

**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**

**SMOKELESS 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On April 3, 2012, FDA issued a draft guidance document titled, "Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food,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 The draft guidance document may assist persons with reporting to FDA the quantities of HPHCs in tobacco products and tobacco smoke under section 904(a)(3) and (c)(1) of the FD&C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 For further discussion, please see the draft guidance document.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 SMOKELESS
TOBACCO PRODUCT REPORT
(FORM FDA 3787b)**

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 smokeless 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 2-7 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 smokeless tobacco product (e.g., Acme).
Subbrand name	Enter the subbrand name of the smokeless tobacco product (e.g., Original).
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)	If this product is portioned, list the number of portions or units per package(s). If this product is unportioned, list the mass of product content (not including the container) for each package.
Category	NA
Subcategory	Enter one of the following subcategories of smokeless tobacco product: <ul style="list-style-type: none">• Chew – loose leaf• Chew – plug• Chimo• Dissolvable• Dry Snuff loose• Dry Snuff loose (nasal)• Dry Snuff pouched• Gul• Gutkha• Iq'mik• Khaini• Liquid/Gel• Mawa• Mishri• Moist Snuff Loose• Moist Snuff pouched• Nass (Naswar, Niswar)• Qiwam• Snus pouches (pasteurized)• Toomback• Zarda• Other
Other subcategory	Specify subcategory if not listed above.

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

Section II. Tobacco Product Identification (Continued)

Term	Instruction
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.
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

In the first part of this section, enter information about the quantity of tobacco in the smokeless tobacco product according to the table below.

Term	Instruction
Portioned?	Is the product composed of individual units of use (e.g., tablets, sticks, strips, pouches)? Check YES or NO.
Mean mass of tobacco	If the product is portioned, enter the mean mass of tobacco in an individual unit of the smokeless tobacco product. The mean mass should include 3 significant figures or more if appropriate. In no case should more than 6 digits be reported. If the product is not portioned, do not enter anything in this field.
Variance of mean mass	Enter the variance of the mean mass of tobacco in the same units as used for mass (e.g., grams). The variance should include 3 significant figures or more if appropriate. In no case should more than 6 digits be reported. If the product is not portioned, do not enter anything in this field.
Type of variance	Enter the type of variance of the mean, such as standard deviation. If the product is not portioned, do not enter anything in this field.
Unit of measurement for mean and variance	Enter the unit of measurement for the mean and variance of the mean, such as grams.

HPHC Tables: There are separate tables for each HPHC that must be reported for smokeless 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 how information should be entered into 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 smokeless 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 smokeless 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).

(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
Manufacture date range	Enter the date or range of dates when the tested samples of smokeless tobacco product were manufactured (i.e., packaged in finished form for distribution to retailers/consumers). If all samples of the smokeless tobacco product were manufactured on the same date, enter the date before the hyphen in the format “mm/dd/yyyy.” If samples of the smokeless 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 HPHC from the smokeless tobacco product (no more than 80 characters). If one is available, provide a reference citation. Alternatively, we would like to know: <ul style="list-style-type: none"> • Solvent • Agitation time This is not applicable to free nicotine.
Separation	Enter the method used to separate the HPHC from other constituents using one of the following abbreviations: <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 This is not applicable to free nicotine.
Other separation method	If the separation method is not listed above, specify the method used without abbreviation (no more than 60 characters).
Detection	Enter the detection method used to determine the quantity of the specific HPHC using one of the following abbreviations: <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 This is not applicable to free nicotine.
Other detection method	If the detection method is not listed above, enter 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
Calculation method	Only applicable to free nicotine. State the method used to determine the quantity of free (unprotonated) nicotine (e.g., CDC). Response is limited to 60 characters.
Mean quantity of HPHC	Enter the mean quantity of the specified HPHC in the smokeless 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 portioned unit (e.g., pouch, tablet, stick, strip) or, if unportioned, per mass of tobacco (e.g., per gram). If unportioned, 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.
Variance of mean HPHC quantity	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.
Type of variance	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.
Unit of measurement for mean and variance per portion or per mass of tobacco	Select the unit of measurement, such as nanograms, for the mean and variance of the mean HPHC quantity per portion or per mass of tobacco. For example, if "nanograms" is selected and the mean quantity of tobacco is reported per pouch (in the "Mean quantity of HPHC per portion or mass of tobacco" field), then the mean quantity of HPHC and variance of the mean are reported as nanograms <i>per pouch</i> . If the quantity is below the limit of detection or limit of quantitation, do not select a unit of measurement.

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**

**SMOKELESS 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

Brand/Subbrand:

Smokeless

II. TOBACCO PRODUCT IDENTIFICATION

Brand name

Subbrand name

Unique product identification number

Type of product identification number

Package size(s)

Product category

Smokeless Tobacco Product

Product subcategory (*Select from drop-down list*)

If other subcategory, specify

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

Quantity of Tobacco

Is the product portioned into individual units of use? <input type="checkbox"/> Yes <input type="checkbox"/> No	If portioned, mean mass of tobacco in individual unit of use _____
If portioned, variance of mean mass _____	Type of variance
Unit of measurement for mean and variance (<i>Select one</i>) <input type="checkbox"/> grams <input type="checkbox"/> milligrams <input type="checkbox"/> micrograms <input type="checkbox"/> nanograms <input type="checkbox"/> picograms	

Acetaldehyde

CAS number 75-07-0	FDA UNII code GO1N1ZPR3B
Number of replicate measurements	Test date range (mm/dd/yyyy) _____ - _____
	Manufacture date range (mm/dd/yyyy) _____ - _____

Extraction method (80 character limit)

Separation method (<i>Select from drop-down list</i>)	If Separation method is "Other," specify here (<i>No abbreviation; 60 character limit</i>)
Detection method (<i>Select from drop-down list</i>)	If Detection method is "Other," specify here (<i>No abbreviation; 60 character limit</i>)

Mean quantity of HPHC per portion or per mass of tobacco _____ per _____ (<i>portion or unit of mass such as gram</i>)	Variance of mean HPHC quantity _____	Type of variance
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Unit of measurement for mean and variance per portion or 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
Number of replicate measurements	Test date range (mm/dd/yyyy) _____ - _____
	Manufacture date range (mm/dd/yyyy) _____ - _____

Extraction method (80 character limit)

Separation method (<i>Select from drop-down list</i>)	If Separation Method is "Other," specify here (<i>No abbreviation; 60 character limit</i>)
Detection method (<i>Select from drop-down list</i>)	If Detection Method is "Other," specify here (<i>No abbreviation; 60 character limit</i>)

Mean quantity of HPHC per portion or per mass of tobacco _____ per _____ (<i>portion or unit of mass such as gram</i>)	Variance of mean HPHC quantity _____	Type of variance
---	---	------------------

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

grams milligrams micrograms nanograms picograms

Other (*Specify unit of mass*): _____

Brand/Subbrand:

Smokeless

Benzo[a]pyrene

CAS number 50-32-8	FDA UNII code 3417WMA06D
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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)
--	---

Detection method (Select from drop-down list)	If Detection Method is "Other," specify here (No abbreviation; 60 character limit)
---	--

Mean quantity of HPHC per portion or per mass of tobacco ____ . ____ per _____ (portion or unit of mass such as gram)	Variance of mean HPHC quantity _____	Type of variance
--	---	------------------

Unit of measurement for mean and variance per portion or 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 00BH33GN GH
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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)
--	---

Detection method (Select from drop-down list)	If Detection Method is "Other," specify here (No abbreviation; 60 character limit)
---	--

Mean quantity of HPHC per portion or per mass of tobacco ____ . ____ per _____ (portion or unit of mass such as gram)	Variance of mean HPHC quantity _____	Type of variance
--	---	------------------

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

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

Crotonaldehyde

CAS number

4170-30-3

FDA UNII code

9G72074TUW

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 portion or per mass of tobacco

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

Variance of mean HPHC quantity

____ . ____

Type of variance

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

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

Formaldehyde

CAS number

50-00-0

FDA UNII code

1HG84L3525

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 portion or per mass of tobacco

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

Variance of mean HPHC quantity

____ . ____

Type of variance

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

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

Brand/Subbrand:

Smokeless

Nicotine (Free)

CAS number

54-11-5

FDA UNII code

6M3C89ZY6R

Method of calculation (60 character limit)

Number of replicate measurements used in calculation

Mean quantity of HPHC per portion or per mass of tobacco

--- . --- per --- (portion or unit of mass such as gram)

Variance of mean HPHC quantity

--- . ---

Type of variance

Unit of measurement for mean and variance per portion or 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 portion or per mass of tobacco

--- . --- per --- (portion or unit of mass such as gram)

Variance of mean HPHC quantity

--- . ---

Type of variance

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

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

Brand/Subbrand:

Smokeless

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 portion or per mass of tobacco

_____ per _____ (portion or unit of mass such as gram)

Variance of mean HPHC quantity

Type of variance

Unit of measurement for mean and variance per portion or 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 portion or per mass of tobacco

_____ per _____ (portion or unit of mass such as gram)

Variance of mean HPHC quantity

Type of variance

Unit of measurement for mean and variance per portion or 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 14 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

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