

GRANDFATHERED TOBACCO PRODUCT REVIEWS

Presented by
Bryan Hills
Deputy Division Director
Office of Compliance and Enforcement
Center for Tobacco Products

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Grandfathered Tobacco Product Reviews

OVERVIEW

1. VOLUNTARY, STANDALONE GRANDFATHERED (GF) TOBACCO PRODUCT DETERMINATION REQUESTS
2. GRANDFATHERED TOBACCO PRODUCT DETERMINATIONS UNDER SUBSTANTIAL EQUIVALENCE (SE) REPORTS

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), and do not require prior marketing authorization to be legally marketed.



VOLUNTARY, STANDALONE GRANDFATHERED (GF) TOBACCO PRODUCT DETERMINATION REQUESTS

Voluntary Standalone GF Requests: General Information



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



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

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

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: Elements 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 Light Hard Pack
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NAME IN 2019	Acme Gold Hard Pack
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Tobacco Product Description

CIGAR CHARACTERISTICS

PACKAGE TYPE

DIAMETER

QUANTITY

TOBACCO CUT SIZE

LENGTH

FLAVOR

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

Test Marketing Information

FULL NAME OF TOBACCO PRODUCT

Product name must match the name identified in the submission and it must 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: 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)



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)



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

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.**

GRANDFATHERED TOBACCO PRODUCT DETERMINATIONS UNDER SUBSTANTIAL EQUIVALENCE (SE) REPORTS

SE Reports/Grandfathered Tobacco Product Reviews



- 1** A cross-reference review is conducted if the predicate tobacco product in the SE report references a previously Grandfathered tobacco product.
- 2** A full review of the predicate tobacco product is conducted if there is no reference made to a previously Grandfathered tobacco product, which is similar to the review process for standalone GF status reviews.

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/>