

APPENDIX 5

TELEPHONE SCRIPTS

FDA Survey of Current Manufacturing Practices Survey Invitation Telephone Call

Hello, this is ____ with RTI International, a research company. I am calling about a study we're conducting on behalf of the U.S. Food and Drug Administration, or FDA.

IF NEEDED: This is not a sales call and in no way will our conversation lead to a sales call.

Confirm Company Mailing Address

CONFIRM

Is this [FILL COMPANY] located at [FILL COMPANY STREET] in [FILL CITY], [FILL STATE], zip code [FILL ZIP]?

YES [SKIP ELIGBL]

NO

IF NEEDED: I am calling to confirm the mailing address and the plant or operation manager's name so that we can discuss an FDA Study, the Survey of Current Manufacturing Practices, which s/he may already be aware of.

CO_CHNGE

Has [FILL COMPANY] been acquired and operating under a new name or has [FILL COMPANY NAME] moved to a new location?

- A. NAME CHANGE ONLY [GO TO CO_NAME]
- B. BUSINESS ACQUIRED BUT OTHERWISE THE SAME [SKIP TO ELIGBL]
- C. ADDRESS CHANGE ONLY [SKIP TO CO_MAIL]
- D. NAME AND ADDRESS DIFFERENT [GO TO CO_NAME THEN CO_MAIL]
- E. WRONG BUSINESS [SKIP TO TERM1]
- F. OUT OF BUSINESS [SKIP TO TERM1]
- G. RESIDENCE [SKIP TO TERM1]
- H. OTHER [GO TO CO_NAME THEN CO_MAIL]

CO_NAME

What is the company name? [RECORD COMPANY NAME]

CO_MAIL

What is the company mailing address? [RECORD FULL MAILING ADDRESS]

NOTE: RECORD THE MAILING ADDRESS WHERE MAIL IS RECEIVED

CO_PHONE

Is this still the best phone number to reach [FILL COMPANY]?

YES

NO [ADD NEW PHONE NUMBER]

Establish Eligibility

ELIGBL

Is [FILL COMPANY NAME] currently manufacturing any cosmetic, health and beauty, personal care products, or tattoo ink? These are defined as “any product intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for... cleansing, beautifying, promoting attractiveness, or altering the appearance”?

IF NEEDED: This includes 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 or over-the-counter drug product (or those with a Drug Facts label).

YES = ELIGIBLE [CONTINUE]

NO = NOT ELIGIBLE [SKIP TO TERM2]

ELIGBL2

Are the products manufactured at this plant sold across state lines, or are these products sold solely in [FILL STATE]?

1=OTHER STATES

2=ONLY [STATE] [SKIP TO TERM2]

Confirm Plant/Operations Manager

The purpose of this FDA Study is to learn about the current manufacturing practices and associated costs to the cosmetics industry in the U.S. The person most knowledgeable about current manufacturing practices and the costs of those practices at [FILL COMPANY NAME] will be asked to complete the FDA survey. Typically, that person is the plant or operations manager.

IF NEEDED: You may have heard about this FDA Study at the [INSERT DETAILS ON PROMO BY TRADE ASSOCIATION TO INCREASE AWARENESS OF THE STUDY]. This study will improve FDA’s understanding of current industry practices and Good Manufacturing Practices, or GMPs, used by the U.S. cosmetics industry.

POC1

May I please have the name of the person most qualified to complete this FDA survey?

[RECORD POC'S FULL NAME; TITLE; EMAIL; PHONE; MAILING ADDRESS]. NOTE: CONFIRM SPELLING

1=SOMEONE ELSE
2=POC ON PHONE

POC1_ASST

["Does [FILL POC1_NAME]" OR "Do you"] have an assistant who may be able to assist us with reaching [him/her/you if we need to call you again]? [IF YES, RECORD ASSISTANT'S FULL NAME; EMAIL; PHONE; MAILING ADDRESS]. NOTE: CONFIRM SPELLING

[IF POC1=1; ELSE SKIP TO POC1_INTRO2]

TRANSF

Are you able to transfer me to [FILL POC1_NAME]?

YES [CONTINUE]

NO [SKIP TO TERM3]

Contact Plant/Operations Manager

[IF POC1=1; ELSE SKIP TO POC1_INTRO2]

POC1_INTRO1

Hello, this is _____ with RTI International, a research organization. I am calling about a study we're conducting on behalf of the U.S. Food and Drug Administration, or FDA. You may already be aware of this study RTI is conducting with manufacturers of cosmetics, health and beauty, personal care products, and tattoo inks.

IF NEEDED: These are defined as "products intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for... cleansing, beautifying, promoting attractiveness, or altering the appearance."

IF NEEDED: This is not a sales call and in no way will our conversation lead to a sales call.

The purpose of this study, the Survey of Current Manufacturing Practices, is to learn about the current manufacturing practices and the associated costs of such practices to the cosmetics industry in the U.S.

POC1_INTRO2

As a manufacturer of these products, your company is eligible for this FDA study. Your participation in this survey is appreciated and important. The data collected as part of this survey will benefit the industry by improving the FDA's understanding of current industry practices and Good Manufacturing Practices, or GMPs.

We understand that you are the most knowledgeable about the current manufacturing practices and the costs of those practices at [FILL COMPANY ADDRESS]. Are you the best person to complete this survey?

YES [CONTINUE]

NO [COLLECT CONTACT INFO FOR POC2]

All responses to the survey will be kept secure and private. Identifying information such as your name, plant name and company name will not be shared with the FDA.

Survey Mode

MODE

Are you able to complete the survey online? It can be completed on a computer, tablet or mobile device.

IF NEEDED: The online survey responses are transmitted over an encrypted connection and stored on RTI's secure network. Access to these data are restricted to the RTI research team only.

IF NEEDED: You will be able to save your answers and return to it if you're unable to complete the survey in one sitting.

IF RESPONDENT IS HESITANT OR IS UNABLE TO COMPLETE ONLINE: We can mail a paper survey if you prefer.

1 = ONLINE SURVEY

2 = USPS HARDCOPY

[IF MODE=1 EMAIL SURVEY]

We will email you the FDA survey link. The email will come from [RTI PROJECT EMAIL ADDRESS - XXX@RTI.ORG] and you will receive the email within the next few days.

The email address I have for you is [FILL POC1_EMAIL]. Is this the best email address to use to reach you? [CONFIRM SPELLING]

[IF MODE=2 USPS HARDCOPY]

CNF_NAME

You should receive the FDA survey in about 5 days. The survey will be sent by the U.S. Postal Service. I need to confirm the spelling of your name and the mailing address.

The name we have for you is: [FILL NAME]. Is this correct? [RECORD REVISED, AS NEEDED]

CNF_ADDR

The mailing address we have for you is: [FILL FULL ADDRESS, CITY, STATE, ZIP]. Is this the correct address to send mail?

YES

NO

[IF ADDRESS IS NOT CORRECT]

What address should we use to mail the survey via the U.S. Postal Service? [RECORD REVISED FULL MAILING ADDRESS, CITY, STATE, ZIP]

Your participation is very important to the FDA. We'd greatly appreciate it if you completed and returned the survey by [INSERT DATE].

If you have any questions about the survey, you can call the RTI Project Director, Catherine Viator, at [INSERT TOLL-FREE PHONE NUMBER]. Her phone number and email address will also be on the survey materials you receive.

We look forward to receiving your completed survey. Thank you for your time and have a nice day.

TERM1

Thank you for your time. Have a nice day.

TERM2

[FILL COMPANY] is not eligible for this survey. Thank you for taking the time to speak with me.

TERM3

Thank you for providing me with the contact information for [POC1_NAME]. I will call him/her directly. Have a nice day.

[INTERVIEWER NOTE: RECORD ANY LANGUAGE BARRIER ISSUES AND ANY INFO THE RESPONDENT SHARED WITH YOU THAT WAS NOT RECORDED ABOVE.]

**FDA Survey of Current Manufacturing Practices Survey Invitation
Telephone Prompt/ Reminder Call**

Hello! May I please speak with [FILL NAME]?

IF NEEDED: This is _____ with RTI International, a research company. I'm calling to remind [FILL NAME] to complete the Survey of Current Manufacturing Practices we're conducting on behalf of the U.S. Food and Drug Administration.

IF NEEDED: This is not a sales call and in no way will our conversation lead to a sales call.

IF NEEDED: When is the best time to reach [FILL NAME]?

In the meantime, would you remind [FILL NAME] to complete the survey by [INSERT DATE]?

FOLLUP1

IF NEEDED: Hello, this is _____ with RTI International. I'm calling on behalf of the U.S. Food and Drug Administration, or FDA.

I'm calling about The Survey of Current Manufacturing Practices, we sent you [INSERT "in the mail" or "via email"]. I'd like to confirm that you received the survey.

1=RECEIVED SURVEY [SKIP TO NOT_COMPL_YET]

2=DID NOT RECEIVE SURVEY [SKIP TO NOTRCVD]

3=GAVE SURVEY TO SOMEONE ELSE TO COMPLETE [SKIP TO DELEGATED]

4=RECEIVED SURVEY BUT MISPLACED IT [SKIP TO MODE2]

5= RECEIVED AND COMPLETED SURVEY [SKIP TO THANK]

8=DON'T KNOW [SKIP TO MODE2]

NOT_COMPL_YET

According to our records, you have not yet returned the survey. I'm calling today to ask that you complete and return the survey.

[SKIP TO THANK_1]

NOTRCVD

I'm sorry you did not receive the survey.

[SKIP TO MODE]

DELEGATED

May I please have his or her name?

1 = YES [ADD CONTACT]

2 = NO [SKIP TO THANK_1]

R_AVAIL3

Are you able to transfer me to this person?

1 = Yes [GO TO INTRO2]

2 = No [SKIP TO TERM]

[TRAINING NOTE: IF R_AVAIL3=2 THANK AND TERMINATE CALL WITH CURRENT RESPONDENT AND SCHEDULE CALLBACK FOR NEW CONTACT]

INTRO2

[R_AVAIL3=1]

Hello, this is _____ with RTI International, a national research company. I'm calling on behalf of the U.S. Food and Drug Administration, or FDA. [INSERT CONTACT NAME] informed me that s/he gave you The Survey of Current Manufacturing Practices to complete. According to our records the survey has not yet been returned. Do you need us to re-send the survey?

1=YES [SKIP TO MODE2]

2=NO [SKIP TO MODE3]

MODE2

We can send you the survey again. Are you able to complete the survey online? It can be completed on a computer, tablet or mobile device.

IF NEEDED: You will be able to save your answers and return to it if you're unable to complete the survey in one sitting.

IF NEEDED: The online survey responses are transmitted over an encrypted connection and stored on RTI's secure network. Access to these data are restricted to the RTI research team only.

[IF RESPONDENT IS HESITANT OR IS UNABLE TO COMPLETE ONLINE: We can mail a paper survey if you prefer.]

1 = ONLINE SURVEY [GO TO R_EMAIL]

2 = USPS HARDCOPY [GO TO R_CONTACT]

MODE3

[ONLY IF POC RECEIVED HARDCOPY SURVEY; MODE=2 HARDCOPY SURVEY]

You previously received a paper survey in the mail. Are you able to complete the survey online? It can be completed on a computer, tablet or mobile device.

IF NEEDED: You will be able to save your answers and return to it if you're unable to complete the survey in one sitting.

IF NEEDED: The online survey responses are transmitted over an encrypted connection and stored on RTI's secure network. Access to these data are restricted to the RTI research team only.

[IF RESPONDENT IS HESITANT OR IS UNABLE TO COMPLETE ONLINE: We can mail a paper survey if you prefer.]

R_EMAIL

[IF MODE=1]

We will email you the FDA survey link. The email will come from [RTI PROJECT EMAIL ADDRESS - XXX@RTI.ORG] and you will receive it by the end of the day today.

[MODE=1 & NO EMAIL]

What is the email address we should use to send you the survey link?

[RECORD EMAIL ADDRESS & CONFIRM SPELLING]

[IF MODE=1 & CONFIRM EMAIL]

The email address I have for you is [FILL POC1_EMAIL]. Is this the best email address to use to reach you? [CONFIRM SPELLING]

R_CONTACT

[IF MODE=2 USPS HARDCOPY]

You should receive the FDA survey in about 5 days. The survey will be sent by the U.S. Postal Service. I need to confirm the spelling of your name and the mailing address.

[IF MODE=2 & CONFIRM CONTACT]

The name we have for you is: [FILL NAME]. Is this correct? [RECORD REVISED, AS NEEDED]

The mailing address we have for you is: [FILL FULL ADDRESS, CITY, STATE, ZIP]. Is this the correct address to send mail?

YES

NO

THANK

Thank you for completing the survey. We look forward to receiving it!

TERM

Thank you for providing me with the contact information for [POC1_NAME]. I will call him/her directly. Have a nice day.

THANK_1

We're asking that manufacturers return the survey by [INSERT DATE]. Since only a sample of manufacturers received the survey, your participation is vital for gaining a true representation of industry practices.

Your answers to the survey will not be linked to identifying information. All information about the survey will be reported in summary form with no identifying information included.

Thanks in advance for your participation.

If you have any questions about the survey, you can call the RTI Project Director, Catherine Viator. Her phone number and email address will be on the survey materials you receive.

[INTERVIEWER NOTE: RECORD ANY INFO THE RESPONDENT SHARED WITH YOU THAT WAS NOT RECORDED ABOVE.]