Grandfathered Tobacco Products

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Topics Covered in Today's Presentation

- What is a grandfathered (GF) tobacco product?
- What does CTP consider in a GF review?
- When does CTP conduct GF reviews?
- Where can I get additional information?

What is a GF Tobacco Product?

- Not a New Tobacco Product
- A GF product was:
  - commercially marketed (other than exclusively in test markets)
  - in the United States
  - as of February 15, 2007

What is a GF Tobacco Product?

- GF tobacco products are not subject to the premarket requirements of the FD&C Act, but may be referenced in two types of premarket submissions:
  - A GF tobacco product can be used as a predicate product in a 905(j) SE report
  - A GF tobacco product can also be referenced in a 905(j)(3) SE exemption request as the product that will be modified

What does CTP consider during a GF Review?

- CTP will review:
  - Commercial marketing evidence
  - Test marketing information
  - Product information

Commercial Marketing Evidence

- Evidence must demonstrate that the product was:
  - commercially marketed
    - in the United States
    - as of February 15, 2007
  - not marketed exclusively in a test market

Commercial Marketing Evidence

- Dated commercial marketing evidence can include but is not limited to:
  - Advertisements
  - Catalog Pages
  - Promotional Materials
  - Trade Publications
  - Bills of Lading
  - Freight Bills
  - Waybills
  - Invoices
  - Purchase Orders
  - Customer Receipts
  - Manufacturing Documents
  - Inventory Lists
  - Other Dated Evidence

Commercial Marketing Evidence

- Evidence with the exact date (February 15, 2007) is not required to demonstrate a product is grandfathered
- FDA suggests you provide evidence dated both before **AND** after February 15, 2007, as close to February 15, 2007 as possible

Commercial Marketing Evidence

- FDA recommends that you submit as much evidence as necessary to demonstrate that your tobacco product was commercially marketed in the United States as of February 15, 2007
- All evidence is reviewed collectively to make a GF determination

Commercial Marketing Evidence

- FDA recommends that evidence:
  - Be dated
  - Identify the specific GF product, for example:
    - If the full GF product name is not clearly described in the evidence (e.g., a code or abbreviation is used), further explanation may be requested
  - Show commercial marketing <u>in the United States</u>

Test Marketing Information

- To help establish that a product was not marketed exclusively in a test market, FDA has been accepting a written statement
  - made by a responsible individual from the firm (or who represents the firm) who has knowledge of the test marketing status of the product

Product Information

- The following information is helpful in specifically identifying a product:
  - Product Description
  - Product Use
  - Package Type
  - Product Size
  - Product Quantity

Product Description and Use Examples

- Product Description
  - Explained the type of tobacco product, for example:
    - Type: cigarette, smokeless, snus, etc.
    - Flavored (e.g. mentholated)
- Product Use
  - Explained how the tobacco product is used by the consumer, for example:
    - Placed between the gum and cheek
    - Rolled in cigarette paper and then smoked

Package Type Information Examples

- Cigarette examples
  - Soft Pack, Hard Pack, Clam Box
- Smokeless examples
  - Metal Tin, Plastic Can, Plastic Can with Metal Lid
- RYO examples
  - Pouch, Tin, Can, Booklet, etc.

Size and Quantity Information Examples

- Cigarette examples
  - Length of Cigarette and Number of Cigarettes per Pack
- Smokeless examples (as applicable)
  - Total Mass
  - Portion Size (mass)
  - Portion Count (e.g., 10 pouches per package)

Size and Quantity Information Examples

- RYO examples (as applicable)
  - Total Mass
  - Component Size
  - Number of Components
  - Dimensions
  - Portion Count
  - Portion Size (mass)

When does CTP Conduct GF Reviews?

- When a stand alone GF submission is received; or
- As part of the review of certain premarket submissions:
  - 905(j) SE report
  - 905(j)(3) SE exemption request

When does CTP Conduct GF Reviews?

- Stand Alone GF Submission
  - Voluntary process
  - Firm submits GF request to CTP
  - Office of Compliance and Enforcement (OCE) is the lead office
  - Firm receives letter with GF determination
- Review as Part of a Premarket Submission
  - Office of Science (OS) requests OCE conduct a GF review of predicate product
  - OCE communicates the GF determination to OS, not to firm
  - OCE does not issue a letter to the firm with GF determination

Reasons for Requesting a Stand Alone GF Review

- Receive a GF determination letter
- Easy to reference that GF product in a current or future premarket submission
- May assist the review of a premarket submission

Requesting a Stand Alone GF Review

- If you request a stand alone GF review, please inform CTP of any pending premarket submissions related to that product

Additional Information

- Final guidance available online:
  - Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007
  - http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm416495.htm
- Questions - send an email to:
  - Smallbiz.tobacco@fda.hhs.gov
  - AskCTP@fda.hhs.gov