

CIGARETTE WARNINGS AND CIGARETTE PLAN REQUIREMENTS

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CENTER FOR TOBACCO PRODUCTS

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I. BACKGROUND, AUTHORITY, AND DEFINITIONS

- On March 17, 2020, FDA issued a final rule, “Tobacco Products; Required Warnings for Cigarette Packages and Advertisements.” The final rule requires new cigarette health warnings on cigarette packages and advertisements. These new warning requirements include 11 new textual warning label statements accompanied by color images depicting the negative health consequences of smoking.
- In addition, FDA published these guidance documents:
 - “Required Warnings for Cigarette Packages and Advertisements Small Entity Compliance Guide (Revised)”
 - “Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised)”

REQUIREMENTS FOR CIGARETTE PRODUCTS



- The required warnings for cigarette packages must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed in accordance with a plan submitted by the tobacco product manufacturer, distributor, or retailer to, and approved by, the Food and Drug Administration (FDA).
- In addition, the required warnings for cigarette advertisements must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, distributor, or retailer to, and approved by, the FDA. Section 4(c) of the FCLAA and 21 C.F.R. § 1141.10(g).

- The Family Smoking Prevention and Tobacco Control Act, or Tobacco Control Act (TCA), amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products.
- TCA also amended section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) to direct FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning label statements. Section 201 of the TCA.
- TCA also modified FCLAA's requirements regarding the submission of cigarette plans for cigarette packages and advertisements and requires that such plans be submitted to FDA for review and approval, rather than to the Federal Trade Commission.

As defined in section 3(1) of FCLAA and the final rule, the term “cigarette” means:

1. Any roll of tobacco wrapped in paper or in any substance not containing tobacco; and
2. Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in subparagraph (1) of this definition. (21 C.F.R. § 1141.3)

II. REQUIRED WARNINGS FOR PACKAGES AND ADVERTISEMENTS

- **Cigarette Packages** must bear one of the required warnings (21 C.F.R. § 1141.10(c)).
- **Cigarette Advertisements** must bear one of the required warnings (21 C.F.R. § 1141.10(d)).
- **Cigarette Plan must Cover:**
 - Random and equal display and distribution of the required warnings on cigarette packages.
 - Quarterly rotation, in alternating sequence, of the required warnings on cigarette advertisements. (21 C.F.R. § 1141.10(g))

Packages/Advertisements – Section 201(b) of the Tobacco Control Act provides that the required warnings for packages and advertisements become effective 15 months after the date the final rule publishes in the Federal Register. Under the Tobacco Control Act, the original effective date for required warnings on packages and advertisements was June 18, 2021. However, due to the COVID-19 pandemic a Federal district court order has postponed this date by 120 days to October 16, 2021.

- As of November 15, 2021 (30 days after the effective date of the rule), manufacturers may not introduce into U.S. domestic commerce any cigarette products that do not bear the required warnings as required by FCLAA and 21 C.F.R. § 1141.

Cigarette Plans – FDA strongly encourages entities to submit their cigarette plans as soon as possible, and in any event within 5 months and 120 days after publication of the final rule (i.e., December 16, 2020).

CIGARETTE WARNING REQUIREMENTS



Effective October 16, 2021, cigarette packages and advertisements must bear one of the following required warnings in accordance with the FCLAA and 21 C.F.R. § 1141. (available at <https://www.fda.gov/cigarette-warning-files>)

 <p>WARNING: Tobacco smoke can harm your children.</p>	 <p>WARNING: Smoking causes type 2 diabetes, which raises blood sugar.</p>	 <p>WARNING: Smoking causes cataracts, which can lead to blindness.</p>	 <p>WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.</p>	 <p>WARNING: Smoking can cause heart disease and strokes by clogging arteries.</p>	 <p>WARNING: Smoking causes COPD, a lung disease that can be fatal.</p>
 <p>WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.</p>	 <p>WARNING: Smoking reduces blood flow to the limbs, which can require amputation.</p>	 <p>WARNING: Smoking causes bladder cancer, which can lead to bloody urine.</p>	 <p>WARNING: Smoking causes head and neck cancer.</p>	 <p>WARNING: Smoking during pregnancy stunts fetal growth.</p>	

a. REQUIREMENTS FOR CIGARETTE PACKAGES

REQUIREMENTS FOR CIGARETTE PACKAGES – 21 C.F.R. § 1141.10(c)



Effective October 16, 2021, it will be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes unless the package bears a required warning.

REQUIREMENTS FOR CIGARETTE PACKAGES – 21 C.F.R. § 1141.10(c)



- Location: Required warnings must appear directly on the package and must be clearly visible underneath any cellophane or other clear wrapping.
- Size: Required warnings must comprise at least the top 50 percent of the front and rear panels; provided, however, that on cigarette cartons, the required warnings must be located on the left side of the front and rear panels and must comprise at least the left 50 percent of these panels.
 - Front and Rear Panels means the two largest sides or surfaces of the package. 21 C.F.R. § 1141.3.
- Orientation: Required warnings must be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation.

REQUIREMENTS FOR CIGARETTE PACKAGES – 21 C.F.R. § 1141.10(c)



- Same or Different Required Warnings: Cigarette manufacturers may use two of the same or two different required warnings on the front and rear panels of a cigarette package.
- Irremovable or Permanent: The required warnings must be indelibly printed on, or permanently affixed to, the package or advertisement. The required warnings, for example, must not be printed or placed on a label affixed to a clear outer wrapper that is likely to be removed to access the product within the package. 21 C.F.R. § 1141.10(e).

REQUIREMENTS FOR CIGARETTE PACKAGES – 21 C.F.R. § 1141.10



- Each required warning, comprising a combination of a textual warning label statement and its accompanying color graphic, must be accurately reproduced as shown in the materials contained in "Required Cigarette Health Warnings, 2020," which is incorporated by reference at 21 C.F.R. § 1141.5.
- FDA recognizes that adaptations to the required warnings may be needed to avoid technical implementation issues due to the varying features, formats, and sizes of cigarette packages and advertisements. To help prevent distortion of the image and text and to minimize the need for adaptation:
 - FDA has created electronic, layered design files, built as Encapsulated PostScript (.eps) files to prevent distortion of the image and text, and to minimize the need for adaptation.
 - These .eps files and accompanying technical specifications are available on FDA's website at <https://www.fda.gov/cigarette-warning-files>.

RETAILER EXCEPTION FOR REQUIRED WARNINGS ON CIGARETTE PACKAGES – 21 C.F.R. § 1141.1(c)

A cigarette retailer will not be in violation of 21 C.F.R. § 1141.10 for packaging that:

- Contains a warning;
- Is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, or distributor; and
- Is not altered by the retailer in a way that is material to the requirements of section 4 of the FCLAA or 21 C.F.R. § 1141.

b. REQUIREMENTS FOR CIGARETTE ADVERTISEMENTS

REQUIREMENTS FOR CIGARETTE ADVERTISEMENTS – 21 C.F.R. § 1141.10(d)



Effective October 16, 2021, it will be unlawful for any manufacturer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless each advertisement bears a required warning in accordance with section 4 of the FCLAA and 21 C.F.R. § 1141.

REQUIREMENTS FOR CIGARETTE ADVERTISEMENTS – 21 C.F.R. § 1141.10(d)



- Location: For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, retail displays, internet web pages, digital platforms, mobile applications, and email correspondence), the required warning must appear directly on the advertisement.
- Size: The required warning must comprise at least 20 percent of the area of the advertisement in a conspicuous and prominent format and location at the top of each advertisement.

REQUIREMENTS FOR CIGARETTE ADVERTISEMENTS – 21 C.F.R. § 1141



- Accurately Reproduced: Each required warning must be accurately reproduced as shown in the materials contained in "Required Cigarette Health Warnings, 2020," which is incorporated by reference at 21 C.F.R. § 1141.5. 21 C.F.R. § 1141.10(b).
- Irremovable or Permanent: Required warnings must be indelibly printed on or permanently affixed to the package or advertisement. These warnings, for example, must not be printed or placed on a label affixed to a clear outer wrapper that is likely to be removed to access the product within the package. 21 C.F.R. § 1141.10(e).

RETAILER EXCEPTION FOR REQUIRED WARNINGS IN CIGARETTE ADVERTISEMENTS – 21 C.F.R. § 1141.1(d)



The warning statement requirements for advertisements applies to a cigarette retailer only if that retailer is responsible for or directs the warnings required under 21 C.F.R. § 1141.10 for advertising.

However, 21 C.F.R. 1141.1(d) does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning or has been altered by the retailer in a way that is material to the requirements of section 4 of the FCLAA or this part.

III. OVERVIEW OF CIGARETTE PLANS

- The required warnings must be displayed and distributed on cigarette packages and rotated in cigarette advertisements, in accordance with an FDA-approved cigarette plan.
- The FDA will review each plan submitted in accordance with the final rule and approve it if the plan:
 - Provides for the equal distribution and display on packaging and the rotation required in advertising for the required warnings; and
 - Assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, distributor, or retailer at the same time.
- FDA does not consider a plan that merely restated the regulatory requirements to be sufficiently detailed to enable approval of the plan.

CIGARETTE PLANS FOR PACKAGES – 21 C.F.R. § 1141.10(g)(1)



For each cigarette brand (or for a set of brands), the plan should list each specific element of the cigarette plan requirement and provide a detailed description of how each element will be met.

Specifically, the cigarette plan should explain how:

- Each of the required warnings will be randomly displayed during each 12-month period on each brand of the product;
- Each of the required warnings will be displayed on each brand of the product in as equal a number of times as possible during each 12-month period;
- Product packages will be randomly distributed in all areas of the United States in which the product is marketed; and
- Each of the required warnings will be displayed at the same time.

CIGARETTE PLANS FOR ADVERTISEMENTS – 21 C.F.R. § 1141.10(g)(2)



For FDA to approve a cigarette plan for cigarette advertisements, the plan must explain how:

- The required warnings are rotated quarterly, in alternating sequence, in advertisements.
- The quarterly rotation is accomplished for each brand of cigarette being advertised.

a. SUBMISSION OF CIGARETTE PLANS

WHO SUBMITS A CIGARETTE PLAN?

- Cigarette plans should be submitted by the responsible cigarette product manufacturer, distributor, or retailer.
- Before any cigarette product is manufactured, packaged, sold, offered for sale, distributed, or imported for sale or distribution within the U.S., it must comply with the applicable requirements for packages and advertisements.
- When the final rule takes effect, it will also be unlawful for any manufacturer, distributor, or retailer to advertise or cause to be advertised within the U.S. any cigarette product unless its advertising bears one of the required warnings in accordance with these new requirements.

Cover Letter

- Subject line: “RE: CIGARETTE PLAN FOR CIGARETTES” and indicate whether the submission is an “(Original),” “(Amendment),” or “(Supplement)”.
- Contact information for the cigarette plan.
- Indication whether proposed cigarette plan is for packages, advertisements, or both.
- A list of all cigarette brands covered by the plan.
- If applicable, a statement by an authorized official of the company that an agent is authorized to submit the cigarette plan on its behalf.

FDA requests that plans submitted for review include representative samples of packages and advertisements with each of the required warning statements.

- Such samples would place the plan in context and, therefore, facilitate FDA's review of the plan. Please note, FDA's review would not include a review of the content of the packages and advertisements.
- Samples of cigarette product packaging could include a range of package sizes for each type of product.
- Samples of advertising could include examples of different types of advertising materials for various brands and/or prototypes of actual advertising materials.

WHEN TO SUBMIT CIGARETTE PLANS



- FDA strongly encourages entities to submit cigarette plans as soon as possible, and in any event within five months and 120 days after the publication of the final rule. FDA encourages these submissions by December 16, 2020.
- Early submission will facilitate timely FDA review prior to the effective date of the required warnings, encourage dialogue with entities regarding any implementation concerns, and provide time to consider proposals by entities in a timely manner.

WHERE TO SUBMIT CIGARETTE PLANS



Written submissions should be addressed to the Office of Compliance and Enforcement and directed to:

Food and Drug Administration
Center for Tobacco Products
Office of Compliance and Enforcement
Document Control Center
RE: Cigarette Plan
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

WHERE TO SUBMIT CIGARETTE PLANS



- Although electronic submission is not mandatory, FDA strongly encourages electronic submission to facilitate efficiency and timeliness of submission and processing. To submit your cigarette plan electronically, please use FDA's Electronic Submissions Gateway, available at:
<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>
- For cigarette plans submitted in electronic format, we recommend that all content (including the cover letter), be a Portable Document Format (PDF) file compatible with Adobe Acrobat 6.0 or higher. Files should not be password protected or encrypted.

b. EXAMPLE CIGARETTE PLANS

EXAMPLE 1: CIGARETTE PLANS FOR PACKAGES

Plan for Random and Equal Display of Required Warnings (Hardpacks):

To ensure that the required warnings are randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product (e.g., based on the date of manufacture), and that all required warnings are displayed at the same time, for hardpack packages we will:

- 1) Utilize an 8x3 cylinder layout (i.e., 8 columns 3 rows).
- 2) Print each of the required warnings on packages in sequential order (i.e., 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11), with different required warnings on the front and back panels of each package. The last two package impressions, representing four required warnings, will display four of the eleven required warnings. The four required warnings will be randomly selected without replacement (i.e. the additional randomly selected required warnings will not contain repeated required warnings, to avoid increasing over-representation), for each brand as illustrated below (see shaded cells). [Alternatively: The last two package impressions will be left blank.]
- 3) Produce a total of 12,000 package labels displaying 24,000 required warnings for hardpack packages for each print run, with four of the eleven required warnings (represented as A, B, C, and D in the grid below) being produced 2,500 times each and seven of the eleven required warnings being produced 2,000 times each. [Alternatively: The last two package impressions are left blank, therefore, the required warnings will all be equally displayed.]

EXAMPLE 1: CIGARETTE PLANS FOR PACKAGES



The required warnings will be arranged on the 8x3 cylinder layout as follows:

8x3 – Hardpack Cylinder Layout of the 11 Required Warnings
 Each Side of the Package Displays a Different Required Warning
 (number represents the corresponding required warning*)

1	7	2	8	3	9	4	10
2	8	3	9	4	10	5	11
3	9	4	10	5	11	6	A+
4	10	5	11	6	1	7	B+
5	11	6	1	7	2	8	C+
6	1	7	2	8	3	9	D+

+Note: Each box in the grid above represents one package. The two different numbers in each box represent that different required warnings will be printed on the front and rear panels of each package. Letters A-D in these shaded cells represent the four randomly selected required warnings without replacement for each brand.

*Required Warning Statements (to include the accompanying color graphics):

1. WARNING: Tobacco smoke can harm your children.
2. WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
3. WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
4. WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
5. WARNING: Smoking causes cataracts, which can lead to blindness.
6. WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
7. WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
8. WARNING: Smoking causes head and neck cancer.
9. WARNING: Smoking can cause heart disease and strokes by clogging arteries.
10. WARNING: Smoking during pregnancy stunts fetal growth.
11. WARNING: Smoking causes COPD, a lung disease that can be fatal.

EXAMPLE 1: CIGARETTE PLANS FOR PACKAGES

Plan for Random Distribution of Required Warnings:

To ensure that the required warnings are randomly distributed in all areas of the United States in which the product is marketed:

Upon cigarettes being manufactured, we will store products in shipping containers. Each container will include all required warnings in as equal numbers as is possible. When an order is placed, we will distribute such container(s) on a first in, first out basis.

EXAMPLE 2: CIGARETTE PLANS FOR PACKAGES

Plan for Random and Equal Display of Required Warnings (Softpacks):

To ensure that the required warnings are randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product (e.g., based on the date of manufacture), and that all required warnings are displayed at the same time, for softpack packages we will:

1. Utilize an 9x5 cylinder layout (i.e., 9 columns 5 rows).
2. Print each of the required warnings on packages in sequential order (i.e., 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11), with the same warning on the front and back panels of each package. The last package impression, representing two required warnings, will display one of the eleven required warnings. The one required warning will be randomly selected without replacement (i.e. the additional randomly selected image will not contain repeated images, to avoid increasing over-representation) for each brand, as illustrated below (see shaded cells). [Alternatively: The last package impression will be left blank.]
3. Produce a total of 11,250 package labels displaying 22,500 required warnings for softpack packages for each print run, with one of the eleven required warnings (represented as A in the grid below) being produced 2,500 times each and ten of the eleven required warnings being produced 2,000 times each. [Alternatively: The last package impression is left blank, therefore, the required warnings will all be equally displayed.]

EXAMPLE 2: CIGARETTE PLANS FOR PACKAGES



The required warnings will be arranged on the 9x5 cylinder layout as follows:

9x5 – Softpack Cylinder Layout of the 11 Required Warnings
 Each Side of the Package Displays the Same Required Warning
 (number represents the corresponding required warning*)

1	6	11	5	10	4	9	3	8
1	6	11	5	10	4	9	3	8
2	7	1	6	11	5	10	4	9
2	7	1	6	11	5	10	4	9
3	8	2	7	1	6	11	5	10
3	8	2	7	1	6	11	5	10
4	9	3	8	2	7	1	6	11
4	9	3	8	2	7	1	6	11
5	10	4	9	3	8	2	7	A+
5	10	4	9	3	8	2	7	A+

+Note: Each box in the grid above represents one package. The two identical numbers in each box represent that the same required warning will be printed on the front and rear panels of the package. Letter A in this shaded cell represents the one randomly selected required warning without replacement for each brand.

*Required Warning Statements (to include the accompanying color graphics):

1. WARNING: Tobacco smoke can harm your children.
2. WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
3. WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
4. WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
5. WARNING: Smoking causes cataracts, which can lead to blindness.
6. WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
7. WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
8. WARNING: Smoking causes head and neck cancer.
9. WARNING: Smoking can cause heart disease and strokes by clogging arteries.
10. WARNING: Smoking during pregnancy stunts fetal growth.
11. WARNING: Smoking causes COPD, a lung disease that can be fatal.

EXAMPLE 2: CIGARETTE PLANS FOR PACKAGES



Plan for Random Distribution of Required Warnings:

To ensure that the required warnings are randomly distributed in all areas of the United States in which the product is marketed:

Upon cigarettes being manufactured, we will store products in shipping containers. Each container will include all required warnings in as equal numbers as is possible. When an order is placed, we will distribute such container(s) on a first in, first out basis.

OR ALTERNATIVELY

We will separate cigarette packages by required warning at the time of manufacture. When an order is placed, we will fill the order with as equal a number of packages as is possible from each separate inventory of these required warnings.

EXAMPLE 3: CIGARETTE PLANS FOR PACKAGES

Plan for Random and Equal Display of Required Warnings:

To ensure that the required warnings are randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product (e.g., based on the date of manufacture), and that all required warnings are displayed at the same time, we will:

Plan for producing and displaying the required warnings on as equal a number of packages as possible for each product during a 12-month period:

1. Produce a total of 11,000 packages for each print run.
2. Print each of the required warnings* on packages in sequential order (i.e., 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11), for a total of 11,000 required warnings (1,000 of each required warning).
3. *OR ALTERNATIVELY*
4. Equally print 1,000 of each of the required warnings* on batches of packages simultaneously (1,000 of required warning 1, 1,000 of required warning 2, etc.) for each print run.
5. This should result in an equal display of each of the different required warnings for each brand of product during a 12-month period, subject to minor variations due to normal commercial printing and manufacturing practices.

*Required Warning Statements (to include the accompanying color graphics):

1. WARNING: Tobacco smoke can harm your children.
2. WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
3. WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
4. WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
5. WARNING: Smoking causes cataracts, which can lead to blindness.

6. WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
7. WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
8. WARNING: Smoking causes head and neck cancer.
9. WARNING: Smoking can cause heart disease and strokes by clogging arteries.
10. WARNING: Smoking during pregnancy stunts fetal growth.
11. WARNING: Smoking causes COPD, a lung disease that can be fatal.

EXAMPLE 3: CIGARETTE PLANS FOR PACKAGES



Plan for Random Distribution of Required Warnings:

To ensure that the required warnings are randomly distributed in all areas of the United States in which the product is marketed:

Upon cigarettes being manufactured, we will store products in shipping containers. Each container will include all required warnings in as equal numbers as is possible. When an order is placed, we will distribute such container(s) on a first in, first out basis.

OR ALTERNATIVELY

We will separate cigarette packages by required warning at the time of manufacture. When an order is placed, we will fill the order with as equal a number of packages as is possible from each separate inventory of these required warnings.

EXAMPLE 1: CIGARETTE PLANS FOR ADVERTISEMENTS



Schedule of Quarterly Rotation of the 11 Required Warnings (number represents the corresponding required warning*) on Cigarette Advertisements (Table 1 – Schedule is Applicable to All Brands)

Quarterly Period	Jun 1 – Aug 31 (Year 2021)	Sept 1 – Nov 30	Dec 1 – Feb 28	Mar 1 – May 31	Jun 1 – Aug 31	Sept 1 – Nov 30	Dec 1 – Feb 28	Mar 1 – May 31	Jun 1 – Aug 31	Sept 1 – Nov 30	Dec 1 – Feb 28	Mar 1 – May 31 [†]
All Brands	1	2	3	4	5	6	7	8	9	10	11	1

[†]Will continue in perpetuity for subsequent quarters

*Required Warning Statements (to include the accompanying color graphics):

1. WARNING: Tobacco smoke can harm your children.
2. WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
3. WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
4. WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
5. WARNING: Smoking causes cataracts, which can lead to blindness.
6. WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
7. WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
8. WARNING: Smoking causes head and neck cancer.
9. WARNING: Smoking can cause heart disease and strokes by clogging arteries.
10. WARNING: Smoking during pregnancy stunts fetal growth.
11. WARNING: Smoking causes COPD, a lung disease that can be fatal.

EXAMPLE 2: CIGARETTE PLANS FOR ADVERTISEMENTS



Schedule of Quarterly Rotation of the 11 Required Warnings (number represents the corresponding required warning*) on Cigarette Advertisements
(Table 2 – Schedule Varies for Each Brand)

Quarterly Period	Jun 1 – Aug 31 (Year 2021)	Sept 1 – Nov 30	Dec 1 – Feb 28	Mar 1 – May 31	Jun 1 – Aug 31	Sept 1 – Nov 30	Dec 1 – Feb 28	Mar 1 – May 31	Jun 1 – Aug 31	Sept 1 – Nov 30	Dec 1 – Feb 28	Mar 1 – May 31 [†]
Brand X	1	2	3	4	5	6	7	8	9	10	11	1
Brand Y	4	5	6	7	8	9	10	11	1	2	3	4
Brand Z	7	8	9	10	11	1	2	3	4	5	6	7

[†]Will continue in perpetuity for subsequent quarters

*Required Warning Statements (to include the accompanying color graphics):

1. WARNING: Tobacco smoke can harm your children.
2. WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
3. WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
4. WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
5. WARNING: Smoking causes cataracts, which can lead to blindness.
6. WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
7. WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
8. WARNING: Smoking causes head and neck cancer.
9. WARNING: Smoking can cause heart disease and strokes by clogging arteries.
10. WARNING: Smoking during pregnancy stunts fetal growth.
11. WARNING: Smoking causes COPD, a lung disease that can be fatal.

EXAMPLES 1 & 2: CIGARETTE PLANS FOR ADVERTISEMENTS



Cigarette brands will be advertised using the types of media listed in the table below. Each type of advertising media will display the required warning in accordance with the schedule of quarterly rotation of the required warnings noted in the previous slide. The reference date(s) will be used to select the appropriate quarter and corresponding required warning for each medium, as indicated in the table below:

Type of Advertising	Reference Date(s) for Quarterly Rotation**
Advertising in periodicals (newspapers, magazines)	["cover date"], ["periodical publication date"], or ["date or publication"]
Posters and placards	["scheduled ad appearance date"]
Email advertisements, direct mail advertisements, and mobile coupons	["date of dissemination"], ["campaign start state"]
Digital media, including websites, banner ads, mobile applications, and social media	["date of posting"], ["scheduled ad appearance date"]
Other advertisements (<i>describe intended advertisement, e.g., Billboard, Point of Sale Shelf Talker</i>)	["date of issuance"], ["order date"], ["date of dissemination"], ["campaign start state"], ["air date"], ["date of posting"], ["date of production"]

(**Note: Do not provide a calendar date in this column; use the examples provided or similar terms to identify the reference date(s) that will be used to assign the corresponding required warning, as described above in Table 1 and 2, Schedule of Quarterly Rotation.)

FOR MORE INFORMATION



Final Guidance: Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised)

- <https://www.fda.gov/media/133839/download>

Cigarette Advertisements and Required Warnings for Cigarette Packages and Advertisements: Small Entity Compliance Guide (Revised)

- <https://www.fda.gov/media/136185/download>

FDA's Cigarette Health Warning Webpage

- <https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-labeling-and-health-warning-requirements>

CTP's Office of Small Business Assistance

- SmallBiz.Tobacco@fda.hhs.gov or at 1-877-CTP-1373 (1-877-287-1373)

Questions on Cigarette Plans?

- CTPWarningPlans@fda.hhs.gov

THE END

FDA

