Form Approved: OMB No. xxxx-xxxx Expiration Date: xx/xx/xxxx See OMB Statement on inside cover

Survey of Current Manufacturing Practices for the Cosmetics Industry

2018

This survey applies only to the facility listed on this label.

Refer to this label as instructed in the survey.

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is xxxx-xxxx. The time required to complete this information collection is estimated to average 60 minutes per response, including the time for reviewing instructions, searching for existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing this burden to:

Carolyn Wolff Food and Drug Administration Office of the Commissioner, Economics Staff

Phone: (240) 402-0519

E-mail: CosmeticsManufacturingSurvey@fda.hhs.gov

Instructions

The U.S. Food and Drug Administration (FDA), has contracted with RTI International to conduct a survey of cosmetics manufacturing facilities. This survey collects information about industry's use of various manufacturing practices and the cost of those practices to the manufacturers. There is no systematic study of the cosmetic industry's current manufacturing practices at the national level. The aim of this survey is to fill this knowledge gap.

Participation in this survey is important to FDA, and we thank you for your help. The survey results will benefit the cosmetics manufacturing industry by improving the agency's understanding of current industry practices and costs. To thank you for participating, you will receive a summary report of the survey results.

Please answer all questions as they pertain to the specific facility named on the mailing label attached to the front of this survey booklet. By facility, we mean all the buildings used for cosmetics manufacturing within the general area of the address shown on the mailing label. To answer, select a response by circling the number associated with the response option.

Please consult with other members of your organization if you do not know the answer to a question. Please try to answer all questions to the best of your ability.- Your best estimate is acceptable. You do not need to consult records to answer the survey. For any word printed in bold type in a question, there is a definition provided near the question.

Participation in this survey is voluntary. The data you provide will be kept secure to the extent permitted by law. Responses to the survey will <u>not</u> be used as the basis of enforcement action against this facility. The data provided to FDA will not contain identifying information about the participant, facility, or manufacturer. The study results will be reported to the public in aggregate form only so that individual facilities or manufacturers cannot be identified.

Please return the completed survey within 10 business days.

Questions?Contact the Survey Helpline

If you have any questions as you complete the survey, please send an email to <u>FDACosmeticSurvey@rti.org</u> or call toll-free at 877-xxx-xxx. We operate the telephone Helpline on weekdays from 9:00 a.m. to 5:00 p.m. EST.

Section 1 About Your Facility

- During the past 12 months, did this facility manufacture **cosmetics**? Select "no" if your facility only manufactures cosmetics with an active ingredient, over-the-counter drug products, or products with a Drug Facts label.
 - 1. Yes
 - 2. No (Please circle response and STOP survey. Please return the survey in the postage paid envelope so we know this facility does not manufacture cosmetics.)
- 1.2 During the past 12 months, did this facility produce cosmetics that were sold across state lines?

By **cosmetics**, we mean the following products: baby cleansing products, bath preparations, fragrances, hair care products, hair colorings, makeup, manicure products, oral hygiene products, personal cleaning products, shaving and skin care products, suntan products, and tattoo ink.

- 1. Yes
- 2. No (Please circle response and STOP survey. Please return the survey in postage paid envelope so we know this facility does not manufacture cosmetics that are sold across state lines.)
- 1.3 What cosmetics did this facility manufacture during the past 12 months? Select all categories that apply.
 - 1. Baby Products (e.g., shampoo, lotion, oil, powder, creams)
 - 2. Bath Preparations (e.g., oils, tablets, salts, capsules, bubble bath)
 - 3. Eye Makeup Preparations (e.g., pencil, liner, shadow, remover, mascara)
 - 4. Makeup Preparations Not Eye (e.g., blush, powder, foundation, lipstick, body paint)
 - 5. Fragrance Preparations (e.g., perfume, cologne, powder, sachet)
 - 6. Hair Preparations (e.g., shampoo, conditioner, rinse, spray, straightener, wave sets)
 - 7. Hair Coloring Preparations (e.g., dye, color, tint, coloring rinses, coloring shampoo, lightener, bleach)
 - 8. Manicuring Preparations (e.g., polish, remover, extenders, cuticle softener, nail cream)
 - 9. Oral Hygiene Products (e.g., dentifrices, mouthwash, breath freshener)
 - 10. Personal Cleanliness (e.g., bath soap, deodorant, douche, feminine deodorant)
 - 11. Shaving Preparations (e.g., shaving cream, soap, pre-shave lotion, aftershave lotion, talcum, beard softener)
 - 12. Skin Care Preparations (e.g., cleaner, depilatories, foot powder and spray, moisturizer, paste mask)
 - 13. Suntan Preparations (e.g., suntan gel, cream, indoor tanning preparation, NOT sunscreen)
 - 14. Tattoo Ink
- 1.4 During the past 12 months, did this facility manufacture any products with a Drug Facts label?
 - 1. Yes
 - 2. No
- 1.5 Does this facility operate under any of the following Good Manufacturing Practices (GMP) guidelines? Select all that apply.
 - 1. FDA Guidance for the Cosmetic Industry (updated in 2013)
 - 2. ISO 22716: Cosmetics Good Manufacturing Practices
 - 3. FDA Drug GMP (21 CFR Parts 210 and 211)
 - 4. ISO 9001
 - 5. Other (specify: _____)
 - 6. None

Section 2 Written Procedures and Documentation

The following definitions are provided for questions 2.1 through 2.4:

By **written procedures**, we mean management approved documents that are issued on paper or electronically to train, guide, and direct employees. Examples include posted signs, policy and procedure (P&P) manuals, and information posted on the company's internal website.

By **records**, we mean information or data that reflects the history of manufacturing operations and supporting activities.

2.1 Does this facility have written procedures or maintain records for the following items related to *personnel*? Select a response in each row of the table below for both written procedures and records.

Itam	Have Written	Procedures	Maintain Records	
Item	Yes	No	Yes	No
a. Personnel hygiene				
b. Personnel apparel				
c. Personnel training on GMPs				

2.2 Does this facility have **written procedures** or maintain **records** for the following items related to *raw materials* and processing? Select a response in each row of the table below for both written procedures and records.

Itom	Have Written	Procedures	Maintain Records		
Item	Yes	No	Yes	No	
a. Receiving raw materials					
b. Storing aw materials					
c. Weighing raw materials					
d. Labeling of raw materials					
e. Labeling of in-process materials					
f. Laboratory testing of raw materials					
g. Laboratory testing of in-process materials					
h. Calibration of measuring instruments					
i. Manufacturing standard operating					
procedures (SOPs)					
j. Investigating failures and deviations					

2.3 Does this facility have **written procedures** or maintain **records** for the following items related to *cleaning and maintenance*? Select a response in each row of the table below for both written procedures and records.

Item	Have Written	Procedures	Maintain	Records
iteiii	Yes	No	Yes	No
a. Equipment cleaning or sanitization				
b. Equipment maintenance				
c. Storage of cleaning and sanitizing materials				
d. Use of cleaning and sanitizing materials				
e. Maintenance of water systems				
f. Sanitization of water systems				
g. Building maintenance				
h. Pest control				

2.4 Does your company or facility have **written procedures** or maintain **records** for the following items related to *finished products*? Select a response in each row of the table below for both written procedures and records.

Itam	Have Written	Procedures	Maintain Records	
Item	Yes	No	Yes	No
a. Labeling of finished products				
b. Laboratory testing of finished products				
c. Distribution of product				
d. Shelf-life monitoring or stability studies				
e. Consumer complaints				
f. Product returns				
g. Product recalls				

- 2.5 What is your best estimate of the average number of *management* labor hours needed to establish written procedures for one manufacturing process?
 - 1. 0 10 hours
 - 2. 11 20 hours
 - 3. 21 40 hours
 - 4. 41 or more hours
- 2.6 What is your best estimate of the average number of *Quality Assurance (QA)/Quality Control (QC) personnel* labor hours needed to establish written procedures for one manufacturing process?
 - 1. 0 10 hours
 - 2. 11 20 hours
 - 3. 21 40 hours
 - 4. 41 or more hours

The following questions ask about training for three employment categories: management, QA/QC, and production. If an employee has responsibilities in more than one category (for example, management and QA/QC), only include them in the employment category that accounts for most of his/her time.

Initial training could include training new employees, training employees who change jobs within the company, or training existing employees on a new procedure.

2.7 Questions 2.1 through 2.4 covered several written procedures that your facility may have in place. What is your best estimate of the number of *management employees* trained annually on the written procedures used by this facility? Select one response for each training type.

	Number of Management Employees							
Training Type	None	1 to 9	10 to 49	50 to 99	100 or			
					more			
a. Initial Training								
b. Refresher Training								

2.8 What is your best estimate of the number of QA/QC employees trained annually on the written procedures used by this facility (listed in Questions 2.1 – 2.4)? Select one response for each training type.

	Number of QA/QC Employees						
Training Type	None	1 to 9	10 to 49	50 to 99	100 or		
					more		

a. Initial Training			
b. Refresher Training			

2.9 What is your best estimate of the number of *production employees* trained annually on the written procedures used by this facility (listed in Questions 2.1 – 2.4)? Select one response for each training type.

		Number of Production Employees							
Training Type	None	1 to 19	20 to 99	100 to 499	500 or more				
a. Initial Training									
b. Refresher Training									

- 2.10 Does this facility keep records by production batch?
 - 1. Yes
 - 2. No
- 2.11 What is your best estimate of the average number of *management* labor hours required to set up a recordkeeping system? A recordkeeping system may also be known as document control.
 - 1. 40 160 hours
 - 2. 161 320 hours
 - 3. 321 480 hours
 - 4. 481 or more hours
- 2.12 What is your best estimate of the number of QA/QC personnel labor hours required to set up a recordkeeping system?
 - 1. 40 160 hours
 - 2. 161 320 hours
 - 3. 321 480 hours
 - 4. 481 or more hours

Section 3 Buildings and Equipment

- 3.1 Which of the following spaces are **separate and defined areas** within the facility? Select all that apply.
 - 1. Production
 - 2. Quality Control / Laboratory
 - 3. Storage / Warehouse
 - 4. Eating area
 - 5. Restrooms
 - 6. None of the above
- 3.2 Does this facility have pest control procedures?
 - 1. No (skip to Question 3.4)
 - 2. Yes, using an outside contractor
 - 3. Yes, using facility employees
- 3.3 How many rodent bait stations are present at this facility?
 - 1. None
 - 2. 1-9
 - 3. 10 19
 - 4. 20 29
 - 5. 30 or more

By **separate and defined areas**, we mean work areas segregated by walls, other barriers, or sufficient space that are identified by signage.

3.4 How frequently are the following surfaces in your production area cleaned? Select only one response for each row of the table below.

		Frequency							
Surface	Never	As Needed (when spill or splashes occur)	End of Shift	Daily	Weekly	Monthly	Semi- Annually	Annually	Not Applicable
a. Floors									
b. Walls									
c. Ceilings									
d. Windows									
e. Drains									

3.5	What is your best estimate of the total gallons of water from all sources used at this facility in a typical month?
	Enter your best estimate in the space below.

_____ gallons of water/month

- 3.6 Of the total estimated in Question 3.5, what is your best estimate of the percentage of water used both as a raw material in product formulas and for final rinses of product contact surfaces when cleaning equipment?
 - 1. 0 25%
 - 2. 26 50%
 - 3. 51 75%
 - 4. 76 100%

3.7	How does your facility treat water used as a raw material in product formulas and for final rinses of product
	contact surfaces when cleaning equipment? Select all that apply.

1. We do not treat water; we use municipal (tap) water that meets federal EPA standards for the quality of drinking water.

2. We use **deionized tap water**.

3. We have a **purified water** system that uses Reverse Osmosis (RO).

4. Other (Specify:)
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By **deionized water**, we mean water made from tap water using vendor delivered ion exchange columns.

By **purified water**, we mean water made from tap water using installed Reverse Osmosis (RO) and additional types of purification.

3.8 What is your best estimate of the monthly costs incurred by this facility for the service, purchase of materials, and maintenance of system(s) for water used in formulas and final rinsing of product contact surfaces?

- 1. Less than \$499 per month
- 2. \$500 1,999 per month
- 3. \$2,000 19,999 per month
- 4. \$20,000 39,999 per month
- 5. \$40,000 59,999 per month
- 6. \$60,000 or more per month

3.9 How many **measuring devices and instruments** from the production floor and laboratories are calibrated on a periodic basis?

1. None (Go to Question 4.1)

- 2. 1 20
- 3. 21 50
- 4. 51 150
- 5. 151 or more

By **measuring devices and instruments**, we mean those fixed in place (e.g., flow meters) and portable (e.g., scales, thermometers).

- 3.10 Who calibrates **measuring devices and instruments** used on the production floor and in laboratories? Select all that apply.
 - 1. No one (i.e., instruments are not calibrated) (Go to Question 4.1)
 - 2. Facility personnel
 - 3. Contractor
 - 4. Equipment supplier or manufacturer
 - 5. Other (specify:
- 3.11 What is your best estimate of your facility's total annual cost of calibrating (to certified standards) the measuring devices and instruments used in all departments? Include costs related to formal calibrations assigned to your employees and to contracted services, but do not include daily or routine calibration checks made by users.
 - 1. Less than \$999 per year
 - 2. \$1,000 \$4,999 per year
 - 3. \$5,000 \$9,999 per year
 - 4. \$10,000 \$19,999 per year
 - 5. \$20,000 or more per year

Section 4 Materials and Manufacturing

Does this facility have an inventory management system for the following products? Select one response in each row of the table

Product

4.1

4.2

acceptance?
1. None

below.

a. Raw materials

2. 1 - 20 hours per week

3. 21 - 40 hours per week

4. 41 - 80 hours per week

5. 81 or more hours per week

	ΔΙνιανο	Most of the	Occasionally	Never	
By labeled , we a. Are containers of raw the package. By materials labeled to	lot or batch nu	ı mber , we mear	Occasionally th words to indica a unique numbe	r assigned by the	of e
materials labeled the compidentify the product by	any for <u>m</u> aterial ti	raceabi <mark>lit</mark> y, ident	ification, and rec	ordkeep <u>m</u> g.	
lot or batch number?					
b. Are original containers of packaging materials					
labeled to identify the					
product by lot or batch					
number?					
c. Are defective raw					1
materials labeled to					
prevent use?					
d. Are in-process		_			
materials stored in					
labeled containers?					
The following questions are	e about raw mater	ial and packagin	g material storage	e. Select one resp	oonse ii
of the table below.	Practice		Yes	No	1

What is your best estimate of the number of labor hours spent per week on monitoring raw material

By monitoring raw material

acceptance, we mean verifying the

shipment against a list of expected shipments, ensuring the product

shipment is sealed, and having an

and sampling.

No

Yes

employee present during unloading

Don't

Know

b. Are containers of <i>packaging</i> materials closed during storage?	
c. Are containers of raw materials stored off the floor?	
d. Are containers of <i>packaging</i> materials stored off the floor?	
e. Is there a stock rotation program to ensure the oldest stock of raw materials is used first?	

4.5 Which of the following procedures are included in this facility's written Standard Operating Procedures (SOPs)? Select one response in each row of the table below.

☐ This facility does not have written SOPs. *Go to Question 5.1.*

Practice	Yes	No	Not Applicable
a. Tamper-resistant packaging for liquid oral hygiene products and vaginal products meet the requirements of 21 CFR 700.25.			
b. The selection, measuring, weighing, and identification of containers of weighed raw materials is reviewed by a second individual.			
c. All containers of in-process materials, including mixing and bulk holding tanks, are labeled with contents.			
d. There are in-process controls for filling and mixing.			
e. Yields of production batches are compared to expected yields.			
f. Packaging materials are stored in a manner to avoid microbial and chemical contamination.			
g. Finished product packages have unique lot or control numbers.			

Section 5 Quality Control / Product Testing

- 5.1 How many people work in QA/QC functions at this facility?
 - 1. None (this facility does not have QA or QC functions)
 - 2. 1-5
 - 3. 6 20
 - 4. 21 35
 - 5. 36 or more
- 5.2 Does this facility conduct laboratory (lab) tests for quality control? Select all that apply.
 - 1. Yes, in an onsite lab.
 - 2. Yes, in an offsite lab owned by the company or by a contract lab.
 - 3. No

Your best estimates are acceptable for Questions 5.3 – 5.6. These can include tests done onsite at your facility or by an outside third-party lab.

5.3 How many *microbiological* lab tests (e.g., ATP, bacteria, mold) are typically conducted on raw materials and finished products each month? Select one response in each row of the table below.

	Number of Microbiological Tests per Month			
	Less than			
Type of Test	100	101-250	251-500	501 or more
a. Raw materials				
b. Finished products				

How many *chemical* lab tests (e.g., HPLC, GC) are typically conducted on raw materials and finished products each month? Select one response in each row of the table below.

Type of Test	Number of Chemical Tests per Month			
	None	1 - 50	51 - 100	101 or more
a. Raw materials				
b. Finished products				

5.5 How many *physical* lab tests (e.g., color, pH, SPG, microscopic) are typically conducted on raw materials and finished products each month? Select one response in each row of the table below.

Type of Test	Number of Physical Tests per Month			
	Less than 25	26 - 75	76 - 150	151 or more
a. Raw materials				
b. Finished products				

- 5.6 How many microbiological lab tests are typically conducted on water each month?
 - 1. None
 - 2. 1 15
 - 3. 16 35
 - 4. 36 or more

- 5.7 What is your best estimate of the number of labor hours spent *monthly* reviewing test results for approval and rejection of raw materials or product?
 - 1. None
 - 2. 1 20 hours each month
 - 3. 21-40 hours each month
 - 4. 41 80 hours each month
 - 5. 81 or more hours each month
- 5.8 Is the effectiveness of preservatives used as ingredients determined during product development?
 - 1. Yes
 - 2. No
 - 3. The products manufactured by this establishment do not contain preservatives.
 - 4. Preservative efficacy is responsibility of the brand owner, not this establishment.
- 5.9 How are rejected or returned products kept separate within this facility? Select all that apply.
 - 1. These products are not kept separate
 - 2. These products are stored in a separate, unenclosed space.
 - 3. These products are stored in a separate, enclosed space.
- 5.10 What is your best estimate of the number of labor hours spent *monthly* reviewing complaints or a complaint log for trends or recurrence of a defect?
 - 1. None
 - 2. 1 10 hours each month
 - 3. 11 20 hours each month
 - 4. 21 or more hours each month
- 5.11 What is your best estimate of the number of labor hours spent annually on **corrective actions** associated with a defective product?
 - 1. 0 20
 - 2. 21 60 hours each year
 - 3. 61 100 hours each year
 - 4. 101 or more hours each year

By **corrective actions**, we mean the identification and elimination of the causes of a problem to prevent its recurrence.

Section 6 Plant Characteristics

- 6.1 How many full-time employees work at this facility?
 - 1. Fewer than 9
 - 2. 10 19
 - 3. 20 99
 - 4. 100 499
 - 5. 500 or more
- 6.2 How many days per week does this facility manufacture **cosmetic** products?
 - 1. 1 day
 - 2. 2 days
 - 3. 3 days
 - 4. 4 days
 - 5. 5 days
 - 6. 6 days
 - 7. 7 days
- 6.3 How many production shifts operate per day at this facility?
 - 1. One
 - 2. Two
 - 3. Three
 - 4. Do not operate daily.
- 6.4 How many production lines does this facility have?
 - 1. None
 - 2. 1
 - 3. 2-5
 - 4. 6 10
 - 5. 11 or more

By **cosmetics**, we mean the following products: baby cleansing products, bath preparations, fragrances, hair care products, hair colorings, makeup, manicure products, oral hygiene products, personal cleaning products, shaving and skin care products, suntan products, and tattoo ink; but it does not include products with an active ingredient, over-the-counter drug products, or those with a Drug Facts label.

- 6.5 What is the square footage of the cosmetics production area of your facility? Do not include office space or warehouse space.
 - 1. Less than 2,000 square feet
 - 2. 2,001 30,000 square feet
 - 3. 30,001 120,000 square feet
 - 4. 120,001 200,000 square feet
 - 5. 200,001 square feet or more
- 6.6 Is this facility also a place of residence?
 - 1. Yes
 - 2. No
- 6.7 Including this facility, how many total facilities are owned by the company that owns this facility?
 - 1. 1 (this facility only)

- 2. 2-5
- 3. 6 10
- 4. 11 or more
- 6.8 What was the approximate value of total sales revenue during the past 12 months for this facility? Your best estimate is acceptable.
 - 1. Under \$249,999
 - 2. \$250,000 \$499,999
 - 3. \$500,000 \$1.49 million
 - 4. \$1.5 million \$2.49 million
 - 5. \$2.5 million \$24.9 million
 - 6. \$25 million \$49.9 million
 - 7. \$50 million \$99.9 million
 - 8. \$100 million or more

Thank you for completing the survey. Please return it in the enclosed postage-paid return envelope, or to

RTI International

Attn: Data Capture (0214322.003.000.005.001) 5265 Capital Blvd. Raleigh, NC 27690-1653