of colors, or any other indicia of product identification
123 similar to, or identifiable with, those used for any brand of cigarettes or smokeless
124 tobacco (21 CFR 1140.34(c)).

125

126 **C. Civil Money Penalties**

127

128 Section 103(q)(2) of the Tobacco Control Act includes two schedules for assessing civil money
129 penalties against retailers for violations of restrictions promulgated under section 906(d) of the
130 FD&C Act, as amended by the Tobacco Control Act.^{4,5} Under each schedule, violators are
131 subject to increasing penalties for subsequent violations within prescribed time periods.

132

133 Specifically, section 103(q)(2)(A) sets forth the civil money penalty structure as follows:⁶

134

135 (i) With respect to a retailer with an approved training program, the amount of the civil
136 penalty shall not exceed –

137

138 (I) in the case of the first violation, \$0.00 together with the issuance of a warning letter to
139 the retailer;

140

141 (II) in the case of a second violation within a 12-month period, \$250;

142

143 (III) in the case of a third violation within a 24-month period, \$500;

144

145 (IV) in the case of a fourth violation within a 24-month period, \$2,000;

146

⁴ FDA re-issued its 1996 final regulation restricting the sale and distribution of cigarettes and smokeless tobacco under section 906(d) of the FD&C Act, as amended by the Tobacco Control Act (75 FR 13225; March 19, 2010; codified at 21 CFR part 1140). This guidance describes the restrictions set forth in 21 CFR part 1140.

⁵ Section 303(f)(9) of the FD&C Act establishes civil money penalties for violations of tobacco product requirements under the FD&C Act. This guidance only applies to civil money penalties for retailer violations of regulations issued under section 906(d) of the FD&C Act; it does not apply to civil money penalties issued under section 303(f)(9) for other violations.

⁶ The Civil Money Penalty amounts listed here have been updated to reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act.

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147 (V) in the case of a fifth violation within a 36-month period, \$5,000; and

148
149 (VI) in the case of a sixth or subsequent violation within a 48-month period, \$11,000 as
150 determined by the Secretary on a case-by-case basis.

151
152 (ii) With respect to a retailer that does not have an approved training program, the amount of
153 the civil penalty shall not exceed –

154
155 (I) in the case of the first violation, \$250;

156
157 (II) in the case of a second violation within a 12-month period, \$500;

158
159 (III) in the case of a third violation within a 24-month period, \$1,100;

160
161 (IV) in the case of a fourth violation within a 24-month period, \$2,000;

162
163 (V) in the case of a fifth violation within a 36-month period, \$5,000; and

164
165 (VI) in the case of a sixth or subsequent violation within a 48-month period,
166 \$11,000 as determined by the Secretary on a case-by-case basis.

167
168 For the first three violations in a 24-month period, retailers with an approved training program
169 are subject to lower maximum penalties than retailers without such programs. Section
170 103(q)(2)(B) of the Tobacco Control Act defines “approved training program” as a training
171 program that complies with standards developed by the FDA for such programs.

172
173 FDA intends to promulgate regulations establishing standards for approved retailer training
174 programs. Until it does, the Agency intends to seek penalties in accordance with section
175 103(q)(2)(A)(i) of the Tobacco Control Act (for retailers with an approved training program),
176 whether or not the retailer has implemented a training program. However, FDA may consider
177 any evidence of a training program (e.g., training curriculum, a test provided to employees and
178 their test scores) in determining whether to further reduce the civil money penalty during
179 settlement negotiations for retailers who violate the regulations.⁷

D. No-Tobacco-Sale Orders

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182
183 In addition to civil money penalties, the statute allows the Secretary to impose no-tobacco-sale
184 orders on retailers who repeatedly violate restrictions promulgated under section 906(d) of the
185 FD&C Act, as amended by the Tobacco Control Act. Specifically, section 103(c) of the Tobacco
186 Control Act amends section 303(f) of the FD&C Act (21 U.S.C. 333(f)) to add the following:

187
188 “If the Secretary finds that a person has committed repeated violations of restrictions
189 promulgated under section 906(d) at a particular retail outlet then the Secretary may impose a

⁷ For additional information, see “Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers,” available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf>.

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190 no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A
191 no-tobacco-sale order may be imposed with a civil penalty....”

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194 **III. GENERAL INFORMATION**

195

196 **A. What definitions apply?**

197

198 The following definitions apply for purposes of this guidance:

199

200 1. *Cigarette*: The term ‘cigarette’ (a) means a product that is a tobacco product and meets
201 the definition of the term “cigarette” in section 3(1) of the Federal Cigarette Labeling and
202 Advertising Act; and (b) includes tobacco, in any form, that is functional in the product,
203 which, because of its appearance, the type of tobacco used in the filler, or its packaging
204 and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as
205 roll-your-own tobacco (section 900(3) of the FD&C Act; 21 U.S.C. 387(3)). This
206 definition refers to a provision of the Federal Cigarette Labeling and Advertising Act
207 which defines the term ‘cigarette’ as:

208 “(1) The term “cigarette” means—

209 (A) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and

210 (B) any roll of tobacco wrapped in any substance containing tobacco which, because of
211 its appearance, the type of tobacco used in the filler, or its packaging and labeling, is
212 likely to be offered to, or purchased by, consumers as a cigarette described in

213 subparagraph (A)” (15 U.S.C. 1332).

214 2. *Cigarette Tobacco*: The term ‘cigarette tobacco’ means any product that consists of
215 loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise
216 stated, the requirements applicable to cigarettes under Chapter IX of the FD&C Act shall
217 also apply to cigarette tobacco (section 900(4) of the FD&C Act; 21 U.S.C. 387(4)).

218 3. *Smokeless Tobacco*: The term ‘smokeless tobacco’ means any tobacco product that
219 consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the
220 oral or nasal cavity (section 900(18) of the FD&C Act; 21 U.S.C. 387(18)).

221 4. *Retailer*: The term ‘retailer’ means any person, government, or entity who sells tobacco
222 products to individuals for personal consumption, or who operates a facility where self-
223 service displays of tobacco products are permitted (section 900(14) of the FD&C Act; 21
224 U.S.C. 387(14)).

225

226 **B. What products are covered by this guidance?**

227

228 The regulations in 21 CFR part 1140 apply to cigarettes, cigarette tobacco⁸, and smokeless
229 tobacco (e.g., moist snuff, snus, dry snuff, loose leaf chewing tobacco, plug chewing tobacco,
230 and twist chewing tobacco).

231

⁸ Unless otherwise stated, the provisions of the regulations applicable to cigarettes also apply to cigarette tobacco (section 900(4) of the FD&C Act and 21 CFR 1140.3(b)).

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232 **IV. RETAILER TRAINING PROGRAMS**

233
234 A retailer training program should provide the information and tools necessary for employees to
235 comply with the Federal laws and regulations restricting the sale and distribution, including
236 youth access, and the advertising and promotion of cigarettes and smokeless tobacco.⁹ FDA
237 believes that the elements described in this guidance are important components of an effective
238 retailer training program based on the best available evidence to date.

239
240 Some retailers may already have a training program in place for other purposes (e.g., company
241 policy, State or local law). FDA recommends that retailers who want to train employees about
242 Federal requirements incorporate the elements described in this guidance into their existing
243 training program, as appropriate.

244
245 As soon as practicable, current employees should receive comprehensive training on the Federal
246 laws and regulations restricting the sale and distribution, including youth access, and the
247 advertising and promotion of cigarettes and smokeless tobacco.¹⁰ New employees should
248 receive the training prior to selling cigarettes and smokeless tobacco.

249 250 **A. What are the recommended elements to be included in a retailer training** 251 **program?**

252
253 The training should include detailed information on the Federal laws and regulations prohibiting
254 the sale of cigarettes and smokeless tobacco to minors, as well as how to ask for and verify the
255 age of customers. Training content should include information on all of the following:

256 257 *1. Applicable Laws and Penalties*

258
259 Training content should describe Federal laws and regulations restricting the sale and
260 distribution, including youth access, and the advertising and promotion of cigarettes and
261 smokeless tobacco. These laws and regulations are briefly summarized in section II of
262 this guidance. Training content also should discuss the penalties for violations of these
263 laws and regulations.

264 265 *2. Health Effects of Youth Tobacco Use*

266
267 Training program content should include a description of the health and economic effects
268 of tobacco use, especially when tobacco use begins at a young age. FDA recommends
269 that retailers describe the negative health effects of youth tobacco use. For example, the
270 Congressional Findings in the Tobacco Control Act, Surgeon General's Reports, and
271 other authoritative scientific studies have reported the following:

272

⁹ See section II of this guidance.

¹⁰ FDA notes that there may be additional, and possibly stricter, State and local laws relating to the sale and distribution of, access to, and advertising and promotion of cigarettes and smokeless tobacco. Retailers should consult with State and local authorities for further information.

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- Tobacco use is the foremost preventable cause of premature death in America. It causes over 440,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking.^{11, 12}
 - Smoking costs the United States \$193 billion every year from health care costs and lost productivity from premature death. The actual costs are even higher because lost productivity from illness is not included in this estimate.¹³
 - Cigarette smoking harms nearly every organ in the body. Smoking is known to cause many serious diseases, including multiple cancers (lung, kidney, bladder, acute myeloid leukemia, mouth and throat, larynx, esophagus, stomach, pancreas, cervix); chronic lung disease; heart attacks; stroke; aortic aneurysm; pneumonia; reduced lung function in infants, adolescents, and adults; respiratory symptoms in children and adolescents; asthma-related symptoms; reduced fertility in women; pregnancy complications including premature birth, low birth weight; sudden infant death syndrome (SIDS); peptic ulcer disease; adverse surgical outcomes; osteoporosis and hip fractures in women; periodontal disease; and cataracts. There are also studies linking many other diseases to cigarettes.¹⁴
 - Smokeless tobacco causes oral cancer, esophageal cancer, and pancreatic cancer. Using smokeless tobacco may also cause heart disease, gum disease, oral lesions other than cancer, reduced sperm count, and pregnancy complications including premature birth and low birth weight.¹⁵
 - The adverse health impact of smoking is not limited to adults. Smoking among children and adolescents causes their lungs to not fully develop and causes a premature and accelerated decline in lung function beginning in early adulthood. Smoking also causes respiratory symptoms and asthma-related symptoms in children and adolescents.¹⁶
 - Cigarettes and smokeless tobacco contain nicotine, an addictive chemical.¹⁷
 - Data suggest that youth are particularly susceptible to becoming addicted to tobacco.¹⁸

¹¹ Section 2(13) of the Tobacco Control Act.

¹² Centers for Disease Control and Prevention, "Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000-2004," *Morbidity and Mortality Weekly Report*, 57(45); 1226-28, Nov. 14, 2008, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm>.

¹³ Centers for Disease Control and Prevention, "Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000-2004," *Morbidity and Mortality Weekly Report*, 57(45); 1226-28, Nov. 14, 2008, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm>.

¹⁴ U.S. Department of Health and Human Services, "The Health Consequences of Smoking," A Report of the Surgeon General; 2004, available at http://www.cdc.gov/tobacco/data_statistics/sgr/2004/index.htm.

¹⁵ World Health Organization. "Smokeless Tobacco and Some Tobacco-specific N-Nitrosamines." International Agency for Research on Cancer (IARC) Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 89; 2007, available at <http://monographs.iarc.fr/ENG/Monographs/vol89/mono89.pdf>.

¹⁶ U.S. Department of Health and Human Services, "The Health Consequences of Smoking," A Report of the Surgeon General; 2004, available at http://www.cdc.gov/tobacco/data_statistics/sgr/2004/complete_report/index.htm.

¹⁷ U.S. Department of Health and Human Services, "The Health Consequences of Smoking: Nicotine Addiction," A Report of the Surgeon General; 1988.

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- 301 • Virtually all new users of tobacco products are under the minimum legal age to
302 purchase such products.¹⁹

303
304 Retailers also should inform employees that one way to prevent the significant adverse
305 consequences of tobacco use is to prevent youth from purchasing cigarettes and
306 smokeless tobacco.

307
308 A retailer may choose to use other examples and/or statistics in its training program than
309 what is recommended above; however, the training program should incorporate specific
310 examples and/or statistics related to the health effects of youth tobacco use.

311 312 3. *Written Company Policies*

313
314 Retailers should adopt and enforce a written policy covering Federal laws and regulations
315 related to the sale and distribution, including youth access, and the advertising and
316 promotion of cigarettes and smokeless tobacco.²⁰ This policy should be shared with all
317 employees both verbally and in writing, acknowledged by the employees, and
318 documented in their training records.

319 320 4. *Comprehensive Description of Tobacco Products Covered by Laws Prohibiting* 321 *the Sale of Tobacco Products to Youth*

322
323 The training curriculum should clearly define which products sold in the retail
324 establishment are considered to be cigarettes and smokeless tobacco under the Tobacco
325 Control Act and are therefore subject to the Federal regulations prohibiting their sale to
326 individuals under the age of 18.

327 328 5. *Age Verification Techniques*

329
330 Program content should clearly describe both Federal law and company policies on
331 requiring identification, including the age that triggers photographic identification
332 verification and what constitutes acceptable forms of identification.

- 333
334 • ***Photographic Identification Containing Date of Birth Requirements.*** Unless
335 otherwise required by law, FDA recommends that retailers have in place a policy
336 that:
337 — Permits only government-issued photographic identification containing a
338 *date of birth* (e.g., State-issued driver’s license or identification card,
339 military identification card, passport, or immigration card) as acceptable

¹⁸ U.S. Department of Health and Human Services, “How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease,” A Report of the Surgeon General; 2010, available at http://www.surgeongeneral.gov/library/tobaccosmoke/report/full_report.pdf.

¹⁹ Section 2(4) of the Tobacco Control Act.

²⁰ See section II of this guidance.

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340 forms of identification for establishing a legal age to purchase cigarettes
341 and smokeless tobacco;

342 — Specifies that the photographic identification cannot be expired;

343 — Includes appropriate measures to determine the authenticity of the
344 government-issued photographic identification (as further described
345 below); and

346 — Instructs employees to decline a sale when the customer has no
347 photographic identification, the photographic identification contains no
348 date of birth, or the photographic identification has expired.

349

- 350 • ***The Importance of Closely Examining Photographic Identification.*** The
351 training curriculum should teach retail personnel about the need to closely
352 examine photographic identification to ensure that it establishes both that the
353 person identified is of legal age to purchase cigarettes and smokeless tobacco and
354 that the identification belongs to the person who is presenting it. The training
355 curriculum also should instruct employees to decline a sale because of concerns
356 about the authenticity of the photographic identification. This portion of the
357 training should stress that many illegal sales are made to minors who produce
358 identifications showing that they are under the legal age to purchase cigarettes and
359 smokeless tobacco. Specifically, studies have shown that illegal sales to minors
360 frequently occur when a retail employee fails to verify the age of the purchaser
361 who has produced the identification, especially when the minor appears to be
362 confident, produces a photographic identification without being asked, and
363 appears to be over the age of 18.^{21, 22}

364

- 365 • ***How to Verify the Authenticity of Photographic Identification.*** Program content
366 should include information on the features of a photographic identification that
367 should be checked. These could include, but are not limited to:

368 — Close examination of the picture and physical characteristics listed on the
369 identification (such as height, weight, and eye color) to ensure that the
370 identification belongs to the person who has presented it;

371 — Examination of the identification to ensure any required watermarks or
372 State seals are present; and

373 — Examination of the identification for visual clues to assist in determining
374 whether it belongs to an of age or underage customer in States where
375 photographic identification has different features for individuals under age
376 21 or under age 18 (such as vertical versus horizontal orientation or
377 different font color on the date of birth).

378

²¹ Pearson, D., *et al.*, “Youth tobacco sales in a metropolitan county: factors associated with compliance,” *American Journal of Preventive Medicine*, 33(2); 91-97, 2007.

²² Klonoff, E., and Landrine, H., “Predicting Youth Access to Tobacco: The Role of Youth Versus Store-Clerk Behavior and Issues of Ecological Validity,” *Health Psychology*, 23(5); 517-24, 2004.

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- ***Altered Photographic Identification.*** Training also should discuss how to determine whether a photographic identification might have been altered and what an employee should do if a photographic identification appears to be altered. Specifically, the training program should provide detailed information on signs of an altered photographic identification, which include, but are not limited to:
 - Any sign of tampering;
 - Peeling lamination;
 - Smudged print; and
 - Differences in font on the date of birth or expiration date.

 - ***Specific Age-Verifying Techniques.*** Training content should include detailed information on company-approved techniques designed to ensure that the date of birth on photographic identification is read and clearly understood. For example, retailers may choose to implement one or more of the following techniques to assist employees in calculating a purchaser’s age:
 - Requiring employees to compare the date of birth on the photographic identification with a calendar that displays the most recent date that can be shown on the photographic identification in order for that person to purchase cigarettes and smokeless tobacco;
 - Installing price scanners that are programmed so that when a tobacco product is scanned, the register displays a message prompting the employee either to request age identification and key in the purchaser’s date of birth or to verify that the purchaser is over the age of 26; and
 - Requiring employees to scan all photographic identifications through an electronic age verification device.

 - ***Insufficient Photographic Identification.*** Training also should inform employees of how and when they should ask for a second piece of photographic identification containing the purchaser’s date of birth and instruct employees to decline a sale when the photographic identification does not appear to be authentic.
6. *Refusing Sales*
- ***Practical Guidance for Refusing Sales When Appropriate.*** FDA recommends that training programs incorporate role-playing (e.g., practice sessions with retail employees playing roles as clerks and customers to simulate possible sales transactions) to ensure that employees can effectively apply training information and perform the tasks outlined in the training program. Role-playing should address difficult situations and should assist employees in determining when and how to:
 - Decline purchase attempts by a minor made with written parental permission;

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- 422 — Decline to sell cigarettes and smokeless tobacco to underage persons who
423 are friends and acquaintances;
- 424 — Decline a sale when the customer has no photographic identification, the
425 photographic identification contains no date of birth, the photographic
426 identification has expired, the photographic identification does not appear
427 to be authentic, or the photographic identification shows the customer to
428 be underage;
- 429 — Resist customer pressure; and
- 430 — Seek management assistance, when necessary.

431
432 Other situations or issues should be included in role-playing exercises, as needed.
433

- 434 • ***The Right to Refuse Sales When Acting in Good Faith.*** The training curriculum
435 should teach retail personnel that employees are not required to make a cigarette
436 or smokeless tobacco sale if there is any question that doing so would violate the
437 law.
438

439 7. *Testing to Ensure that Employees Have the Knowledge Required* 440

441 Retailers should require employees to take a written test, using any content, format, and
442 method determined by the retailer to be appropriate, that covers the Federal laws and
443 regulations related to the sale and distribution, including youth access, and the advertising
444 and promotion of cigarettes and smokeless tobacco.²³ Each employee should attain a
445 score sufficient to demonstrate that he or she possesses the knowledge necessary to
446 comply with the law. Retailers should maintain records documenting that all individual
447 employees have been trained, including:

- 448 • One copy of the test given to employees and the correct answers; and
- 449 • A record of the test results for each employee, including the employee's name, the
450 date(s) of testing, the test given to the employee (if the retailer has more than one
451 test for such training), and the employee's test score.²⁴
452

453 Retailers should determine the format of the records (e.g., paper, electronic) and should
454 retain the records for 4 years in order to be able to provide evidence of a training program
455 during the 48-month time period covered by the civil money penalty schedules in section
456 103(q)(2)(A) of the Tobacco Control Act.
457

²³ See section II of this guidance.

²⁴ Retailers may determine how to document and retain this information (e.g., logbook, spreadsheet, database).

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458 **B. What are the recommendations for training frequency, methods, and** 459 **review?**

460 461 1. *Frequency*

462
463 Current employees should be trained as soon as practicable. New retail employees
464 should be trained prior to selling cigarettes and smokeless tobacco. All employees should
465 receive refresher training, including, but not limited to, any necessary re-training, updates
466 to company policies or the law, testing, and role-playing exercises. Refresher training
467 should be provided at least yearly and more frequently as needed. For instance, retailers
468 should consider requiring refresher training and testing for employees if a retail employee
469 is found selling cigarettes or smokeless tobacco to persons under the age of 18.

470 471 2. *Methods*

472
473 The training curriculum may be delivered by any appropriate method, including, but not
474 limited to, in-store training while on the job, a trainer in a classroom setting, via written
475 materials provided to store personnel for self-study, or via Web or other computer-based
476 applications.

477 478 3. *Training Program Review Following a Violation of the Regulations*

479
480 FDA recommends that retailers review and update their training program, as needed, and
481 take appropriate corrective action after any violation of the regulations restricting sale
482 and distribution, including youth access, and advertising and promotion of cigarettes and
483 smokeless tobacco. Retailers should document any modifications to the training program
484 following such a review and should retain the records for 4 years in order to be able to
485 provide evidence of a training program during the 48-month time period covered by the
486 civil money penalty schedules in section 103(q)(2)(A) of the Tobacco Control Act.

487 488 **C. What hiring and management practices support a retailer training program?**

489
490 FDA recommends that appropriate retailer hiring and management practices be implemented as
491 part of a retailer training program.

492 493 1. *Hiring Practices*

494
495 FDA recommends that retailers consider requiring employees who sell cigarettes and
496 smokeless tobacco to be at least 18 years of age.²⁵ Studies have shown that employees
497 under the age of 18 are more likely to sell tobacco to minors than are older clerks.²⁶
498 Also, facilities that employ persons younger than 18 years of age must not have vending

²⁵ FDA regulations do not establish a minimum age for employees who sell cigarettes and smokeless tobacco, but some State or local laws may do so. FDA recommends that retailers contact State and local authorities for information about any age requirements.

²⁶ DiFranza, J.R., and Coleman, M., "Sources of tobacco for youths in communities with vigorous enforcement of tobacco sales laws," *Tobacco Control*, 10; 323-328, 2001.

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499 machines or self-service displays for sale of cigarettes or smokeless tobacco (21 CFR
500 1140.16(d)).

501
502 *2. Management Practices*

503
504 Retailers should consider implementing an internal compliance check program, also
505 known as a mystery shopper program, taking into account any State or local laws related
506 to such programs. Internal compliance checks should be performed at random and
507 varying times of the day and at least once every 6 months. Employees who fail the
508 internal compliance check should be notified immediately and given additional training.

509
510 Retailers who have in-store videotaping should periodically review the tapes to ensure
511 that employees are complying with sales to minor laws and store policies related to
512 reducing the illegal sale of cigarettes and smokeless tobacco to underage youth.
513 Specifically, retailers should review the tapes to ensure that store employees are
514 requesting and examining photographic identification from customers who appear to be
515 under the age of 27.

516
517 Retailers should consider establishing company policies that take employee performance
518 on compliance checks into account. In particular, retailers should consider establishing
519 appropriate corrective measures, in accordance with State and local law, for employee
520 noncompliance. FDA recommends that retailers document the procedures and corrective
521 actions for their internal compliance check program. Such records should be retained for
522 4 years in order to be able to provide evidence of a training program during the 48-month
523 time period covered by the civil money penalty schedules in section 103(q)(2)(A) of the
524 Tobacco Control Act.

525
526 To ensure that management has a vested interest in employee compliance with laws
527 prohibiting the sale of cigarettes and smokeless tobacco to underage youth, retailers also
528 should consider making a store's compliance rate a component of a retail supervisor's
529 performance reviews, if permitted by law.

530
531

532 **V. HOW CIVIL MONEY PENALTIES WILL BE ASSESSED FOR VIOLATIONS**
533 **OF REGULATIONS**

534

535 The Tobacco Control Act does not require retailers to implement retailer training programs.
536 However, it provides for two schedules of civil money penalties for violations of restrictions
537 promulgated under section 906(d) of the FD&C Act, as amended by the Tobacco Control Act,
538 pertaining to the sale and distribution of tobacco products, including youth access, advertising,
539 and promotion restrictions—a schedule of lower penalties for retailers who have implemented a
540 training program that complies with the standards set by FDA and a schedule of higher penalties
541 for those who have not.

542

543 Retailers are under no obligation to submit their training programs for FDA review since this is a
544 voluntary program. Until FDA promulgates regulations establishing standards for approved

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545 retailer training programs, the Agency intends to seek penalties in accordance with section
546 103(q)(2)(A)(i) of the Tobacco Control Act (for retailers with an approved retailer training
547 program), whether or not the retailer has implemented a training program. FDA may consider
548 further reducing the civil money penalty for retailers who have implemented a training program.
549

550 Retailers who have received a Complaint for Civil Money Penalties and who wish to submit
551 evidence that they have a training program in place, for purposes of settlement negotiations, may
552 do so when filing an Answer to the Complaint. Retailers who have not received a notice of
553 Complaint should not submit their training programs for FDA review.
554

555 The Complaint for Civil Money Penalties and the accompanying cover letter will include
556 detailed information on how to file an Answer and submit related documentation, including
557 evidence that a retailer has a training program. Until FDA promulgates regulations establishing
558 standards for approved retailer training programs, the Agency may consider any evidence of a
559 training program (e.g., the training curriculum, the test provided to employees and their test
560 scores) in determining whether to further reduce the civil money penalty for retailers who violate
561 the regulations.²⁷
562

563 **VI. PAPERWORK REDUCTION ACT OF 1995**

565 This guidance contains information collection provisions that are subject to review by the Office
566 of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C.
567 3501-3520).

568 The time required to complete this information collection is estimated to average 10 hours per
569 response, including the time to review instructions, search existing data sources, gather the data
570 needed, and complete and review the information collection. Send comments regarding this
571 burden estimate or suggestions for reducing this burden to:

572 Food and Drug Administration
573 Center for Tobacco Products
574 Document Control Center
575 Building 71, Room G335
576 10903 New Hampshire Avenue
577 Silver Spring, MD 20993
578

579 An agency may not conduct or sponsor, and a person is not required to respond to, a collection of
580 information unless it displays a currently valid OMB control number. The OMB control number
581 for this information collection is 0910-0745 (expires 08/31/2016).
582

583 **Document History:**

²⁷ For additional information, see “Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers,” available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM252955.pdf>.

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- 585 • September 2013 – Final guidance was issued.
- 586 • June 2014 – Pages 4-5 were updated with new Civil Money Penalty amounts that reflect
- 587 inflation, as required by the Federal Civil Penalties Inflation Adjustment Act; references
- 588 to CTP's address updated throughout the document.