U.S. FOOD & DRUG ADMINISTRATION

TOBACCO COMPLIANCE WEBINAR

STANDALONE GRANDFATHERED SUBMISSIONS

Presented by
LCDR Michael Gu
Branch Chief
Office of Compliance and Enforcement, CTP, FDA

CONTENTS

A **grandfathered tobacco product** is a tobacco product 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 authorization to be legally marketed.

A **grandfathered tobacco product** is not considered a new tobacco product and does not need prior authorization through a substantial equivalence application, exemption to substantial equivalence application, or premarket tobacco product application.

1. Standalone grandfathered submissions are for regulated tobacco products

2. Submissions are for finished tobacco products

3. Submissions are voluntary

A **tobacco product** is "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." *(section 201(rr) of the FD&C Act)*

A **finished tobacco product** is a tobacco product, including all components and parts, sealed in final packaging intended for consumer use.

FDA does not intend to review grandfathered status for component parts and accessories of regulated tobacco products that are sold or distributed solely for further manufacturing into finished tobacco products.

1. Grandfathered products may serve as predicate tobacco products in a substantial equivalence report

2. Helps with future biennial tobacco manufacture inspections conducted by FDA investigators

1. Submissions should be labeled as “Grandfathered Submissions”, identified with applicant’s name, and the tobacco product name as of February 15, 2007

2. Each tobacco product should be submitted as a separate grandfathered submission

3. Submit electronically via CTP Portal using FDA’s eSubmitter or mail to CTP’s Document Control Center

1 UNIQUE IDENTIFICATION

2 TEST MARKET INFORMATION

3 EVIDENCE OF COMMERCIAL MARKETING AS OF FEBRUARY 15, 2007

1 UNIQUE IDENTIFICATION

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 X Hard Pack**
NAME IN 2009	**Acme Y Hard Pack**

1 UNIQUE IDENTIFICATION

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 Lights 100's**
NAME IN 2009	**Acme Y 100's**

CIGAR
CHARACTERISTICS

PACKAGE TYPE

QUANTITY

LENGTH

DIAMETER

TOBACCO CUT SIZE

FLAVOR

These are examples of the characteristics we have received in previous submissions. FDA may need additional characteristics for your specific product to uniquely identify the tobacco product

SMOKELESS
CHARACTERISTICS

PACKAGE TYPE

QUANTITY

PORTION COUNT

PORTION MASS

TOBACCO CUT SIZE

FLAVOR

These are examples of the characteristics we have received in previous submissions. FDA may need additional characteristics for your specific product to uniquely identify the tobacco product

RYO:CO-PACKAGE/KITS

CHARACTERISTICS

SUB-PRODUCT A: RYO FILLER

PACKAGE TYPE / QUANTITY / FLAVOR

SUB-PRODUCT B: FILTERED CIGARETTE TUBES

PACKAGE TYPE / QUANTITY / LENGTH / DIAMETER / FLAVOR

These are examples of the characteristics we have received in previous submissions. FDA may need additional characteristics for your specific product to uniquely identify the tobacco product

2 TEST MARKET INFORMATION

FULL NAME OF TOBACCO PRODUCT

Name must match the name identified in the submission and it must be the name of the product as it was marketed as of February 15, 2007

RESPONSIBLE OFFICIAL

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

STATEMENT

Definitive statement that the tobacco product under review was commercially marketed other than for test marketing in the United States as of February 15, 2007

2 TEST MARKET 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 for test marketing in the United States as of February 15, 2007."

John Smith

Vice President

3 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

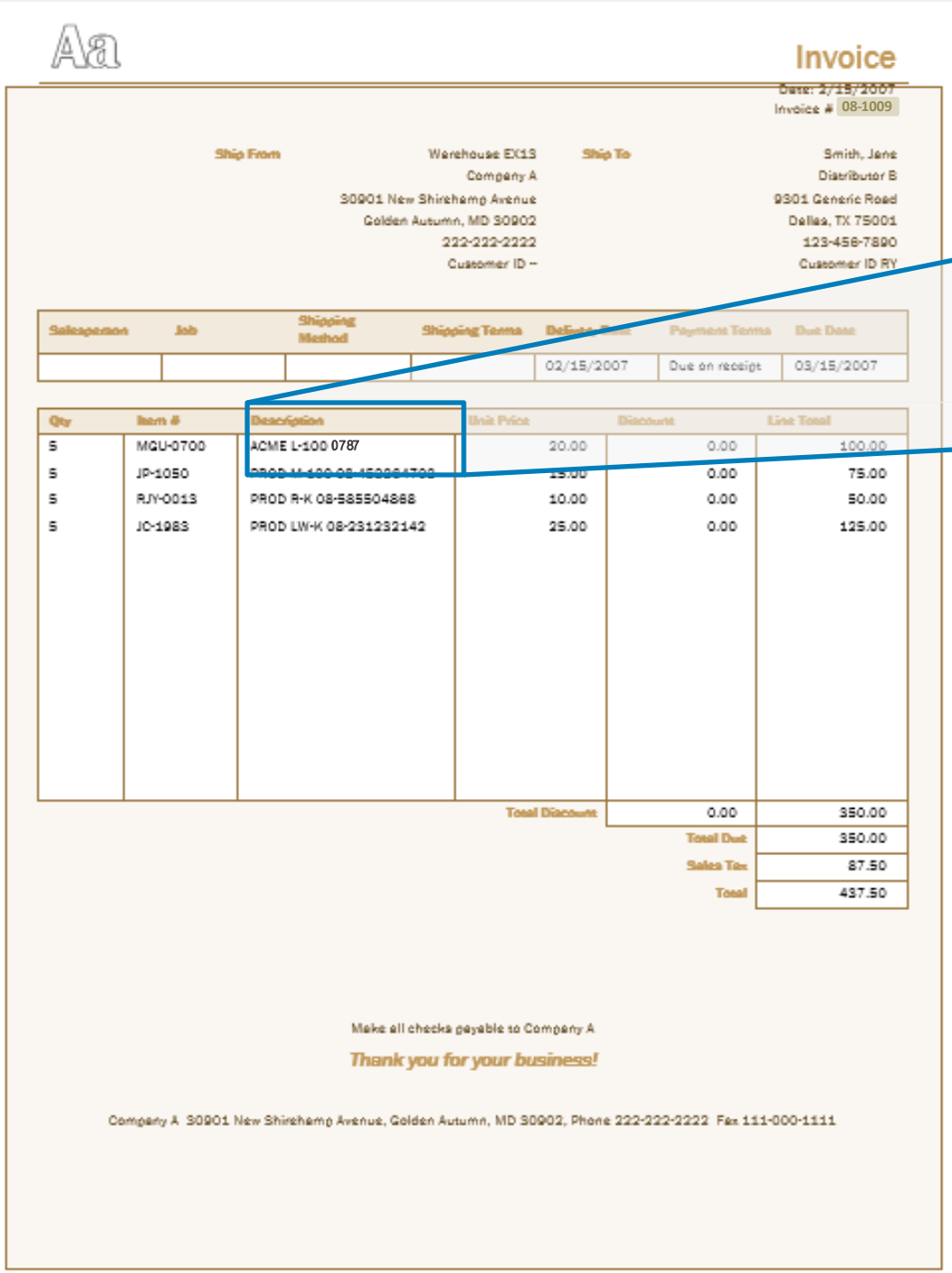
3 EVIDENCE OF COMMERCIAL MARKETING

PROVIDE LINK BETWEEN EVIDENCE & NAME

For example, a statement or chart to correlate the product code in an invoice to the product that is the subject of the grandfather submission. An explanation breaking down the various elements of the code to explain how it is linked to the tobacco product under review.

HIGHLIGHT ANY DIFFERENCES

For example, if an invoices says there are five boxes in a pack, the manufacturer would inform FDA that the tobacco product is shipped to the retailer in packs of five, but are broken up and sold individually.



Aa

Invoice

Date: 1/15/2007
Invoice # 08-1009

Ship From		Ship To	
	Warehouse EX13		Smith, Jane
	Company A		Distributor B
	30901 New Shirehamp Avenue		9301 Generic Road
	Golden Autumn, MD 30902		Dallas, TX 75001
	222-222-2222		123-456-7890
	Customer ID --		Customer ID RY

Salesperson	Job	Shipping Method	Shipping Terms	Delivery Date	Payment Terms	Due Date
				02/15/2007	Due on receipt	03/15/2007

Qty	Item #	Description	Unit Price	Discount	Line Total
5	MGU-0700	ACME L-100 0787	20.00	0.00	100.00
5	JP-1050	PROD M-100-08-452884700	15.00	0.00	75.00
5	RJY-0013	PROD R-K 08-585504888	10.00	0.00	50.00
5	JC-1983	PROD LW-K 08-231232142	25.00	0.00	125.00
				Total Discount	0.00
				Total Due	350.00
				Sales Tax	87.50
				Total	437.50

Make all checks payable to Company A

Thank you for your business!

Company A 30901 New Shirehamp Avenue, Golden Autumn, MD 30902, Phone 222-222-2222 Fax 111-000-1111

Description
ACME L-100 0787

"The item noted on Invoice #08-1009 as 'ACME L-100 0787' is the same as 'Acme Lights 100's."

John Smith
Vice President

3 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

CENTER FOR TOBACCO PRODUCTS

Mr. John Smith
Vice President
Company A
30901 New Shirehamp Ave.
Golden Autumn, MD 30902

Re: Submission Tracking Number (STN): GF1500787
Tobacco Product Name: Acme Lights 100's
Date of Submission: January 03, 2015
FDA Receipt Date: January 03, 2015

Dear Mr. Smith:

This letter acknowledges the Food and Drug Administration's (FDA) receipt of your grandfathered (GF) submission for which you have asked the Center for Tobacco Products (CTP) for a determination whether the referenced tobacco product was commercially marketed as of February 15, 2007. It has been assigned the Submission Tracking Number (STN) designated above. Please refer to this STN for all future correspondence and questions that relate to this GF submission. If further information is needed or a determination about your submission is made, you will be notified.

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

We encourage you to submit all regulatory correspondence electronically via the CTP Portal (https://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm) using eSubmitter (http://www.fda.gov/ForIndustry/FDAeSubmitter). The FDA's Electronic Submission Gateway (ESG) is still available as an alternative to the CTP Portal. If necessary, submissions may be mailed to:

Food and Drug Administration
Center for Tobacco Products
Document Control Center (DCC)
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

Re: Submission Tracking Number (STN): GF1500787
Tobacco Product Name: Acme Lights 100's
Date of Submission: January 03, 2015
FDA Receipt Date: January 03, 2015

1	INCONSISTENT NAMING
2	INADEQUATE EVIDENCE OF COMMERCIAL MARKETING AS OF FEBRUARY 15, 2007
3	EVIDENCE PROVIDED DOES NOT COLLECTIVELY SHOW COMMERCIAL MARKETING AS OF FEBRUARY 15, 2007

1 INCONSISTENT NAMING

UNIQUE IDENTIFICATION

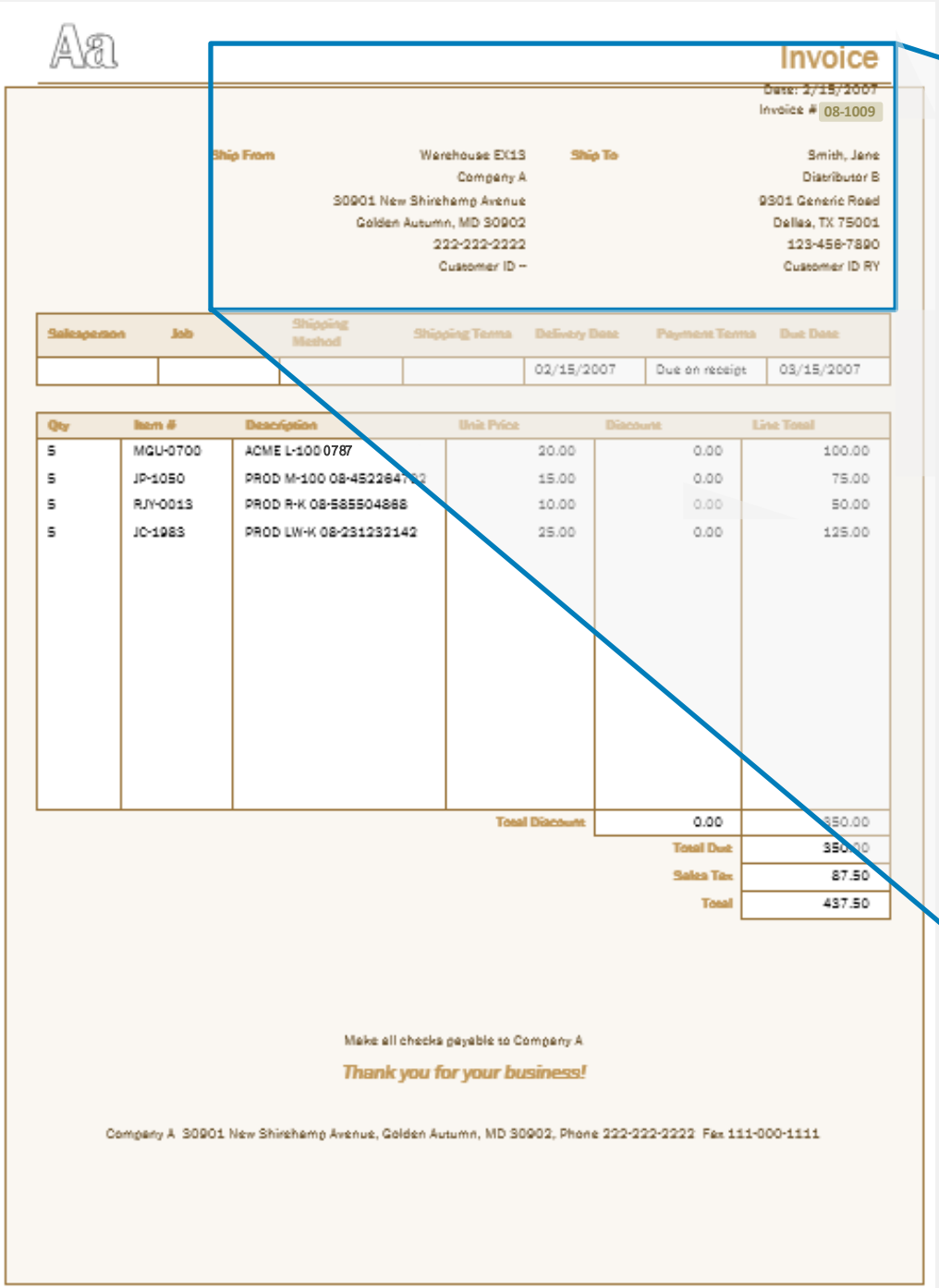
"The name of the product associated with this Grandfathered Submission is '**Acme Lights 100's**'"

TEST MARKET INFORMATION

"I, John Smith, confirm that the tobacco product associated with this Grandfathered Submission, **Acme Lights 100's**, was commercially marketed other than for test marketing in the United States as of February 15, 2007.**"**

COMMERCIAL MARKETING EVIDENCE AS OF FEBRUARY 15, 2007

"The item noted on Invoice #08-1009 as 'ACME L-100 0787' is the same as '**Acme Lights 100's**"



Invoice

Date: 2/15/2007
Invoice # 08-1009

Ship From		Ship To	
	Warehouse EX13		Smith, Jane
	Company A		Distributor B
	30901 New Shirehamp Avenue		9301 Generic Road
	Golden Autumn, MD 30902		Dallas, TX 75001
	222-222-2222		123-456-7890
	Customer ID –		Customer ID RY

Salesperson	Job	Shipping Method	Shipping Terms	Delivery Date	Payment Terms	Due Date
				02/15/2007	Due on receipt	03/15/2007

Qty	Item #	Description	Unit Price	Discount	Line Total
5	MGU-0700	ACME L-100 0787	20.00	0.00	100.00
5	JP-1050	PROD M-100 08-452264702	15.00	0.00	75.00
5	RJY-0013	PROD R-K 08-585504868	10.00	0.00	50.00
5	JC-1983	PROD LW-K 08-231232142	25.00	0.00	125.00

Total Discount	0.00	350.00
Total Due		350.00
Sales Tax		87.50
Total		437.50

Make all checks payable to Company A

Thank you for your business!

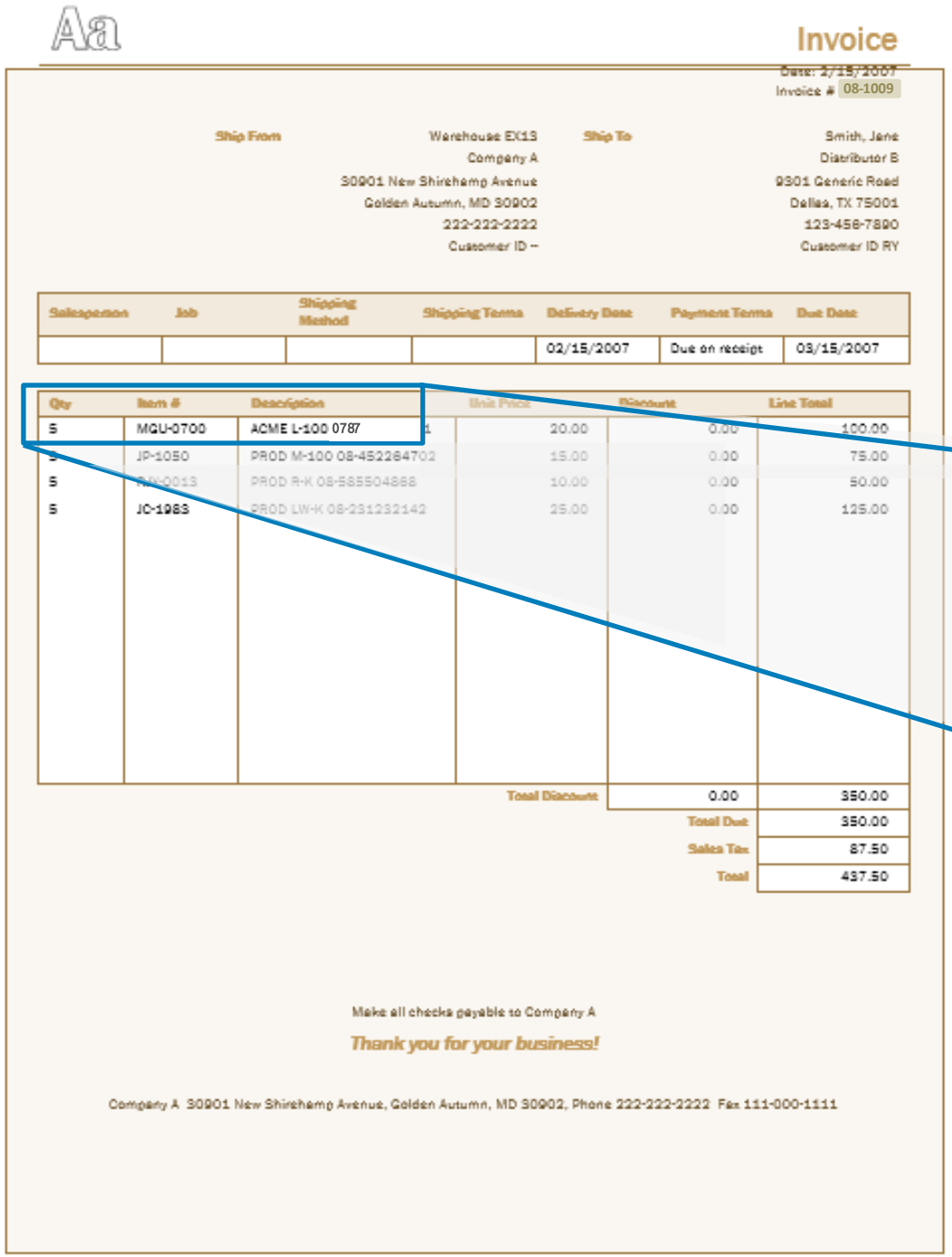
Company A 30901 New Shirehamp Avenue, Golden Autumn, MD 30902, Phone 222-222-2222 Fax 111-000-1111

FDA

Invoice

Date: 2/15/2007
Invoice # 08-1009

Ship From		Ship To	
	Warehouse EX13		Smith, Jane
	Company A		Distributor B
	30901 New Shirehamp Avenue		9301 Generic Road
	Golden Autumn, MD 30902		Dallas, TX 75001
	222-222-2222		123-456-7890
	Customer ID –		Customer ID RY



Invoice

Date: 1/15/2007
Invoice # 08-1009

Ship From		Ship To	
	Warehouse EX13		Smith, Jane
	Company A		Distributor B
	30901 New Shirehamp Avenue		9301 Generic Road
	Golden Autumn, MD 30902		Dallas, TX 75001
	222-222-2222		123-456-7890
	Customer ID --		Customer ID RY

Salesperson	Job	Shipping Method	Shipping Terms	Delivery Date	Payment Terms	Due Date
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Qty	Item #	Description	Unit Price	Discount	Line Total
5	MGU-0700	ACME L-100 0787	20.00	0.00	100.00
5	JP-1050	PROD M-100 08-452284702	15.00	0.00	75.00
5	RW-0013	PROD R-K 08-585504888	10.00	0.00	50.00
5	JC-1983	PROD LW-K 08-231232142	25.00	0.00	125.00
			Total Discount	0.00	350.00
				Total Due	350.00
				Sales Tax	87.50
				Total	437.50

Make all checks payable to Company A

Thank you for your business!

Company A 30901 New Shirehamp Avenue, Golden Autumn, MD 30902, Phone 222-222-2222 Fax 111-000-1111

Qty	Item #	Description
5	MGU-0700	ACME L-100 0787

U.S. PRODUCT CATALOG
FALL 2006

PRODUCT L

NAME	SIZE	QUANTITY	UNIT PRICE	PROMO PRICE
PROD L-100	5.5x56	20	20.00	18.00
PROD L-200	6.5x44	20	20.00	18.00
PROD L-300	6x40	20	20.00	18.00
PROD L-400	6x52	25	25.00	20.00

INVENTORY LIST

COMPANY A

30901 New Shirehamp Avenue
Golden Autumn, MD 30902
222-2222-2222
111-000-1111

DATE: 2/1/2007

Inventory No.	Item Description	Purchase Price	Quantity	Location
MGU-0700	PROD L-100 0787	20.00	5	Dallas, TX
JJ-5110	PROD Z-500 843599513	25.00	2	Dallas, TX

A&A

Invoice

Date: 2/19/2007
Invoice # 08-0830

To	Ship To
Smith, Jane Company B 9301 Generic Road Dallas, TX 75001 123-456-7890 Customer ID RY	Smith, Jane Company B 9301 Generic Road Dallas, TX 75001 123-456-7890 Customer ID RY

Salesperson	Job	Shipping Method	Shipping Terms	Delivery Date	Payment Terms	Due Date
				02/25/2007	Due on receipt	03/15/2007

Qty	Item #	Description	Unit Price	Discount	Line Total
10	MGU-0700	PROD L-100 0787	20.00	0.00	200.00
5	JJ-5110	PROD Z-500-843599513	25.00	0.00	125.00

[25]

CENTER FOR TOBACCO PRODUCTS

Mr. John Smith
Vice President
Company A
30901 New Shirehamp Ave.
Golden Autumn, MD 30902

Re: Submission Tracking Number (STN): GF1500787
Tobacco Product Name: Acme Lights 100's
Date of Submission: January 03, 2015
FDA Receipt Date: January 03, 2015

Dear Mr. Smith:

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.

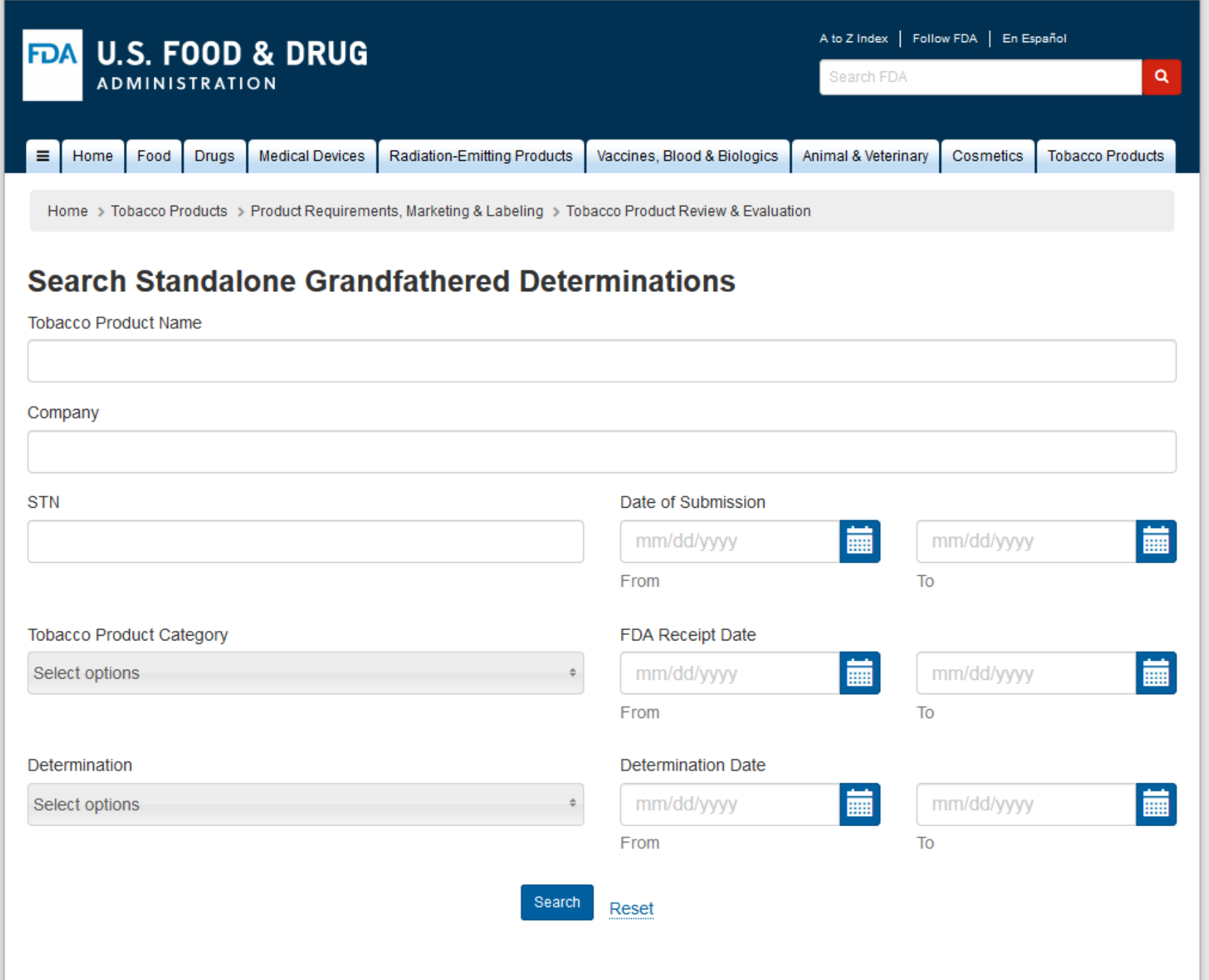
Our grandfather status determination for this product is based on the information you provided in support of this submission. We did not review information concerning the composition, design, or ingredients of this product in order to make our determination. Please note that our determination applies only to this product in the form it was marketed as of February 15, 2007. Any modification to the product 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.

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.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To
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Select options
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LINKS

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

CTP'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/