U.S. FOOD & DRUG ADMINISTRATION

VOLUNTARY, STANDALONE GRANDFATHERED TOBACCO PRODUCT STATUS DETERMINATION PROGRAM

Presented by

Office of Compliance and Enforcement
Center for Tobacco Products

Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.

Voluntary Standalone GF Program

OVERVIEW

1. VOLUNTARY, STANDALONE GRANDFATHERED (GF) TOBACCO PRODUCT STATUS DETERMINATION REQUESTS

2. UPDATES TO THE VOLUNTARY, STANDALONE GF TOBACCO PRODUCT STATUS DETERMINATION PROGRAM

Grandfathered Tobacco Product

WHAT IS A GRANDFATHERED TOBACCO PRODUCT?

- A **grandfathered tobacco product** is a tobacco product that was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007.

- Grandfathered products are regulated under the Federal Food, Drug, and Cosmetic Act (FD&C Act), but do not require premarket authorization to be legally marketed.

VOLUNTARY, STANDALONE GRANDFATHERED (GF) TOBACCO PRODUCT STATUS DETERMINATION REQUESTS

Voluntary Standalone GF Requests: General Information

Standalone grandfathered status determinations are made for finished, regulated tobacco products.

Finished tobacco products are tobacco products, sealed in final packaging, intended for consumer use.

Submitting a request to determine the grandfathered status of a tobacco product is voluntary.

Voluntary Standalone GF Requests: Things to Remember

Please utilize the resources on FDA's website including the GF guidance and this Webinar. For specific questions regarding a voluntary GF request e-mail CTP-Grandfather@fda.hhs.gov.

Requests should be labeled as "Grandfathered Submission," identify the applicant's name, and include the tobacco product name used as of February 15, 2007.

Voluntary Standalone GF Requests: Things to Remember

If submitting more than one request, each tobacco product should be submitted as a separate grandfathered submission.

Multiple products within one request will not be accepted. Each product must be submitted in an individual request through CTP portal or mail.

Submit electronically via CTP Portal using FDA's eSubmitter or mail to CTP's Document Control Center (DCC).

- Questions: CTP-Grandfather@fda.hhs.gov

Voluntary Standalone GF Requests: Contents of a Submission

1. TOBACCO PRODUCT NAME and DESCRIPTION
2. TEST MARKET INFORMATION
3. EVIDENCE OF COMMERCIAL MARKETING IN THE U.S. AS OF FEBRUARY 15, 2007

Tobacco Product Name

Name of the tobacco product listed in submission should be the **exact name** of the tobacco product as it was commercially marketed **on February 15, 2007.**

NAME ON 2/15/2007	**Acme Churchill Robusto 5 Pack**
NAME IN 2019	**Emily's Churchill Robusto 5 Pack**

Tobacco Product Description

CIGAR CHARACTERISTICS

PACKAGE TYPE	DIAMETER
QUANTITY	TOBACCO CUT SIZE
LENGTH	FLAVOR

**These are examples of the descriptions from previous submissions. FDA requests specific product information to uniquely identify the tobacco product.*

Test Marketing Information

FULL NAME OF TOBACCO PRODUCT

Product name should match the name identified in the submission and it should be the name of the product as it was commercially marketed in the U.S. as of February 15, 2007

RESPONSIBLE OFFICIAL

Should be from an individual who has knowledge of the test marketing and commercial marketing status of the tobacco product as of February 15, 2007 and has the authority to make such a statement

STATEMENT

Affirmative statement that the tobacco product under review was commercially marketed other than exclusively for test marketing in the U.S. as of February 15, 2007

Test Marketing Information

"I, *(insert name and position title of responsible official)*, confirm that the tobacco product associated with this Grandfathered Submission, *(insert name of tobacco product as it was on February 15, 2007)*, was commercially marketed other than exclusively for test marketing in the United States as of February 15, 2007."

John Smith

Vice President

Evidence of Commercial Marketing

EXAMPLES OF DOCUMENTATION OF COMMERCIAL MARKETING

- **Dated Copies of Advertisements**
- **Dated Catalog Pages**
- **Dated Promotional Material**
- **Dated Trade Publications**
- **Dated Bills of Lading**
- **Dated Freight Bills**
- **Dated Waybills**
- **Dated Invoices**
- **Dated Purchase Orders**
- **Dated Customer Receipts**
- **Dated Manufacturing Documents**
- **Dated Distributor or Retailer Inventory Lists**

Evidence of Commercial Marketing

COMMON PUBLIC RESOURCES FOR FINDING COMMERCIAL MARKETING EVIDENCE

Internet Website Archives

Online Libraries

USPTO Trademark Database

United States Copyright Office Copyright Catalog

SEC Edgar Database

Search Engines

Voluntary Standalone GF Requests: Common Submission Issues

1	INCONSISTENT NAMING OF THE TOBACCO PRODUCT
2	INADEQUATE EVIDENCE OF COMMERCIAL MARKETING IN THE U.S. **ON** FEBRUARY 15, 2007
3	COLLECTIVE EVIDENCE DOES NOT DEMONSTRATE COMMERCIAL MARKETING IN THE U.S. BEFORE **AND** AFTER FEBRUARY 15, 2007

GF Letter (EXAMPLE)

CENTER FOR TOBACCO PRODUCTS

NAME OF CONTACT POST-NOMINAL TITLES
TITLE / MANUFACTURER NAME
SUBMITTER NAME / C/O SUBMITTER NAME
STREET ADDRESS
CITY, STATE ZIP CODE

Re: Submission Tracking Number (STN): STN
Tobacco Product Name: TOBACCO PRODUCT NAME
Date of Submission: Month DD, YYYY
FDA Receipt Date: Month DD, YYYY

Dear NAME OF CONTACT:

We have reviewed your submission, in which you ask the Food and Drug Administration (FDA) to determine whether the tobacco product referenced above was commercially marketed in the United States as of February 15, 2007 and, therefore, is a "grandfathered" tobacco product. Based on the information you provided, we have determined that the tobacco product qualifies for grandfathered status and is not subject to the premarket review requirements set forth in Section 910(a)(2) of the Federal, Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act.

Further, we have determined that the tobacco product is eligible to serve as a predicate tobacco product for a 905(j) report (demonstrating substantial equivalence) because the tobacco product was commercially marketed (other than in a test market) as of February 15, 2007. Please be advised that this letter reflects FDA's determination of the above-referenced tobacco product's grandfathered and predicate status only. It does not reflect an agency determination to grant or deny a marketing application referencing the product.

Our grandfather status determination for this product is based on the information you provided in support of this submission. We did not review information concerning the composition, design, or ingredients of this product in order to make our determination. Please note that our determination only applies if this product was marketed as of February 15, 2007, and the product was not modified. Any modification to the product after February 15, 2007, would render the product a "new tobacco product" subject to premarket review requirements.

Please note that all regulated tobacco products, including grandfathered tobacco products, are subject to other requirements of the FD&C Act and implementing regulations, including, but not limited to, annual registration, listing of products, listing of ingredients, labeling and advertising requirements, misbranding, and adulteration. In addition, tobacco products may be subject to other federal statutes and regulations. It is your responsibility to ensure that your products comply with all applicable statutory and regulatory requirements.

For more information on your responsibilities under the FD&C Act, we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

For specific questions regarding this letter or the submission referenced above, please send an email to CTP-Grandfather@fda.hhs.gov and reference STN.

Sincerely,

Ann Simoneau, J.D.
Director
Office of Compliance and Enforcement
Center for Tobacco Products

U.S. Food & Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

We have reviewed your submission, in which you ask the Food and Drug Administration (FDA) to determine whether the tobacco product referenced above was commercially marketed in the United States as of February 15, 2007 and, therefore, is a "grandfathered" tobacco product. Based on the information you provided, we have determined that the tobacco product qualifies for grandfathered status and is not subject to the premarket review requirements set forth in Section 910(a)(2) of the Federal, Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act.

UGF Letter (EXAMPLE)

CENTER FOR TOBACCO PRODUCTS

NAME OF CONTACT POST-NOMINAL TITLES
TITLE / MANUFACTURER NAME
SUBMITTER NAME / C/O SUBMITTER NAME
STREET ADDRESS
CITY, STATE ZIP CODE

Re: Submission Tracking Number (STN): STN
Tobacco Product Name: TOBACCO PRODUCT NAME
Date of Submission: Month DD, YYYY
FDA Receipt Date: Month DD, YYYY

Dear NAME OF CONTACT:

The Center for Tobacco Products (CTP), Office of Compliance and Enforcement (OCE), received the above referenced submission, in which you requested the Food and Drug Administration (FDA) to determine whether the subject tobacco product was commercially marketed (other than exclusively in test markets) in the United States as of February 15, 2007, and therefore "grandfathered." On [Date of Letter (Month DD, YYYY)], we sent a letter requesting additional information within 30 calendar days for OCE to determine the grandfathered status and predicate eligibility of the subject tobacco product.

As of the date of this letter, OCE has received insufficient information regarding [GFXXXXXX], and therefore, OCE is unable to make a grandfathered status and predicate eligibility determination. The submission referenced above has been closed. This does not preclude you from providing a new Grandfathered Submission, which will be assigned a different STN.

As a reminder, to legally market a new tobacco product in the United States, you must receive a written order from FDA permitting the marketing of your new tobacco product under one of three pathways: a premarket tobacco product application (PMTA), a substantial equivalence (SE) report, or an exemption from SE request.

For more information on your responsibilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act), we encourage you to visit our website at http://www.fda.gov/TobaccoProducts. You may also obtain information by contacting FDA's Center for Tobacco Products at 1-877-CTP-1373, AskCTP@fda.hhs.gov, or SmallBiz.Tobacco@fda.hhs.gov.

For specific questions regarding this letter or the submission referenced above, please send an email to CTP-Grandfather@fda.hhs.gov and reference [STN].

Sincerely,

Ele Ibarra Pratt, Division Director
Division of Promotion Advertising and Labeling
Office of Compliance and Enforcement
Center for Tobacco Products

U.S. Food & Drug Administration
Center for Tobacco Products
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

As of the date of this letter, OCE has received insufficient information regarding [GFXXXXXX], and therefore, OCE is unable to make a grandfathered status and predicate eligibility determination. The submission referenced above has been closed. This does not preclude you from providing a new Grandfathered Submission, which will be assigned a different STN.

UPDATES TO THE VOLUNTARY, STANDALONE GF PROGRAM

Voluntary Standalone GF Program: Unable to Accept (UTA) letters

Multiple products within one request will not be accepted. Each product must be submitted in an individual request through CTP portal or mail.

Page four of the Guidance for Industry, Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007, states that "[e]ach tobacco product should be submitted in a separate Grandfathered Submission."

Voluntary Standalone GF Program: Unable to Review (UTR) letters

Once a firm submits an individual GF request and FDA accepts the submission, the firm will receive an acknowledgment letter and an assigned GF STN. FDA will then conduct an initial evaluation of the GF submission.

If after this evaluation FDA determines that the request does not include sufficient information for FDA to find that the tobacco product is grandfathered and continued agency review of the submission would be an inefficient use of agency resources, the agency will issue an Unable to Review (UTR) letter.

Voluntary Standalone GF Program: Unable to Review (UTR) letters

UTR letters will be issued for one or more of the following problems:

1. FDA determines that the specific product identified in the GF submission is not a tobacco product.

2. The information in the submission does not clearly identify the name and contact information of the firm on whose behalf the request is submitted.

Voluntary Standalone GF Program: Unable to Review (UTR) letters

3. The submission or evidence is not in English.

4. The submission is missing two or more of the following pieces of information:

    - Tobacco Product Name and Description
    - Test Marketing Information
    - Commercial Marketing Evidence

Voluntary Standalone GF Program: Unable to Review (UTR) letters

If FDA is unable to review the GF submission request for any of the reasons mentioned above, the submission request and STN will be closed and a UTR letter will be issue to the firm.

This does not preclude the firm from submitting the same product for a voluntary, standalone GF status determination in the future.

Voluntary Standalone GF Program: Request for Information (RFI) letters

FDA may reach out to a firm to request additional information to clarify parts of a submission. The firm will have thirty (30) calendar days from the date the letter was received to respond.

During that time, if the firm has additional questions, the firm may request a teleconference to discuss the requested information. Please contact CTP-Grandfather@fda.hhs.gov.

Once the thirty (30) calendar days have passed, FDA will review all information submitted, including a review of any information provided within the 30-day period, to determine whether there is sufficient information to find that the tobacco product is grandfathered.

Voluntary Standalone GF Program: Request for Information (RFI) letters

FDA will not send multiple RFI letters for individual GF status determination requests. Firms should expect to receive only one (1) RFI letter, if needed.

Multiple GF STNS may be included in a single RFI letter if the STNs are submitted by the same firm.

Responses to a request for information (RFI) may address all GF STNs from that specific RFI letter, batched in a single response. This approach has proven helpful in facilitating FDA review. Firms utilizing this approach have not individually separated each response by each individual GF STN. Instead, firms have identified in the response which answers apply to each specific GF STN or product name as it was commercially marketed as of February 15, 2007.

RESOURCES

GF QUESTIONS
CTP-Grandfather@fda.hhs.gov

GRANDFATHERED TOBACCO PRODUCT WEBSITE
https://www.fda.gov/tobaccoproducts/labeling/tobaccoproductreviewevaluation/ucm304380.htm

SECTION 910 of the FD&C ACT
https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm262073.htm#910_a_1_B

CTP PORTAL
https://ctpportal.fda.gov/ctpportal/login.jsp

FDA ESUBMITTER
https://www.fda.gov/ForIndustry/FDAeSubmitter/ucm189469.htm

FDA's DOCUMENT CONTROL CENTER ADDRESS
https://www.fda.gov/TobaccoProducts/AboutCTP/ContactUs/ucm20081474.htm#write

STANDALONE GRANDFATHERED SUBMISSION DATABASE
https://www.accessdata.fda.gov/scripts/ctpgnd/