

Reporting of Harmful and Potentially Harmful Constituents
in Accordance with Section 904(a)(3) and (c)(1) of the
Federal Food, Drug, and Cosmetic Act
ROLL-YOUR-OWN (RYO)
TOBACCO PRODUCT REPORT

Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended on June 22, 2009, requires each tobacco product manufacturer or importer, or an agent, to report to FDA, beginning 3 years after the date of enactment of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), all harmful and potentially harmful constituents (HPHCs), including those in smoke where applicable, by brand and by quantity in each brand and subbrand. Section 904(c)(1) of the FD&C Act requires manufacturers of tobacco products not on the market on the date of enactment of the Tobacco Control Act to provide this same information to FDA at least 90 days prior to introducing the products into interstate commerce.

On April 3, 2012, FDA issued a draft guidance document titled, "Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act." The draft guidance document may assist persons with reporting to FDA the quantities of HPHCs in tobacco products and tobacco smoke under section 904(a)(3) and (c)(1) of the FD&C Act.

This document contains a paper form that can be completed and submitted to FDA in reporting HPHC quantities. It requests information required by the statute as well as information that would assist FDA in assessing HPHC data and in tracking submissions. For further discussion, please see the draft guidance document. The form is found immediately after the instructions that begin on the next page of this document. The instructions explain the information requested in each field on the form. In addition, the instructions specify the format that should be followed when entering information in some fields on the form. The instructions should not be submitted to FDA; only the completed form should be submitted to FDA. If a manufacturer or importer would like to submit HPHC quantities for multiple products in a single submission, the manufacturer or importer needs to submit only "Section I. Manufacturer or Importer Identification" for the first product in the submission (assuming the company information is identical for all products in the submission), and submit Sections II and III for each of the products in the submission.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 0910-0732 (expires March 31, 2016).

**INSTRUCTIONS FOR
ROLL YOUR OWN (RYO) TOBACCO PRODUCT REPORT
(FORM FDA 3787c)**

Section I. Manufacturer or Importer Identification

Section Header: Select the role of the company (Manufacturer or Importer). FDA requests that you indicate whether the company meets the definition of a small tobacco product manufacturer (STPM) (fewer than 350 employees) as stated in section 900(16) of the FD&C Act. Check the YES box if the manufacturer is an STPM and NO if it is not. Finally, FDA requests that you indicate whether the person completing this form is acting as an agent for the company (check YES or NO).

Use the information in the tables below to complete Section I of this submission.

Manufacturer or Importer Name and Address

Term	Instruction
Name	Enter the name of the manufacturer or importer for which this report is being submitted.
Country	Enter the country.
Address 1	Enter line 1 of the address.
Address 2	Enter line 2 of the address if needed.
City	Enter the city.
State	Enter the state (2-letter abbreviation), province, or territory.
ZIP	Enter the ZIP or postal code.
Telephone	For U.S. numbers, enter the telephone number in the format (area code) ###-####. For non-U.S. numbers, enter the country code followed by the telephone number.
Fax	Enter the information as requested for the telephone number above.
FEI	Enter the FDA Establishment Identifier (if known).
D-U-N-S	Enter the Dun & Bradstreet (D&B) D-U-N-S number for the establishment listed above (see the guidance document).

(Section I. Manufacturer or Importer Identification continued on next page)

Section I. Manufacturer or Importer Identification (Continued)**Point of Contact**

Term	Instruction
Prefix	Enter the prefix (e.g., Dr., Mr., Ms., Mrs.).
First name	Enter the first or given name of the person who can be contacted if questions arise about this submission.
Middle name	Enter the middle name or initial.
Last name	Enter the last name.
Degree(s)	Enter the degree or degrees (e.g., PhD, JD).
Title	Enter the title of the point of contact (e.g., Agent, CEO).
Email	Enter the e-mail address of the point of contact.
Company name	Enter the name of the company for which the point of contact works.
Country	Enter the country.
Address 1	Enter line 1 of the address.
Address 2	Enter line 2 of the address if needed.
City	Enter the city.
State	Enter the state (2-letter abbreviation), province, or territory.
ZIP	Enter the ZIP or postal code.
Telephone	For U.S. numbers, enter the telephone number in the format (area code) ###-####. For non-U.S. numbers, enter the country code followed by the telephone number.
Fax	Enter the information as requested for the telephone number above.

Section II. Tobacco Product Identification

Page Headers: Enter the RYO tobacco product brand and subbrand in the blank space at the top of each page of the form. If the form is filled out in Adobe Acrobat/Adobe Reader, the information will automatically be entered on pages 2-5 of this form based on the information provided for Brand/Subbrand in Section II.

Use the information in the table below to complete Section II of this submission.

Term	Instruction
Brand name	Enter the brand name of the RYO tobacco product (e.g., Acme).
Subbrand name	Enter the subbrand name of the RYO tobacco product (e.g., Menthol).
Unique ID	Enter the unique identifying name or number used by the manufacturer/importer.
ID Type	Enter the type of identification (e.g., internal manufacturer number, catalog number, UPC).
Package size(s)	List the mass of tobacco in the package(s).
Category	NA
Testing Laboratory #1	
Name	Enter the name of the testing laboratory.
Country	Enter the country.
Address 1	Enter line 1 of the address.
Address 2	Enter line 2 of the address if needed.
City	Enter the city.
State	Enter the state (2-letter abbreviation), province, or territory.
ZIP	Enter the ZIP or postal code.
Telephone	For U.S. numbers, enter the telephone number in the format (area code) ###-####. For non-U.S. numbers, enter the country code followed by the telephone number.
Fax	Enter the information as requested for the telephone number above.

(Section II. Tobacco Product Identification continued on next page)

Section II. Tobacco Product Identification (Continued)

Term	Instruction
Testing Laboratory #2*	
Name	Enter the name of the testing laboratory.
Country	Enter the country.
Address 1	Enter line 1 of the address.
Address 2	Enter line 2 of the address if needed.
City	Enter the city.
State	Enter the state (2-letter abbreviation), province, or territory.
ZIP	Enter the ZIP or postal code.
Telephone	For U.S. numbers, enter the telephone number in the format (area code) ###-####. For non-U.S. numbers, enter the country code followed by the telephone number.
Fax	Enter the information as requested for the telephone number above.

*Complete only if more than one laboratory was used.

Section III. HPHC Quantities and Testing Information

HPHC Tables: There are separate tables for each HPHC that must be reported for RYO tobacco products. HPHCs are listed alphabetically by name and include CAS numbers and FDA UNII codes.

Information should be entered in all cells of a given HPHC table. The table below includes details about the information that should be entered in each cell.

Term	Instruction
Replicates	Enter the number of replicate measurements made in determining the quantity of the HPHC.
Test date range	Enter the date or range of dates when samples of the RYO tobacco product were tested for the specific HPHC. If all tests of the samples for the specific HPHC were performed in a single day, enter the date before the hyphen in the format "mm/dd/yyyy." If samples of the RYO tobacco product were tested on more than one date, enter the earliest and latest dates before and after the hyphen, respectively (mm/dd/yyyy - mm/dd/yyyy).
Manufacture date range	Enter the date or range of dates when the tested samples of the RYO tobacco product were manufactured (i.e., packaged in finished form for distribution to retailers/consumers). If all samples of the RYO tobacco product were manufactured on the same date, enter the date before the hyphen in the format "mm/dd/yyyy." If samples of the RYO tobacco product were manufactured on more than one date, enter the earliest and latest dates before and after the hyphen, respectively (mm/dd/yyyy - mm/dd/yyyy).
Extraction	Enter the method used to extract the constituent from the RYO tobacco product (no more than 80 characters). If one is available, please provide a reference citation. Alternatively, we would like to know: <ul style="list-style-type: none">• Solvent• Agitation time
Separation	Enter the method used to separate the specific HPHC from other constituents using one of the following abbreviations. If the method is not listed, enter "Other" and specify the method in the "Other Separation Method" entry that follows: <ul style="list-style-type: none">• GC: Gas Chromatography• HPLC: High Pressure Liquid Chromatography• IC: Ion Chromatography• LC: Liquid Chromatography• UPLC: Ultra Pressure Liquid Chromatography
Other separation method	If the separation method is not listed above, specify the method used without abbreviation (no more than 60 characters).

(Section III. HPHC Quantities and Testing Information, HPHC Tables Information, continued on next page)

Section III. HPHC Quantities and Testing Information, HPHC Tables Information (Continued)

Term	Instruction
Detection	<p>Enter the detection method used to determine the quantity of the specific HPHC using one of the following abbreviations. If the method is not listed, enter "Other" and specify the method in the "Other Detection Method" entry that follows.</p> <ul style="list-style-type: none"> • AED: Atomic Emission Detector • ECD: Electron Capture Detector • ELSD: Evaporative Light-Scattering Detector • FID: Flame Ionization Detector • FPD: Flame Photometric Detector • FD: Fluorescence Detector • MSD: Mass Spectrometry Detector • NCD: Nitrogen Chemiluminescence Detector • NPD: Nitrogen-Phosphorous Detector • PID: Photoionization Detector • SCD: Sulfur Chemiluminescence Detector • MSMS: Tandem Mass Spectrometry • TCD: Thermal Conductivity Detector • UVD: Ultraviolet Detector
Other detection method	<p>If the detection method is not listed above, enter the method used without abbreviation (no more than 60 characters).</p>
Mean quantity of HPHC	<p>Enter the mean quantity of the specified HPHC in the RYO tobacco product. The mean quantity should include 3 significant figures or more if appropriate. In no case should more than 6 digits be reported. The mean quantity is expressed per mass of tobacco (e.g., per gram). Also, enter the unit of mass in the blank provided. For example, 123.456 per gram. If the quantity is below the limit of detection or limit of quantitation, enter 0.000 in this field.</p>
Variance of mean HPHC quantity	<p>Enter the variance in mean HPHC quantity. The variance is to be expressed in the same unit of measurement as the mean HPHC quantity. The variance should include 3 significant figures or more if appropriate. In no case should more than 6 digits be reported. If the quantity is below the limit of detection or limit of quantitation, leave this field blank.</p>
Type of variance	<p>Enter the type of variance of the mean, such as standard deviation. If the quantity is below the limit of detection or limit of quantitation, enter NA (not applicable) in this field.</p>
Unit of measurement for mean and variance per mass of tobacco	<p>Select the unit of measurement, such as nanograms, for the mean and variance of the mean HPHC quantity per mass of tobacco. For example, if "nanograms" is selected and mean quantity of tobacco is reported per gram (in the "Mean quantity of HPHC per mass of tobacco" field), then the mean quantity of HPHC and variance of the mean are being reported as nanograms <i>per gram of tobacco</i>. If the quantity is below the limit of detection or limit of quantitation, do not select a unit of measurement.</p>

NOTE: If you would like to submit information for HPHCs other than those listed on this form, please make copies of Sections II and III, complete the new pages, and attach them to the form.

**Reporting of Harmful and Potentially Harmful Constituents
in Accordance with Section 904(a)(3) and (c)(1) of the
Federal Food, Drug, and Cosmetic Act**

**ROLL-YOUR-OWN (RYO)
TOBACCO PRODUCT REPORT**

I. MANUFACTURER OR IMPORTER IDENTIFICATION

Role of the company for which this report is being submitted

Manufacturer Importer

Is the company a small tobacco product manufacturer?

Yes No

Are you an agent submitting on behalf of the company?

Yes No

Manufacturer or Importer Name and Address

Company name

Country

Address – line 1

Address – line 2

City

State, Province, or Territory

Post office or ZIP code

Telephone number

Fax number

FDA Establishment Identifier (FEI)

D&B D-U-N-S Number

Point of Contact

Prefix

First/given name

Middle name

Last name

Degree(s)

Title

Email address

Company name

Country

Address – line 1

Address – line 2

City

State, Province, or Territory

Post office or ZIP code

Telephone number

Fax number

II. TOBACCO PRODUCT IDENTIFICATION

Brand name

Subbrand name

Unique product identification number

Type of product identification number

Package size(s)

Product category

RYO Tobacco Product

Testing Laboratory #1

Laboratory name

Country

Address – line 1

Address – line 2

City

State, Province, or Territory

Post office or ZIP code

Telephone number

Fax number

Testing Laboratory #2

Laboratory name

Country

Address – line 1

Address – line 2

City

State, Province, or Territory

Post office or ZIP code

Telephone number

Fax number

III. HPHC QUANTITIES AND TESTING INFORMATION

Ammonia

CAS number 7664-41-7	FDA UNII code 5138Q19F1X
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Number of replicate measurements	Test date range (mm/dd/yyyy) _____ - _____	Manufacture date range (mm/dd/yyyy) _____ - _____
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Extraction method (80 character limit)

Separation method (Select from drop-down list)	If Separation method is "Other," specify here (No abbreviation; 60 character limit)
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Detection method (Select from drop-down list)	If Detection method is "Other," specify here (No abbreviation; 60 character limit)
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Mean quantity of HPHC per mass of tobacco ____ . ____ per _____ (unit of mass such as gram)	Variance of mean HPHC quantity ____ . ____	Type of variance
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Unit of measurement for mean and variance per mass of tobacco (Select one)

- grams
 milligrams
 micrograms
 nanograms
 picograms
 Other (Specify unit of mass): _____

Arsenic

CAS number 7440-38-2	FDA UNII code N712M78A8G
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Number of replicate measurements	Test date range (mm/dd/yyyy) _____ - _____	Manufacture date range (mm/dd/yyyy) _____ - _____
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Extraction method (80 character limit)

Separation method (Select from drop-down list)	If Separation Method is "Other," specify here (No abbreviation; 60 character limit)
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Detection method (Select from drop-down list)	If Detection Method is "Other," specify here (No abbreviation; 60 character limit)
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Mean quantity of HPHC per mass of tobacco ____ . ____ per _____ (unit of mass such as gram)	Variance of mean HPHC quantity ____ . ____	Type of variance
--	--	------------------

Unit of measurement for mean and variance per mass of tobacco (Select one)

- grams
 milligrams
 micrograms
 nanograms
 picograms
 Other (Specify unit of mass): _____

Cadmium

CAS number

7440-43-9

FDA UNII code

00BH33GNHG

Number of replicate measurements

Test date range (mm/dd/yyyy)

Manufacture date range (mm/dd/yyyy)

Extraction method (80 character limit)

Separation method (Select from drop-down list)

If Separation Method is "Other" specify here (No abbreviation; 60 character limit)

Detection method (Select from drop-down list)

If Detection Method is "Other" specify here (No abbreviation; 60 character limit)

Mean quantity of HPHC per mass of tobacco

____ . ____ per _____ (unit of mass such as gram)

Variance of mean

HPHC quantity ____ . ____

Type of variance

Unit of measurement for mean and variance per mass of tobacco (Select one)

 grams milligrams micrograms nanograms picograms Other (Specify unit of mass): _____

Nicotine (Total)

CAS number

54-11-5

FDA UNII code

6M3C89ZY6R

Number of replicate measurements

Test date range (mm/dd/yyyy)

Manufacture date range (mm/dd/yyyy)

Extraction method (80 character limit)

Separation method (Select from drop-down list)

If Separation Method is "Other" specify here (No abbreviation; 60 character limit)

Detection method (Select from drop-down list)

If Detection Method is "Other" specify here (No abbreviation; 60 character limit)

Mean quantity of HPHC per mass of tobacco

____ . ____ per _____ (unit of mass such as gram)

Variance of mean

HPHC quantity ____ . ____

Type of variance

Unit of measurement for mean and variance per mass of tobacco (Select one)

 grams milligrams micrograms nanograms picograms Other (Specify unit of mass): _____

Brand/Subbrand:

RYO

NNK

CAS number

64091-91-4

FDA UNII code

7S395EDO61

Number of replicate measurements

Test date range (mm/dd/yyyy)

Manufacture date range (mm/dd/yyyy)

Extraction method (80 character limit)

Separation method (Select from drop-down list)

If Separation Method is "Other," specify here (No abbreviation; 60 character limit)

Detection method (Select from drop-down list)

If Detection Method is "Other," specify here (No abbreviation; 60 character limit)

Mean quantity of HPHC per mass of tobacco

____ . ____ per ____ (unit of mass such as gram)

Variance of mean HPHC quantity

Type of variance

Unit of measurement for mean and variance per mass of tobacco (Select one)

- grams milligrams micrograms nanograms picograms
- Other (Specify unit of mass): _____

NNN

CAS number

16543-55-8

FDA UNII code

X656TZ86DX

Number of replicate measurements

Test date range (mm/dd/yyyy)

Manufacture date range (mm/dd/yyyy)

Extraction method (80 character limit)

Separation method (Select from drop-down list)

If Separation Method is "Other," specify here (No abbreviation; 60 character limit)

Detection method (Select from drop-down list)

If Detection Method is "Other," specify here (No abbreviation; 60 character limit)

Mean quantity of HPHC per mass of tobacco

____ . ____ per ____ (unit of mass such as gram)

Variance of mean HPHC quantity

Type of variance

Unit of measurement for mean and variance per mass of tobacco (Select one)

- grams milligrams micrograms nanograms picograms
- Other (Specify unit of mass): _____

FDA Contact Telephone Numbers:

FD1-877-CTP-1373; 1-877-287-1373
(9am EST - 4pm EST)

Tobacco Information:

For General Inquiries:
AskCTP@fda.hhs.gov

Mail completed form to:

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 12 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the following address:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”