

**APPENDIX 2**  
**WEB SURVEY INSTRUMENT**



## Survey of Current Manufacturing Practices for the Cosmetics Industry

### Introduction & 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 the 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 in the email that you received. By facility, we mean all the buildings used for cosmetics manufacturing within the general area of the address shown in the email.

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.

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 not be used as the basis of enforcement action against this establishment. The data provided to FDA will not contain identifying information about the participant or the cosmetic manufacturer. The study results will be reported to the public in aggregate form only so that individual facilities or firms cannot be identified.

Please complete the survey within 10 business days.

If you have any questions as you complete the survey, please send an email to [FDACosmeticSurvey@rti.org](mailto:FDACosmeticSurvey@rti.org) 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.

OK

NEXT



## Survey of Current Manufacturing Practices for the Cosmetics Industry

### OMB Statement

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  
Email: CosmeticsManufacturingSurvey@fda.hhs.gov



## Survey of Current Manufacturing Practices for the Cosmetics Industry

### Section 1. About Your Facility

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.

OK

1. During the past 12 months, did this facility manufacture cosmetics? Select "no" if your establishment only manufactures cosmetics with an active ingredient, over-the-counter drug products, or products with a Drug Facts label.

Yes  
 No

2. During the past 12 months, did this facility produce cosmetics that were sold across state lines?

Yes  
 No

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

4. During the past 12 months, did this facility manufacture any products with a Drug Facts label?

- Yes
- No

5. Does this facility operate under any of the following Good Manufacturing Practices (GMP) guidelines? Select all that apply.

- FDA Guidance for the Cosmetic Industry (updated in 2013)
- ISO 22716: Cosmetics – Good Manufacturing Practices
- FDA Drug GMP (21 CFR Parts 210 and 211)
- Other (please specify)
- ISO 9001
- None

PREV

NEXT



## Survey of Current Manufacturing Practices for the Cosmetics Industry

### Section 2. Written Procedures & Documentation

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.

OK

6. 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.

	Written Procedures	Maintain Records
Personnel hygiene	↑	↑
Personnel apparel	↑	↑
Personnel training on GMPs	↑	↑

7. 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.

	Written Procedures	Maintain Records
Receiving raw materials	↑	↑
Storing raw materials	↑	↑
Weighing raw materials	↑	↑
Labeling of raw materials	↑	↑
Labeling of in-process materials	↑	↑
Laboratory testing of raw materials	↑	↑
Laboratory testing of in-process materials	↑	↑
Calibration of measuring instruments	↑	↑
Manufacturing standard operating procedures (SOPs)	↑	↑
Investigating failures and deviations	↑	↑



8. 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.

	Written Procedures	Maintain Records
Equipment cleaning or sanitization	↔	↔
Equipment maintenance	↔	↔
Storage of cleaning and sanitizing materials	↔	↔
Use of cleaning and sanitizing materials	↔	↔
Maintenance of water systems	↔	↔
Sanitization of water systems	↔	↔
Building maintenance	↔	↔
Pest control	↔	↔

9. 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.

	Written Procedures	Maintain Records
Labeling of finished products	↔	↔
Laboratory testing of finished products	↔	↔
Distribution of product	↔	↔
Shelf-life monitoring or stability studies	↔	↔
Consumer complaints	↔	↔
Product returns	↔	↔
Product recalls	↔	↔

10. What is your best estimate of the average number of *management* labor hours needed to establish written procedures for one manufacturing process?

- 0 - 10 hours
- 11 - 20 hours
- 21 - 40 hours
- 41 or more hours

11. 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?

- 0 - 10 hours
- 11 - 20 hours
- 21 - 40 hours
- 41 or more hours

PREV      NEXT



### Survey of Current Manufacturing Practices for the Cosmetics Industry

#### Section 2. Written Procedures & Documentation (continued)

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.

OK

12. Questions 6 through 9 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.

Employees Trained	
Initial Training	<input type="text"/>
Refresher Training	<input type="text"/>

13. 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 6 through 9)? Select one response for each training type.

Employees Trained	
Initial Training	<input type="button" value="▼"/>
Refresher Training	<input type="button" value="▼"/>

14. What is your best estimate of the number of *production employees* trained annually on the written procedures used by this facility (listed in Questions 6 through 9)? Select one response for each training type.

Employees Trained	
Initial Training	<input type="button" value="▼"/>
Refresher Training	<input type="button" value="▼"/>

15. Does this facility keep records by production batch?

- Yes
- No

16. 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.

- 40 - 160 hours
- 161 - 320 hours
- 321 - 480 hours
- 481 or more hours

17. What is your best estimate of the number of *QA/QC* personnel labor hours required to set up a recordkeeping system?

- 40 - 160 hours
- 161 - 320 hours
- 321 - 480 hours
- 481 or more hours



## Survey of Current Manufacturing Practices for the Cosmetics Industry

### Section 3. Buildings & Equipment

18. Which of the following spaces are **separate and defined areas** within the facility? By **separate and defined areas**, we mean work areas segregated by walls, other barriers, or sufficient space that are identified by signage. Select all that apply.

<input type="radio"/> Production	<input type="radio"/> Eating area
<input type="radio"/> Quality Control / Laboratory	<input type="radio"/> Restrooms
<input type="radio"/> Storage / Warehouse	<input type="radio"/> None of the above

19. Does this facility have pest control procedures?

<input type="radio"/> No
<input type="radio"/> Yes, using an outside contractor
<input type="radio"/> Yes, using facility employees

20. How many rodent bait stations are present at this facility?

<input type="radio"/> None	<input type="radio"/> 20 - 29
<input type="radio"/> 1 - 9	<input type="radio"/> 30 or more
<input type="radio"/> 10 - 19	

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

	Frequency
Floors	▲
Walls	▲
Ceilings	▲
Windows	▲
Drains	▲

22. 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.

23. Of the total estimated in Question 22, what is your best estimate of the combined percentage of water used as a raw material in product formulas or used for final rinses of product contact surfaces when cleaning equipment?

- 0 - 25%
- 26 - 50%
- 51 - 75%
- 76 - 100%

24. 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.

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.

- We do not treat water; we use municipal (tap) water that meets federal EPA standards for the quality of drinking water.
- We use deionized tap water.
- We have a purified water system that uses Reverse Osmosis (RO).
- Other (please specify)

25. 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?

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

26. How many **measuring devices and instruments** from the production floor and laboratories are calibrated on a periodic basis? By **measuring devices and instruments**, we mean those fixed in place (e.g., flow meters) and portable (e.g., scales, thermometers).

- None
- 1 - 20
- 21 - 50
- 51 - 150
- 151 or more

27. Who calibrates measuring devices and instruments used on the production floor and in laboratories? Select all that apply.

- No one (i.e., instruments are not calibrated)
- Facility personnel
- Contractor
- Equipment supplier or manufacturer
- Other (please specify)

28. 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

PREV

NEXT

Survey of Current Manufacturing Practices for the Cosmetics Industry

Section 4. Materials & Manufacturing

29. What is your best estimate of the number of labor hours spent per week on **monitoring raw material acceptance**? 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 employee present during unloading and sampling.

- None
- 1 - 20 hours per week
- 21 - 40 hours per week
- 41 - 80 hours per week
- 81 or more hours per week

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

	Yes / No / Don't know
Raw materials	<input type="button" value="▼"/>
Chemicals, such as cleaning supplies, laboratory reagents, and boiler additives	<input type="button" value="▼"/>
Stored finished product	<input type="button" value="▼"/>
Product shipments	<input type="button" value="▼"/>

31. The following questions are about raw materials.

By **labeled**, we mean either with a barcode or with words to indicate the contents of the package.

By **lot or batch number**, we mean a unique number assigned by the receiving company for material traceability, identification, and recordkeeping.

Select one response in each row of the table below.

	Frequency
Are containers of raw materials <b>labeled</b> to identify the product by lot or batch number?	<input type="button" value="▼"/>
Are original containers of packaging materials <b>labeled</b> to identify the product by <b>lot or batch number</b> ?	<input type="button" value="▼"/>
Are defective raw materials <b>labeled</b> to prevent use?	<input type="button" value="▼"/>
Are in-process materials stored in <b>labeled</b> containers?	<input type="button" value="▼"/>

32. The following questions are about raw material and packaging material storage. Select one response in each row of the table below.

Yes / No / Don't know	
Are containers of raw materials closed during storage?	<input type="button" value="▼"/>
Are containers of packaging materials closed during storage?	<input type="button" value="▼"/>
Are containers of raw materials stored off the floor?	<input type="button" value="▼"/>
Are containers of packaging materials stored off the floor?	<input type="button" value="▼"/>
Is there a stock rotation program to ensure the oldest stock of raw materials is used first?	<input type="button" value="▼"/>

33. 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.

Yes / No / Not applicable	
Tamper-resistant packaging for liquid oral hygiene products and vaginal products meet the requirements of 21 CFR 700.25.	<input type="button" value="▼"/>
The selection, measuring, weighing, and identification of containers of weighed raw materials is reviewed by a second individual.	<input type="button" value="▼"/>
All containers of in-process materials, including mixing and bulk holding tanks, are labeled with contents.	<input type="button" value="▼"/>



There are in-process controls for filling and mixing.

Yields of production batches are compared to expected yields.

Packaging materials are stored in a manner to avoid microbial and chemical contamination.

Finished product packages have unique lot or control numbers.

PREV

NEXT



## Survey of Current Manufacturing Practices for the Cosmetics Industry

### Section 5. Quality Control / Product Testing

#### 34. How many people work in QA/QC functions at this facility?

None (this facility does not have QA or QC functions)  21 - 35  
 1 - 5  36 or more  
 6 - 20

#### 35. Does this facility conduct laboratory (lab) tests for quality control?

Select all that apply.

Yes, in an onsite lab.  
 Yes, in an offsite lab owned by the company or by a contract lab.  
 No

#### 36. 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 tests per month

Raw materials

Finished products

37. 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.

Number of tests per month	
Raw materials	<input type="button" value="▼"/>
Finished products	<input type="button" value="▼"/>

38. 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.

Number of tests per month	
Raw materials	<input type="button" value="▼"/>
Finished products	<input type="button" value="▼"/>

39. How many microbiological lab tests are typically conducted on *water* each month?

- None
- 1-15
- 16-35
- 36 or more

40. 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?

- None
- 1-20 hours each month
- 21-40 hours each month
- 41-80 hours each month
- 81 or more hours each month

41. Is the effectiveness of preservatives used as ingredients determined during product development?

- Yes
- No
- The products manufactured by this establishment do not contain preservatives.
- Preservative efficacy is responsibility of the brand owner, not this establishment.

42. How are rejected or returned products kept separate within this facility? Select all that apply.

- These products are not kept separate.
- These products are stored in a separate, unenclosed space.
- These products are stored in a separate, enclosed space.

43. 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?

- None
- 1 - 10 hours each month
- 11 - 20 hours each month
- 21 or more hours each month

44. What is your best estimate of the number of labor hours spent annually on corrective actions associated with a defective product?

- 0 - 20 hours each year
- 21 - 60 hours each year
- 61 - 100 hours each year
- 101 or more hours each year

PREV

NEXT



#### Survey of Current Manufacturing Practices for the Cosmetics Industry

#### Section 6. Facility Characteristics

45. How many full-time employees work at this facility?

<input type="radio"/> Less than 9	<input type="radio"/> 100 - 499
<input type="radio"/> 10 - 19	<input type="radio"/> 500 or more
<input type="radio"/> 20 - 99	

46. How many days per week does this facility manufacture cosmetic products?

<input type="radio"/> 1 day	<input type="radio"/> 5 days
<input type="radio"/> 2 days	<input type="radio"/> 6 days
<input type="radio"/> 3 days	<input type="radio"/> 7 days
<input type="radio"/> 4 days	

47. How many production shifts operate per day at this facility?

- One
- Two
- Three
- Do not operate daily.

48. How many production lines does this facility have?

- None
- 1
- 2 - 5
- 6 - 10
- 11 or more

49. What is the square footage of the cosmetics production area of your facility? Do not include office space or warehouse space.

- Less than 2,000 square feet
- 2,001 - 30,000 square feet
- 30,001 - 120,000 square feet
- 120,001 - 200,000 square feet
- 200,001 square feet or more

50. Is this facility also a place of residence?

- Yes
- No

51. Including this facility, how many total facilities are owned by the company that owns your facility?

- 1 (this facility)
- 2 - 5
- 6 - 10
- 11 or more

52. What was the approximate value of total sales revenue during the past 12 months for this facility? Your best estimate is acceptable.

- Under \$249,999
- \$250,000 - \$499,999
- \$500,000 - \$1.49 million
- \$1.5 million - \$2.49 million
- \$2.5 million - \$24.9 million
- \$25 million - \$49.9 million
- \$50 million - \$99.9 million
- \$100 million or more

Thank you for completing the survey!

OK

PREV

DONE