Revival Products, Inc,
200 Peddycord Park Court
Kernersville, NC 27284-9827

September 03, 2020

Patricia F. Hudson
Compliance Officer
U.S. Food and Drug Administration
60 8th Street, NE
Atlanta GA 30309

Re: CMS #606640

RESPONSE TO THE FDA LETTER DATED AUGUST 14, 2020

Dear Patricia,

Thank you for giving us the opportunity to adequately respond to your requested documents. It is noted that in our response you received in March 2020 we failed to send the existing 'documentation' we had put in place.

I have attached 4 responses for your review to coincide with your numbered issues.

The last page of your letter addresses the Multivitamin Multimineral 100 and gorgeous roses dietary supplements.

Consistent with our long-term business policy, if a label has a mistake, we pull the products from distribution. We have been out of the Multimineral 100 for several months as COVID-19 impacted many smaller manufacturers. We will not be bringing either of these two products back.
Calcium is the only supplement we presently offer for distribution.

Please let me know if you have further questions or comments. As a conscientious business owner, I long to comply with each regulation no matter how great or small. You are always welcome to our facility and we appreciate the help your agency extends to us small business owners.

Kindest regards,

Suzanne Tabor
President and CEO
Revival Products, Inc

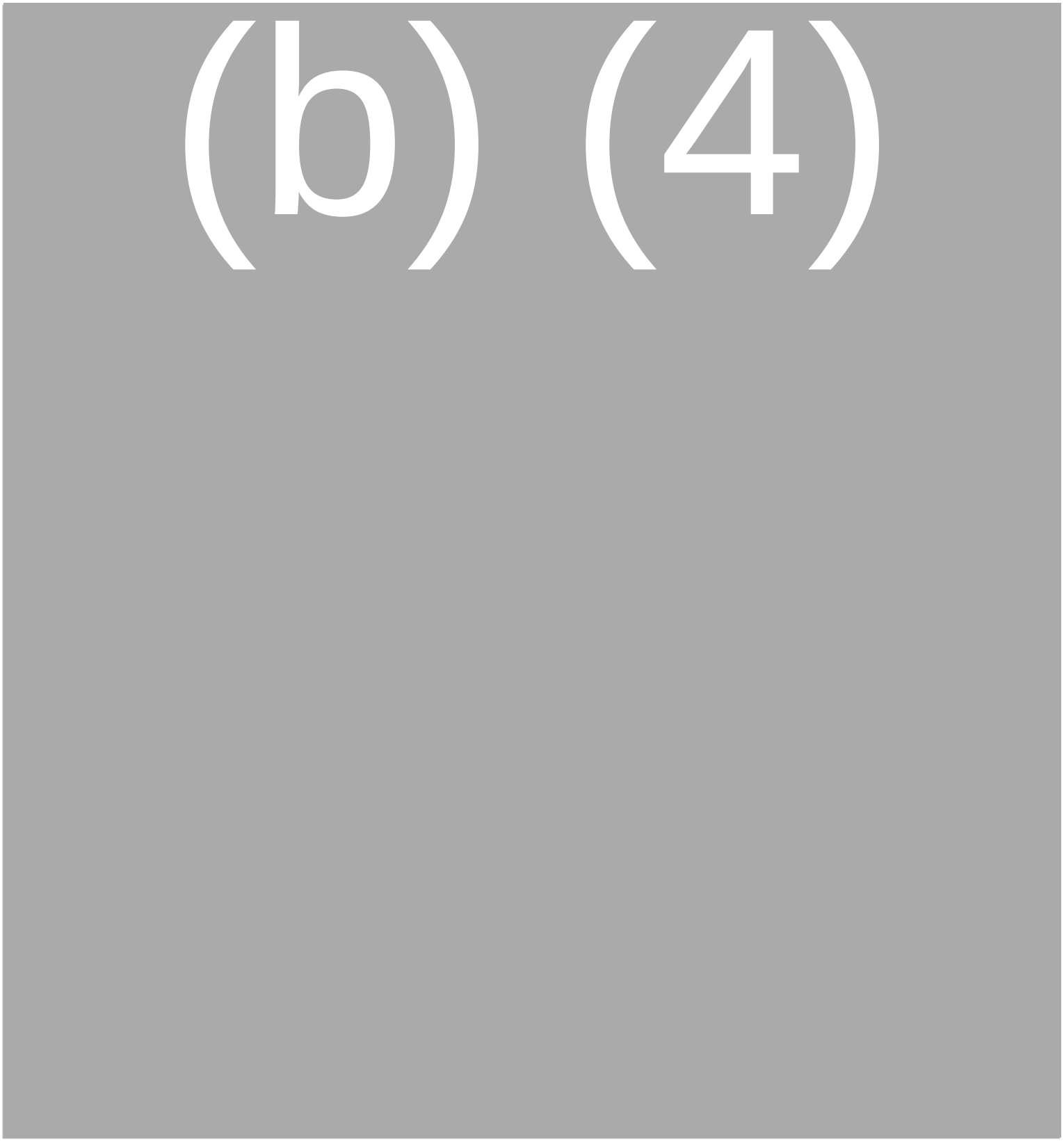
BLANK 1.

Date Product Received: _____

RPI STANDARD OPERATING PROCEDURES FOR RECEIVING AND QUALITY CONTROL. INCLUDES REVIEW AND APPROVAL FOR RELEASE OF DIETARY SUPPLEMENTS FOR DISTRIBUTION.

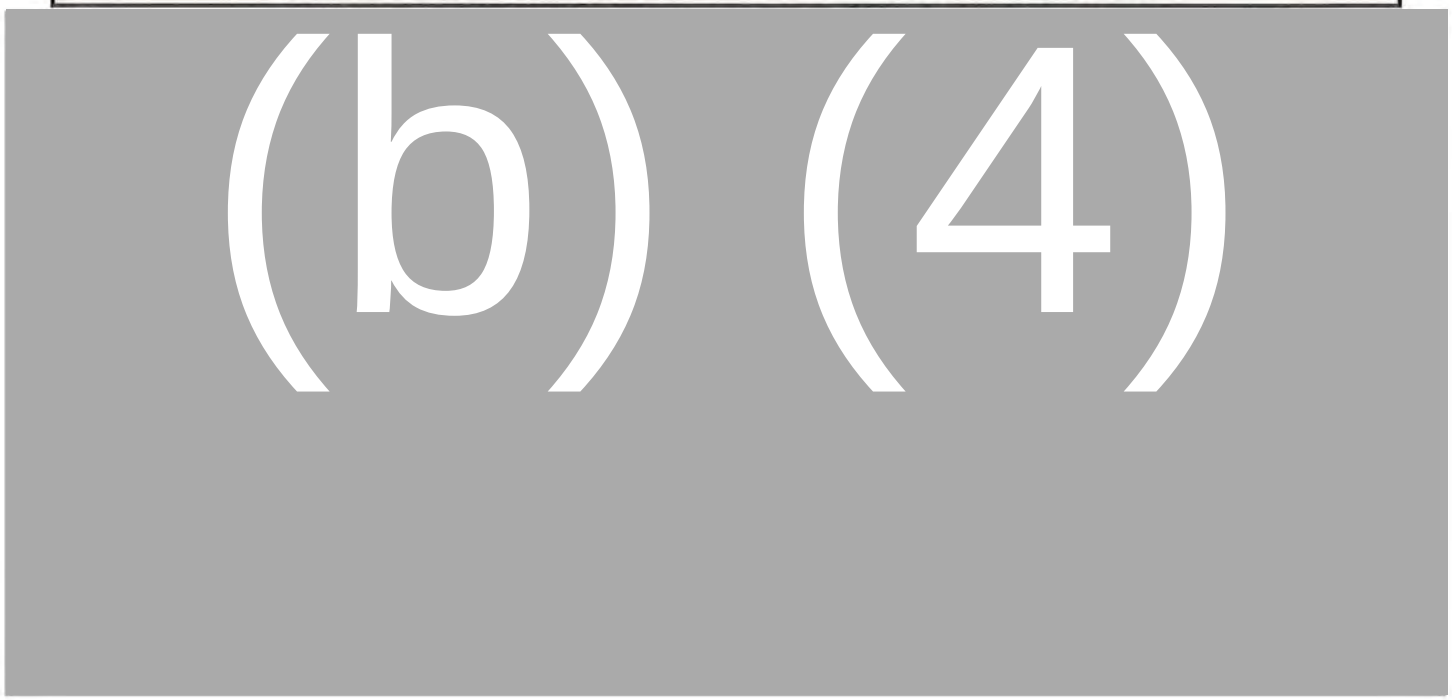
21 C.F.R. §111.103, §111.105, §111.110, §111.113, §111.117, §111.120, §111.123, §111.127, §111.130, §111.135, §111.140, §111.153, §111.155, §111.160, §111.165, §111.170, §111.180 (2019)

(b) (4)


(b) (4)

Date Product Received: _____

STANDARD OPERATING PROCEDURE FOR QUALITY CONTROL (QC) AND/OR UPPER LEVEL MANAGEMENT REVIEW AND CHECKOFF



1.

Date Product Received: 7-10-19

RPI STANDARD OPERATING PROCEDURES FOR RECEIVING AND QUALITY CONTROL. INCLUDES REVIEW AND APPROVAL FOR RELEASE OF DIETARY SUPPLEMENTS FOR DISTRIBUTION.

21 C.F.R. §111.103, §111.105, §111.110, §111.113, §111.117, §111.120, §111.123, §111.127, §111.130, §111.135, §111.140, §111.153, §111.155, §111.160, §111.165, §111.170, §111.180 (2019)

(b) (4), (b) (6)

Date Product Received: 7-10-19

(b) (4), (b) (6)

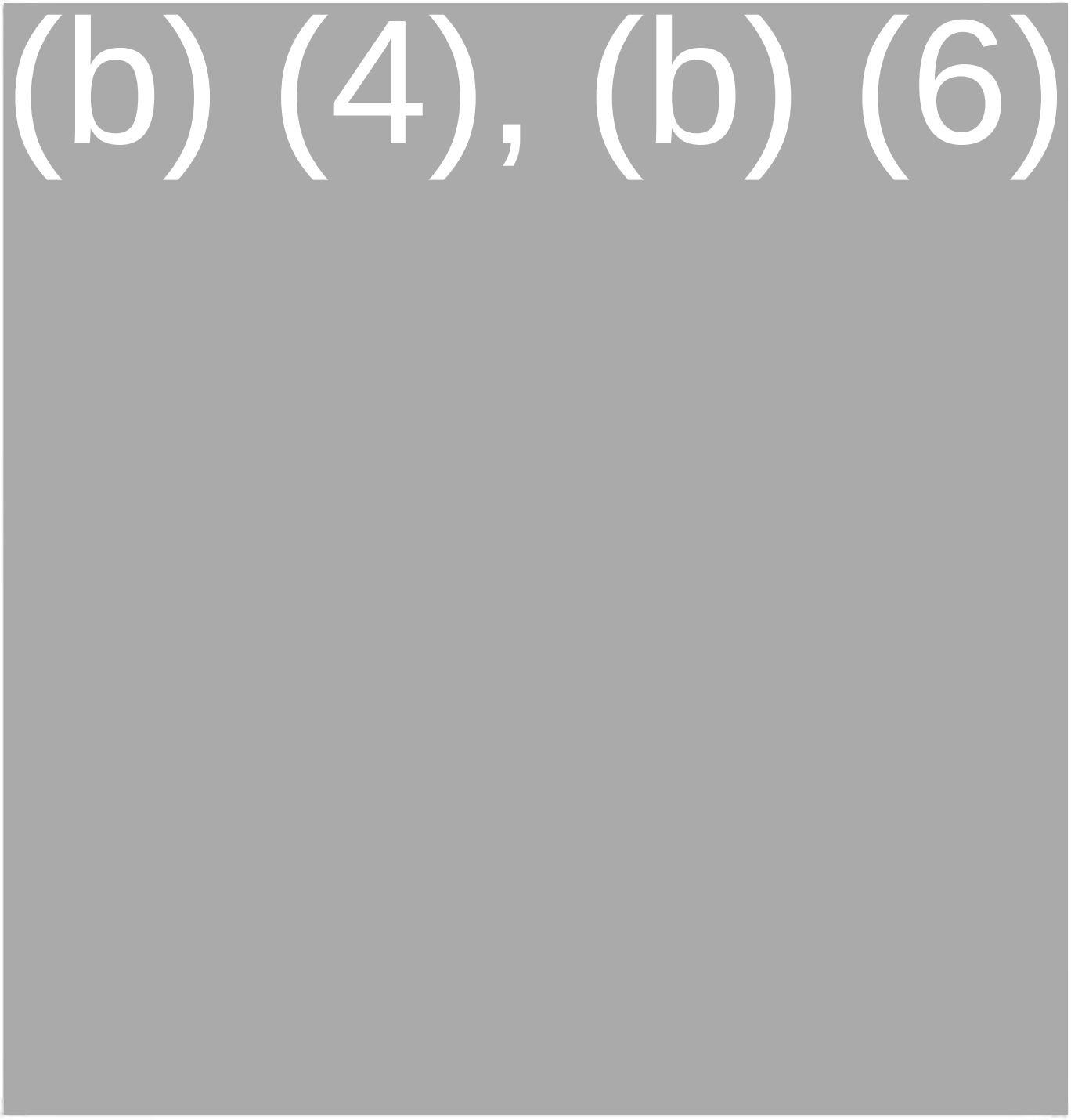
Date Product Received: 7-10-19

STANDARD OPERATING PROCEDURE FOR QUALITY CONTROL (QC) AND/OR UPPER LEVEL MANAGEMENT REVIEW AND CHECKOFF

(b) (4), (b) (6)

RECEIVING REPORT FOR SUPPLIMENTS

PRODUCT: CALCIUM



Revival Products, Inc

200 Peddycord Park Court
Kernersville, NC 27284

Purchase Order

Date	P.O. No.
2/13/2019	(b) (4)

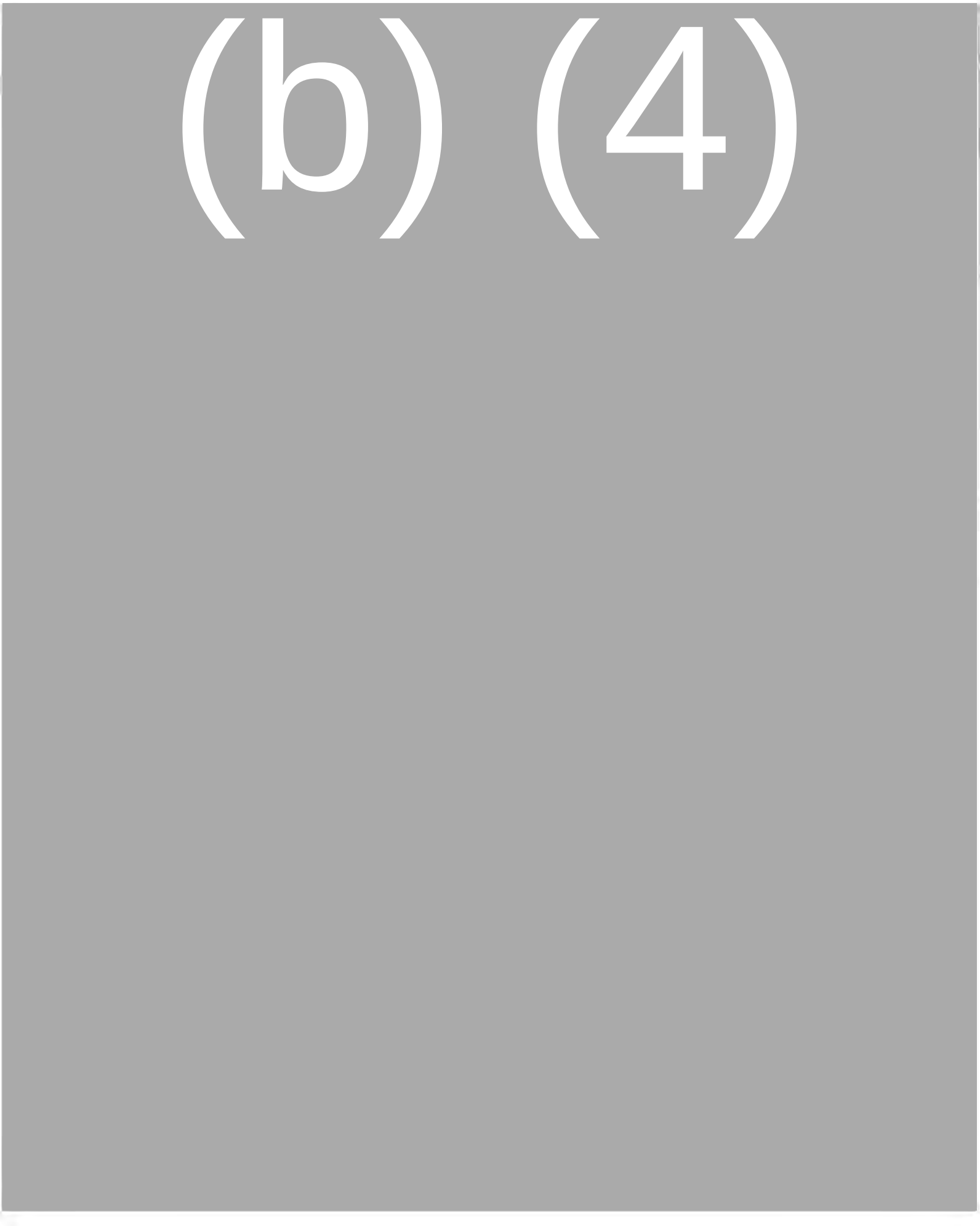
Vendor	Ship To
(b) (4)	Revival Products, Inc 200 Peddycord Park Court Kernersville, NC 27284

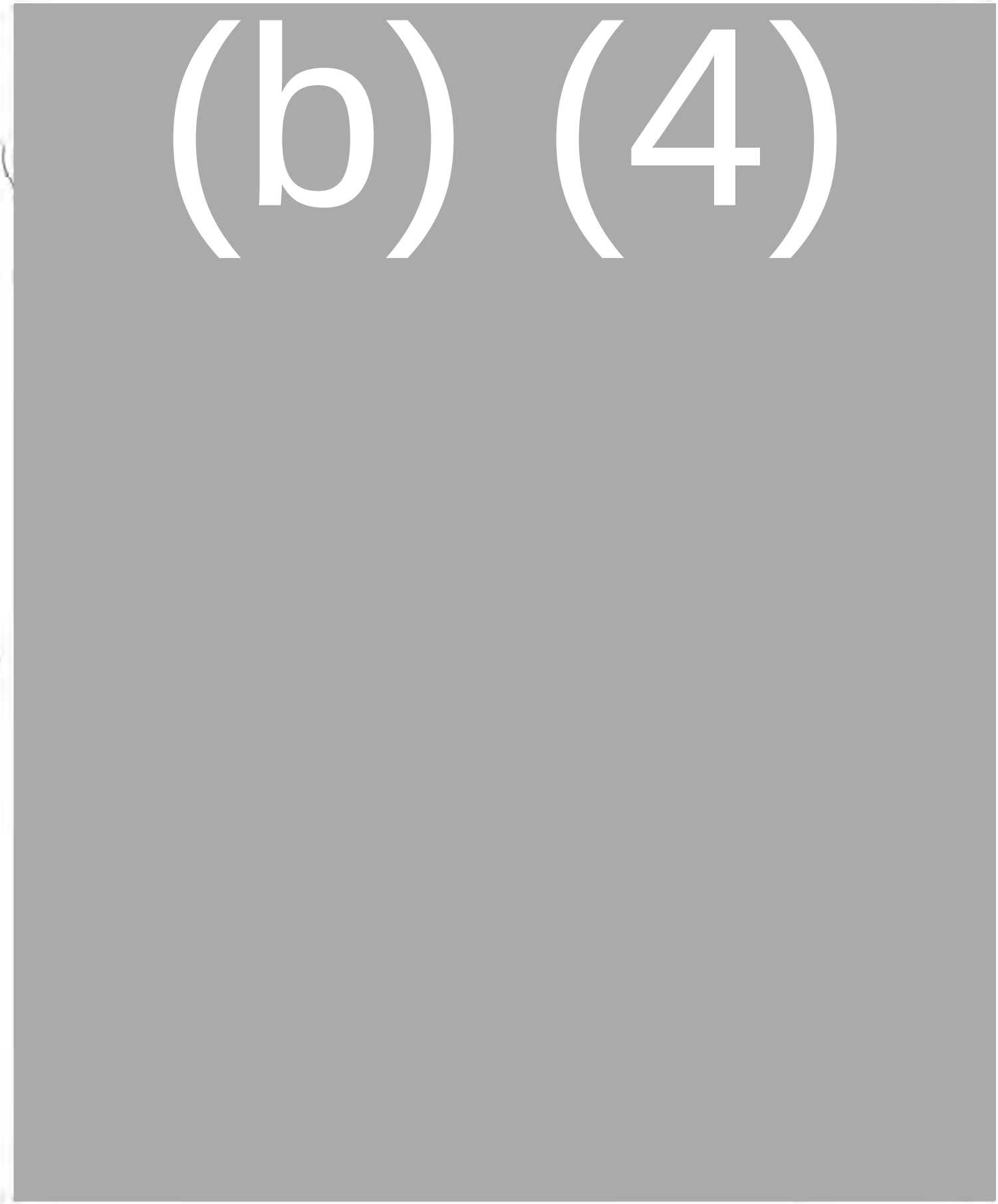
Terms	Due Date	Ship Via
	4/9/2019	

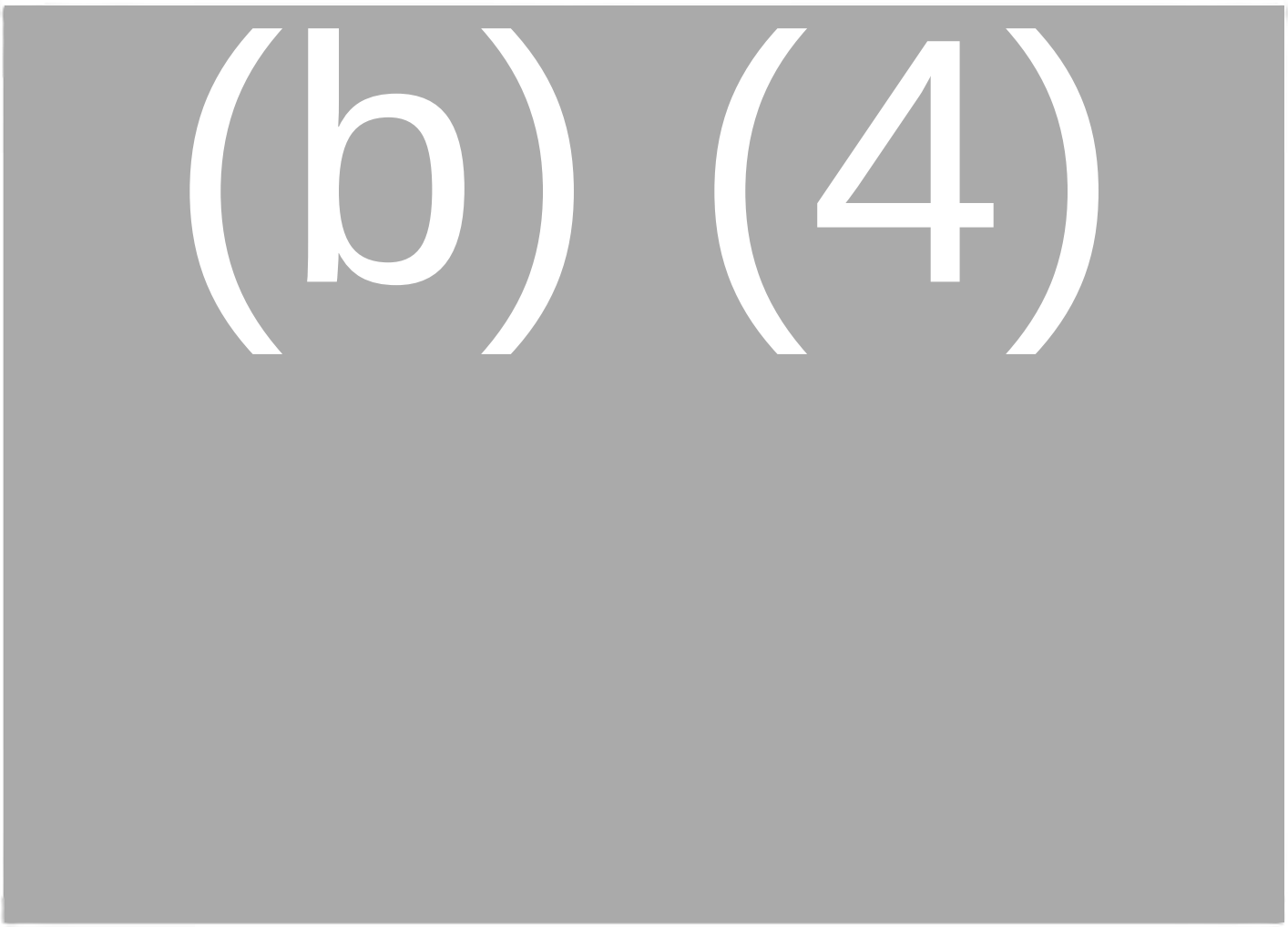
Item	Description	Qty	U/M	Rate	Amount
Calcium	(b) (4) (b) (4)	(b) (4)		(b) (4)	(b) (4)

Total (b) (4)

Please let us know if you have any questions.
Rich Davis 336-416-0463 revivalproducts.richdavis@gmail.com.
Thank you for your service!


(b) (4)


(b) (4)



Reviewed by: (b) (4)

Product: Calcium Blend 120 Capsule Bottle	Lot #: 066389
Product Code: (b) (4)	PO #: (b) (4)

(b) (4), (b) (6)

(b) (4), (b) (6)

Product: Calcium Blend 120 Capsule Bottle	Lot #: 066389
Product Code: (b) (4)	PO #:

(b) (4)

Performed Checked Date:

(b) (4), (b) (6)

Product: Calcium Blend 120 Capsule Bottle	Lot #: 066389
Product Code: (b) (4)	PO #: (b) (4)

Performed By: Checked By: Date:

(b) (4), (b) (6)

PART 3 - BLENDING PROCEDURE

Performed By: Checked By: Date:

(b) (4), (b) (6)

Product: Calcium Blend 120 Capsule Bottle	Lot #: 066389
Product Code: (b) (4)	PO #: (b) (4)

PART 4 - TESTING PROCEDURE

Performed By: Checked By: Date:

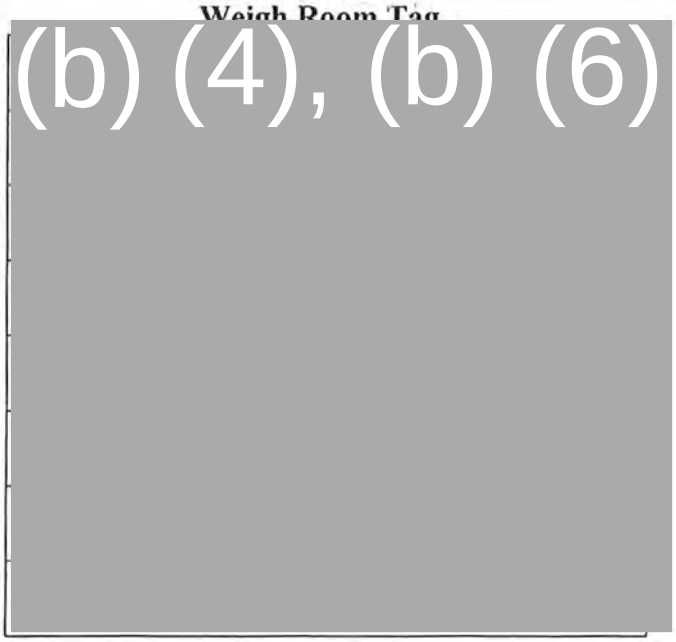
(b) (4), (b) (6)

(b) (4) requires a Quality Assurance investigation before proceeding.

Performed By: Checked By: Date:

(b) (4), (b) (6)

Weigh Room Tag



Rel
07/10/19

Form# 0.002 SOP Ref. 11.200

Product: Calcium Blend 120 Capsule Bottle	Lot #: 066389
Product Code: (b) (4)	PO #: (b) (4)

(b) (4)

Performed By: Checked By: Date:

07/10/19

(b) (4), (b) (6)

(b) (4)

Checked By: Date:

(b) (4), (b) (6)

Product: Calcium Blend 120 Capsule Bottle	Lot #: 066389
Product Code: (b) (4)1	PO #: (b) (4)

PART 8 - ENCAPSULATION PROCEDURE

07/18/19

Performed By: Checked By: Date:

(b) (4), (b) (6)

(b) (4) requires a Quality Assurance investigation before proceeding.

Performed By: Checked By: Date:

(b) (4), (b) (6)

Product: Calcium Blend 120 Capsule Bottle	Lot #: 066389
Product Code: (b) (4)	PO #: (b) (4)

Encapsulation Testing
(To be completed by Quality Assurance personnel only)

07/10/19

TESTED FOR:
APPEARANCE:

Size/Shape	0, White Vegetable Capsule		
Powder Color:	Off White Powder	By:	Date:

(b) (4), (b) (6)

TESTED FOR:
WEIGHT VARIATION: Of the 30 capsules tested, they are broken down as follows. By: Date:

(b) (4), (b) (6)

Performed By: Checked By: Date:

(b) (4), (b) (6)

Product: Calcium Blend 120 Capsule Bottle	Lot #: 066389
Product Code: (b) (4)	PO #: (b) (4)

(b) (4)

Performed By: Checked By: Date:

(b) (4), (b) (6)

Product: Calcium Blend 120 Capsule Bottle	Lot #: 066389
Product Code: (b) (4)	PO #: (b) (4)

(b) (4) - Quality Assurance Release To Packaging

Checked Date:

(b) (4), (b) (6)

(b) (4)

Performed By: Checked By: Date:

(b) (4), (b) (6)

Attach Product Label / Sleeve Below.
(If product label / sleeve does not fit below, attach to back of this page.)

(b) (4) - Packaging Line Assembly

Performed By: Checked By: Date:

(b) (4), (b) (6)

(b) (4)

NOTE: Colors shown on your monitor or printer are an approximation only and are not intended as a color match. For (b) (4) for exact color match.

2.5" x 7"

Approved
7/10/19

FREE of animal gelatin, binders, compression agents, colors, preservatives, flavors, sugar, starch, salt, wheat, gluten, yeast, potassium, phosphorous, chloride, lactose and dairy products.**

We suggest the customer to take along with our Multivitamin Multimineral 100.

SUGGESTED USAGE: Take 4 capsules per day for 50% Daily Values. Take with meal for best absorption. If you are not taking this product with our Multivitamin Multimineral 100 and/or our Revival Soy bars or shakes, we suggest taking a second 4 capsule serving later in the day to obtain 100% of your daily value of calcium. Use only as directed. Keep away from children. Consult a physician before use if you are pregnant/nursing, using medication or suffer from chronic disease.

**Produced in a plant that uses dairy, wheat, soy, egg, fish, shellfish and tree nuts.

ORDER/CUSTOMER CARE:
1-800-REVIVAL
CustomerCare@Soy.com

WEBSITE:
www.soy.com

Physicians Laboratories: Serving you with good nutrition, education and medical research to help you live a life you love.™

64649-4

LAB TESTED

REVIVAL FIRM FOUNDATION®

Doctor-Formulated

Calcium Blend 500

Calcium from 5 Sources

500 mg

120 All-Vegetable Capsules

DAILY DIETARY SUPPLEMENT

Important: Doctor-formulated to work with the Firm Foundation Multivitamin Multimineral 100 and Revival Soy bars and shakes for best results.

Supplement Facts

Serving Size: 4 Capsules
Servings Per Container: 30

Amount Per Serving		%DV
Total Carbohydrate	<1 g	<1%†
Fiber	<1 g	2%
Calcium	500 mg	50%
(as Calcium Aspartate, Calcium Citrate, Calcium Malate, Calcium Succinate and Calcium Carbonate)		
Boron Citrate	3 mg	*

†Daily Value (DV) based on a 2,000 calorie diet.
*Daily Value (DV) not established.

Other Ingredients: Cellulose and water.

©2005 Distr. by Physicians Laboratories
200 Peddycord Park Court
Kennesville, NC 27284

7 11638 00300 3

ATTENTION: This is the FINAL PROOF before sending artwork to production. Please double check the document for any errors. Your approval of this final proof marks your acceptance that this art is correct and approval is given to send this art to production.

FREE of animal gelatin, binders, compression agents, colors, preservatives, flavors, sugar, starch, salt, wheat, gluten, yeast, potassium, phosphorous, chloride, lactose and dairy products.**

We suggest the customer to take along with our Multivitamin Multimineral 100.

SUGGESTED USAGE: Take 4 capsules per day for 50% Daily Values. Take with meal for best absorption. If you are not taking this product with our Multivitamin Multimineral 100 and/or our Revival Soy bars or shakes, we suggest taking a second 4 capsule serving later in the day to obtain 100% of your daily value of calcium. Use only as directed. Keep away from children. Consult a physician before use if you are pregnant/nursing, using medication or suffer from chronic disease.

**Produced in a plant that uses dairy, wheat, soy, egg, fish, shellfish and tree nuts.

ORDER/CUSTOMER CARE:
1-800-REVIVAL
CustomerCare@Soy.com

LAB TESTED

WEBSITE:
www.soy.com

Physicians Laboratories: Serving you with good nutrition, education and medical research to help you live a life you love.™

64649-4

REVIVAL FIRM FOUNDATION®

Doctor-Formulated

Calcium Blend 500

Calcium from 5 Sources

500 mg

120 All-Vegetable Capsules

DAILY DIETARY SUPPLEMENT

Important: Doctor-formulated to work with the Firm Foundation Multivitamin Multimineral 100 and Revival Soy bars and shakes for best results.

Supplement Facts

Serving Size: 4 Capsules
Servings Per Container: 30

Amount Per Serving		%DV
Total Carbohydrate	<1 g	<1%
Fiber	<1 g	2%
Calcium	500 mg	50%
(as Calcium Aspartate, Calcium Citrate, Calcium Malate, Calcium Succinate and Calcium Carbonate)		
Boron Citrate	3 mg	*

†Daily Value (DV) based on a 2,000 calorie diet
*Daily Value (DV) not established

Other ingredients: Cellulose and water

7 11638 00300 3

Product: Calcium Blend 120 Capsule Bottle	Lot #: 066389
Product Code: (b) (4)	PO #: (b) (4)

(b) (4) - PACKAGING PROCEDURE

Performed By: Checked By: Date:

(b) (4), (b) (6)

Product: Calcium Blend 120 Capsule Bottle	Lot #: 066389
Product Code: (b) (4)	PO #: (b) (4)

(b) (4)

07-10-20

Performed By: Checked By: Date:

(b) (4), (b) (6)

Product: Calcium Blend 120 Capsule Bottle	Lot #: (b) (4)
Product Code: (b) (4)	3986

Finished Product Testing Sheet

TESTED FOR:
APPEARANCE & COMPONENTS:

QC: 7/10/19

Container Type:	Bottle
Capsule Appearance:	0, White, Vegetable Capsule
Closure type:	Pull Tab Closure
Neckband:	Neckband
Inner Seal:	Inner Seal is Sealed
Cotton:	Cotton is Visible
Capsule Count:	120 Capsules
Label / Sleeve:	Calcium Blend 120 Capsule Label

By: Date:

(b) (4), (b) (6)

19
9
19

Encapsulator Weigh Sheet

Read 07/10/19

(b) (4)

Total weight of page (b) (4)

Completed by: (b) (6) Check by: (b) (6)

Final weight average: (b) (4)

Encapsulator Weigh Sheet

Rec 07/10/19

(b) (4)

Total weight of pag (b) (4)

Completed by (b) (6)

Check by: (b) (6)

Final weight average: (b) (4)

Encapsulator Weigh Sheet

07/10/17

(b) (4)

Total weight of page (b) (4)

Completed by: (b) (6) Check by: (b) (6)

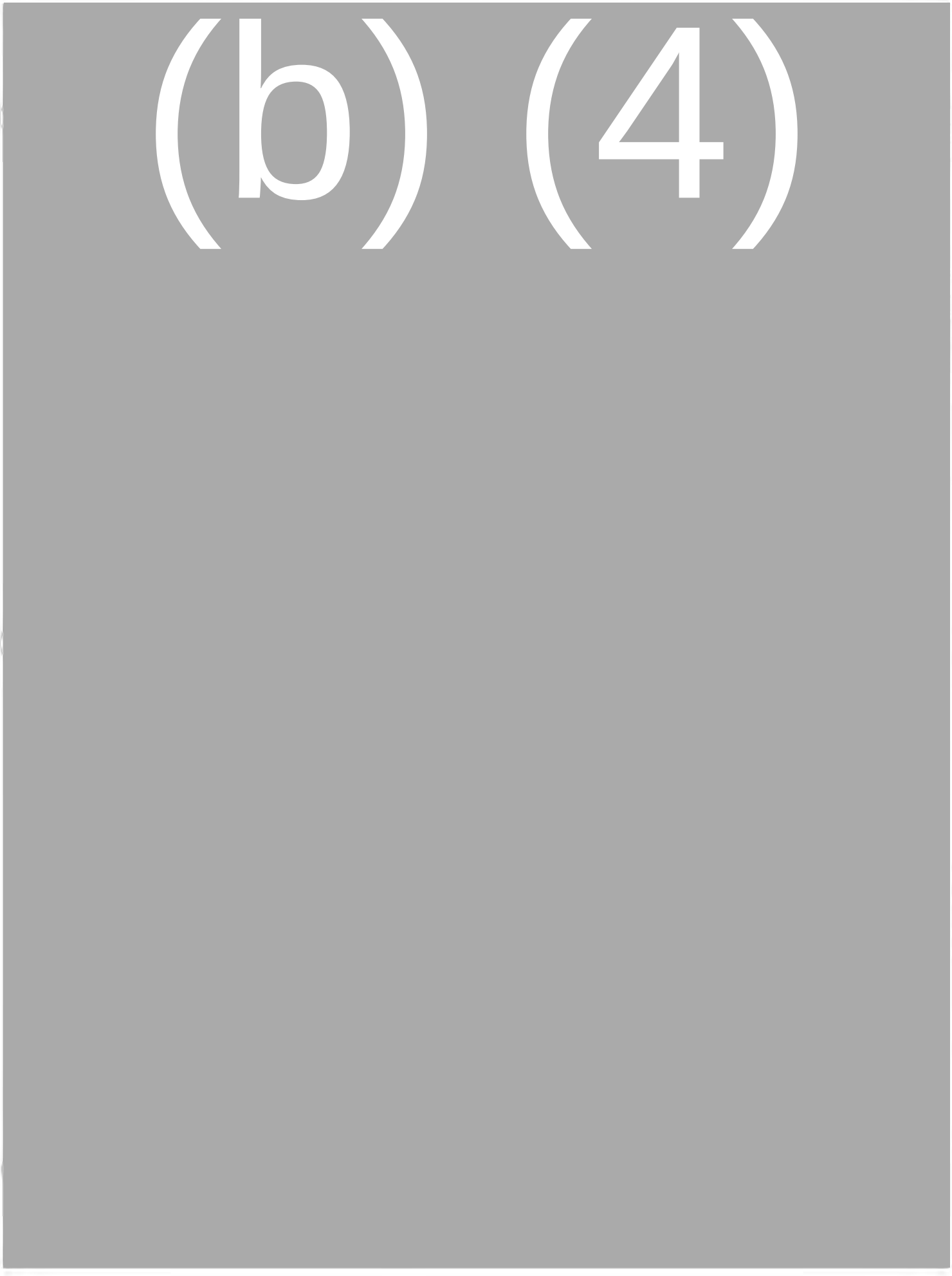
Final weight average: (b) (4)

Mixing Notes

Raw Material Vendor	Item Number	Raw Material Description	Quantity Used (Kg)	Raw Material Lot Number

(b) (4)

7/10/19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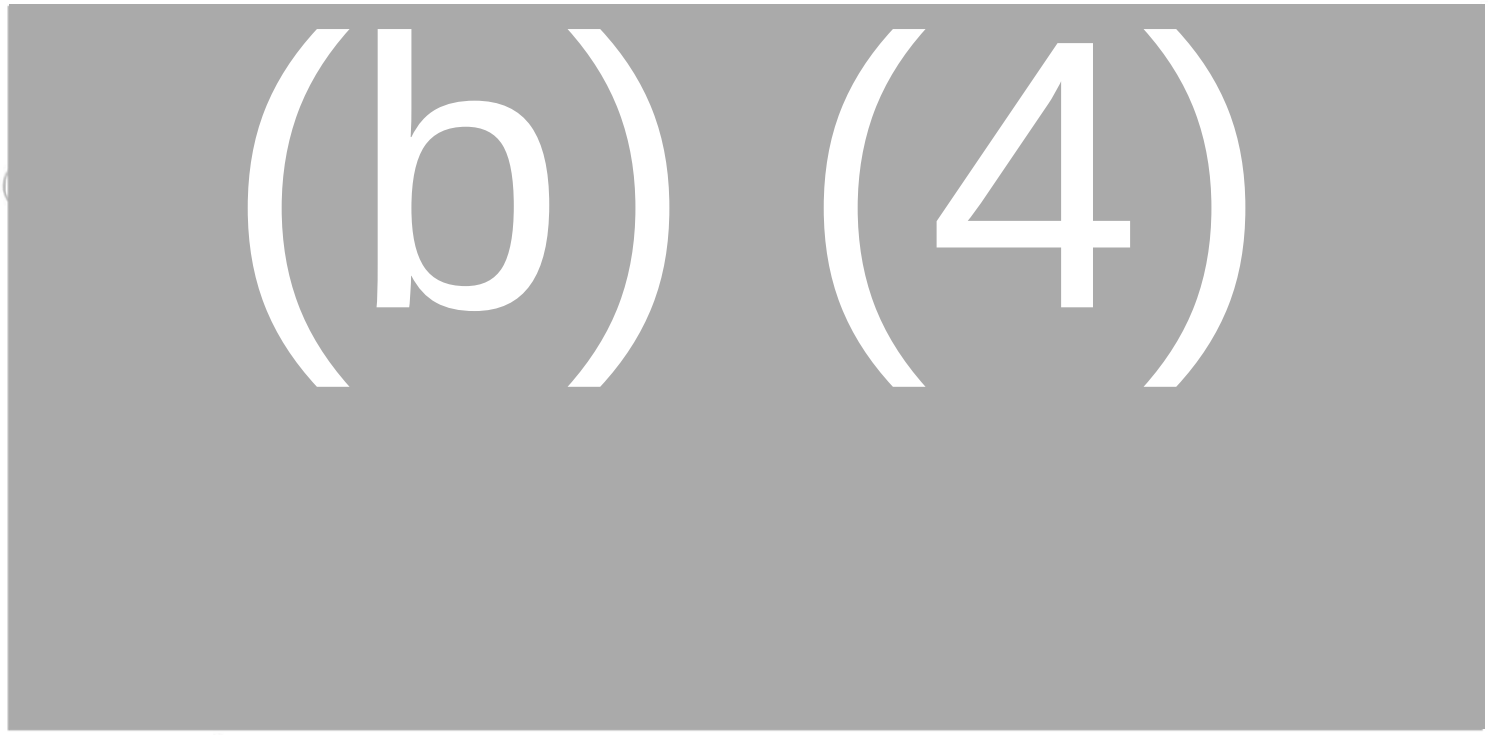
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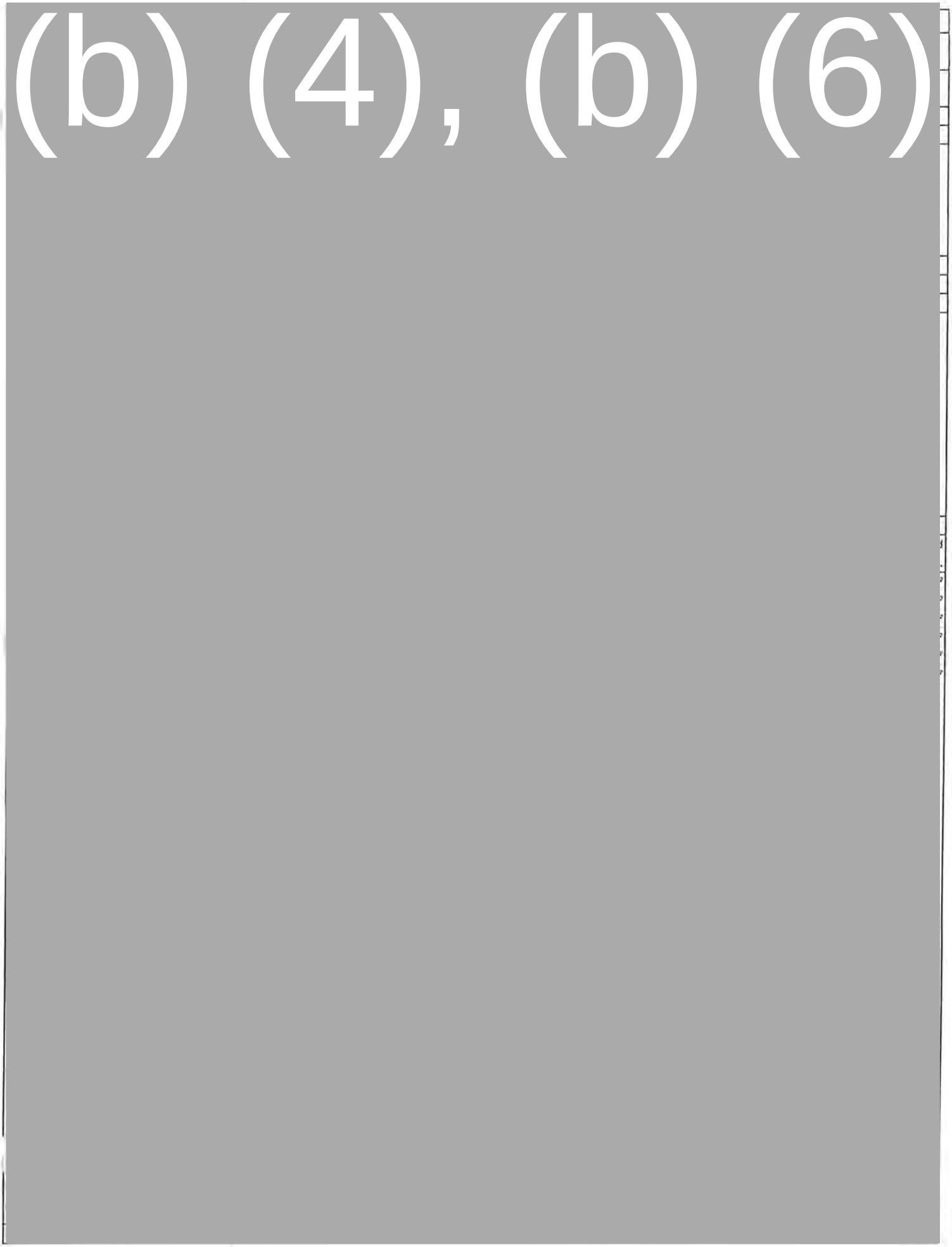
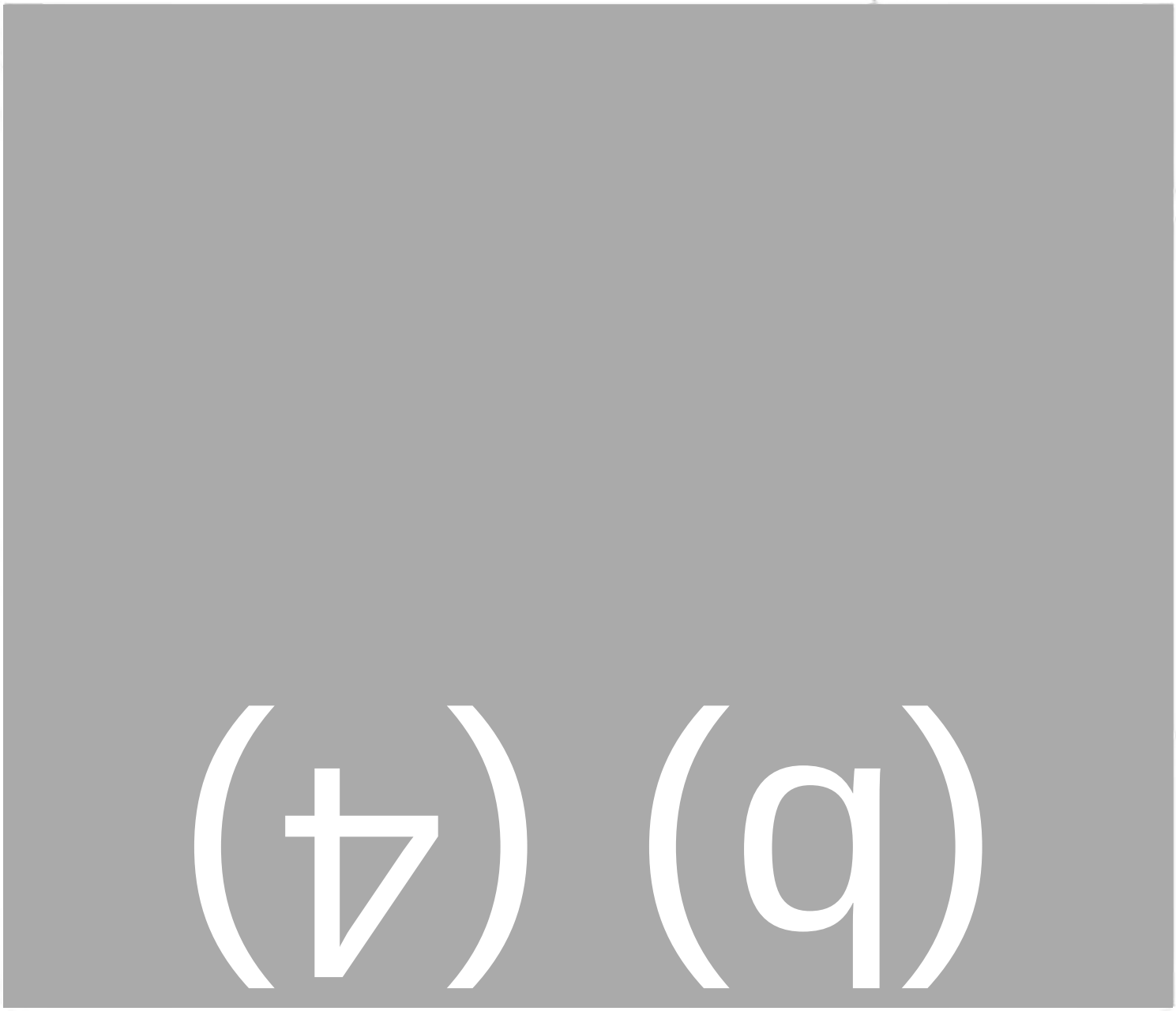

(b) (4), (b) (6)


(∀) (q)


(b) (4), (b) (6)

Complaint Date: _____ 2.

RPI STANDARD OPERATING PROCEDURE FOR A DIETARY SUPPLEMENT COMPLAINT

21 C.F.R. §111.553, §111.560, §111.570, §111.605, §111.610 (2019)

Person taking complaint:

Customer Care - initials: _____ Date:_____

Quality Control Mgr - initials: _____ Date: _____

RESPONSIBILITIES

If Customer Care or Quality Control (QC) or Supervising Mgr receives a complaint via phone or email (or written) about a product, it is the responsibility of QC to follow up, review, investigate and resolve the complaint including the requirements and specifications or possible failure of the product that may result in a risk of illness or injury.

Each line of information is to be checked off and initialed by the person collecting or validating the information, so nothing is overlooked.

PROCEDURES

Section 1:

Customer's Name

_____

Address _____

_____

Phone Number and or email address_____

Date the complaint was received and method of reception (i.e., email, phone, written)

_____

Name and description of the product in question

_____

_____

Complaint Date: _____

How much product was used and over what time period_____

Nature of the complaint including, if known, how the product was used

_____

_____

_____

_____

Batch/batches, lot or control numbers of the product in question.

_____

_____

Section 2: Once all pertinent information is gathered, QC will review and determine if an investigation is necessary by assuring the correct and complete information is collected from the complainant and reaching out to the manufacturer to review the processes and specifications of the dietary supplement to establish if there is a possible failure with the dietary supplement that could result in a risk of illness or injury and necessitate a recall. NOTE: [redacted]. **Make sure the finding extends to all relevant batches and records. Use additional sheets as needed. Initial and attach to this document.**

Section 3: The returned dietary supplement may be tested by a third party (other than the manufacturer) if a complaint is validated and established that it may be possible that the manufacturer did not comply with reported GMP standard practices for manufacturing processes or specifications that could lead of risk of illness or injury.

_____

_____

Complaint Date: _____

QC is to Reply to the complainant, if applicable, and the findings of the investigation and follow-up action taken when an investigation is performed, including any testing of the product by a third party_____

_____

_____

_____

_____

_____

Section 4: **THESE RECORDS MUST BE KEPT FOR [redacted], OR [redacted] OF DIETARY SUPPLEMENTS ASSOCIATED WITH THESE RECORDS. These records will be readily available in their original state (or photocopies) during the retention period if the FDA wishes to inspect them.**

Below is a list of more serious complaints involving dietary supplements and links to file this mandatory report.

Dietary supplements include vitamins, minerals, herbs, amino acids, whey protein, creatine, and weight loss pills. FDA does not approve dietary supplement products before they are sold to the public. Therefore, it is particularly important for consumers, health professionals, and industry members to report serious health-related reactions or illnesses (also known as adverse events) to FDA, so we can take action to protect the public from unsafe products.

Serious reactions or illnesses may include:

- itching, rash, hives, throat/lip/tongue swelling, wheezing
- low blood pressure, fainting, chest pain, shortness of breath, palpitations, irregular heart beat
- severe, persistent nausea, vomiting, diarrhea, or abdominal pain
- difficulty urinating, decreased urination
- fatigue, appetite loss, yellowing skin/eyes, itching, dark urine
- severe joint/muscle pain
- slurred speech, one-sided weakness of face, arm, leg, vision (stroke)
- abnormal bleeding from nose or gums

Complaint Date: _____

- blood in urine, stool, vomit, or sputum
- marked mood, cognitive, or behavioral changes, thoughts of suicide
- visit to Emergency Room or hospitalization

For Industry:

Members of the dietary supplement industry may now use the reporting form on the Safety Reporting Portal to meet the reporting requirements established in section 761 of the FD&C Act.

If You Need Assistance: If you have any questions about reporting on dietary supplements, please contact DSRSupport@fda.hhs.gov. For technical support with submitting a safety report, please contact SRPSupport@fda.hhs.gov.

Complaint is closed as of this date: _____

Quality Control signature_____

RETURN DATE: _____

3.

RPI STANDARD OPERATING PROCEDURE FOR A DIETARY SUPPLEMENT RETURN

21 C.F.R. §111.503, §111510, §111515, §111.520, §111.525, §111.530, §111.535, §111.70(e)

Person facilitating return for customer:

Customer Care: _____

Quality Control Mgr_____

RPI POLICY: RPI never restocks a returned dietary supplement; HOWEVER, RPI complies with the FDA regulations on conducting a material review and disposition decision prior to destroying the returned dietary supplement.

RESPONSIBILITIES:

If Customer Care or QC authorizes a return OR if a customer simply sends in a return without preauthorization, Customer Care or Quality Control is responsible for contacting the customer to collect the information if possible. QC is to do a material review and disposition decision of all returned dietary supplements. Until the material review and disposition are completed, the returned supplement is held in quarantine.

NOTE: If a return implicates other batches, then an investigation of the manufacturers processes and specifications of other batches will also be reviewed to determine compliance.

PROCEDURE

INFORMATION THAT MUST BE COLLECTED: QC is to check and initial each 'line' as it is completed.

Customer's Name

_____

Address_____

_____

Phone Number: _____

RETURN DATE: _____

Email Address: _____

Name and description of the Dietary Supplement returned:

_____

_____

Batch/batches Number:

_____

Lot Number/numbers:

_____

Nature of the reason for the return.

_____

_____

If known, how the product was used and for how long

_____

_____

Determine whether tests or examinations are necessary to determine compliance with product specifications

_____

_____

NOTE: As stated above: If the return touches other batches, an investigation of the other batches manufacturing processes and specifications will be conducted as well as the batch of the returned dietary supplement.

_____

If an investigation is done, Review the results of any tests or examinations that are conducted to determine compliance with product specifications

_____

_____

RETURN DATE: _____

Follow up with manufacturer and customer to inform them of your final investigative and disposition decision.

_____

_____

NOTE: **THESE RECORDS MUCT BE KEPT FOR** [redacted] **OF DIETARY SUPPLEMENTS ASSOCIATED WITH THESE RECORDS. These records will be readily available in their original state (or photocopies) during the retention period if the FDA wishes to inspect them.**_____

Return is closed as of this date: _____

Quality Control signature_____

4.

RPI STANDARD OPERATING PROCEDURE FOR TRAINING as per FDA regulations 21 C.F.R. 111.14 (b)(2) (2019)

Generally, our training takes place [redacted] to go over procedures, outstanding and changing issues.

Most of our training is done via [redacted (b) (4)] since COVID-19.

The records are signed by the participants and placed in our 'training' manual and generally a copy place in the employee's personnel file.

This training manual is available for FDA review as requested.

4. A

(b) (4) **Training**

March 16, 2020, March 25, 2020

- COVID RULES FOR WORKPLACE
- QUALITY CONTROL - COVID RULES ON RETURNS FROM REVIVAL CUSTOMERS AND (b) (4) CUSTOMERS

March 16, 2020

From: Suzanne Tabor, President & CEO of Revival Products and (b) (4)

Re: EMPLOYEE MEMO on COVID-19 virus. **Considering the CDC recommendations** please follow the instructions as listed below carefully. This is in addition to our regular cleaning.

- **Distance from coworkers:** Stay at least 6 feet apart at work.
- **Washing hands**: wash hands 20 seconds with warm water and soap OR use our hand sanitizer in quantity enough to massage for 20 seconds. Wash when you arrive to work, before eating, going to bathroom or handling incoming materials.
- If you go out for food or to the PO Box, etc. wash your hands when you return. Remember to wipe down the doorknobs after your 'outings' since you have touched them before washing your hands.
- **Coughing and SNEEZING:** If you cough or sneeze-use a tissue or cough/sneeze in elbow.
- **Mail and Product Returns**: Open outside. Do not touch your face until your hands have been washed. Use disposable gloves when handling - (b) (4) and (b) (4) wash hands.....if you are not using gloves immediately wash your hands being careful to de-contaminate the doorknobs and faucet handles.
- **Clothing:** Your clothes need to be washed (b) (4) that you wear to work. Don't wear your clothes out in public and then wear them to work without washing them.
- **Surfaces:** Light switches, doorknobs, keypads, computer keypad and any other common surfaces in the kitchen, bathroom or shipping areas should be regularly wiped down (b) (4) Bathrooms have been assigned to each employee, that employee must disinfect faucet, toilet handles, doorknobs, etc. as appropriate.
- **Vendor pickup or delivery:** stay 6 feet back from them. Do not shake anyone's hand.
- **Your health:** If you develop a sore throat or have a fever or feel sick you should not come to work. It is advised that you restrict your movements with others when off site, so you do not expose yourself. If you have any person in your 'circle' that you have come in contact with that is COVID-19 positive, immediately let management know so the proper actions can be taken to protect you and your co-workers.

Until the coronavirus is better understood and stabilized these are the new rules for Revival Soy and (b) (4) employees. We hope this procedure is short lived but please take this seriously and do not assume you cannot be infected. If you have any questions or concerns, please let me know.

EMPLOYEE SIGNATURE: _____ DATE 3/16/20

March 16, 2020

From: Suzanne Tabor, President & CEO of Revival Products and Glad Game, LLC

Re: EMPLOYEE MEMO on COVID-19 virus. **Considering the CDC recommendations** please follow the instructions as listed below carefully. This is in addition to our regular cleaning.

- **Distance from coworkers:** Stay at least 6 feet apart at work.
- **Washing hands**: wash hands 20 seconds with warm water and soap OR use our hand sanitizer in quantity enough to massage for 20 seconds. Wash when you arrive to work, before eating, going to bathroom or handling incoming materials.
- If you go out for food or to the PO Box, etc. wash your hands when you return. Remember to wipe down the doorknobs after your 'outings' since you have touched them before washing your hands.
- **Coughing and SNEEZING:** If you cough or sneeze-use a tissue or cough/sneeze in elbow.
- **Mail and Product Returns**: Open outside. Do not touch your face until your hands have been washed. Use disposable gloves when handling - (b) (4) (b) (4), wash hands.....if you are not using gloves immediately wash your hands being careful to de-contaminate the doorknobs and faucet handles.
- **Clothing:** Your clothes need to be washed (b) (4) that you wear to work. Don't wear your clothes out in public and then wear them to work without washing them.
- **Surfaces:** Light switches, doorknobs, keypads, computer keypad and any other common surfaces in the kitchen, bathroom or shipping areas should be regularly wiped down (b) (4). Bathrooms have been assigned to each employee, that employee must disinfect faucet, toilet handles, doorknobs, etc. as appropriate.
- **Vendor pickup or delivery:** stay 6 feet back from them. Do not shake anyone's hand.
- **Your health:** If you develop a sore throat or have a fever or feel sick you should not come to work. It is advised that you restrict your movements with others when off site, so you do not expose yourself. If you have any person in your 'circle' that you have come in contact with that is COVID-19 positive, immediately let management know so the proper actions can be taken to protect you and your co-workers.

Until the coronavirus is better understood and stabilized these are the new rules for Revival Soy and Glad Game employees. We hope this procedure is short lived but please take this seriously and do not assume you cannot be infected. If you have any questions or concerns, please let me know.

EMPLOYEE SIGNATURE: Jane Sunhatt DATE 03/16/2020

Richmond Davis

From: Suzanne Tabor [sstabor1@gmail.com]
Sent: Wednesday, March 25, 2020 8:00 PM
To: Revival Products
Cc: (b) (4)
Subject: Suspended returns to RPI facility

Jane,
As discussed with Rich, until further notice we will no longer be receiving any returns back to our facility from any customers. Our 30 day moneyback guarantee is still in place so you can credit them back if they don't like; however do not issue any return authorizations. When on the phone to a customer for sales do not mention this because you may have people that would take advantage of it.

Rich I'm not sure what (b) (4) policy is if someone returns our product to (b) (4) but we certainly do not want anything coming back to us from (b) (4)
Not even our own inventory that we've sent in there. It's been reported today that 14 (b) (4) shipping facilities are now COVID-19 positive with their employees. We really don't know how long this virus lives on cardboard so we're not taking any chances.
Press on- we will make it through this!
Thanks,

Suzanne Tabor
CEO, Revival Products Inc.
Please excuse any spelling errors. Sent from my iPhone

Jane Sweatt 3/26/2020

3/26/20

(b) (4) Training – Refresher Training

June 16, 2020

(b) (4), (b) (6)

I. More serious complaints involving dietary supplements and links to file this mandatory report. (Literature attached)

II. Company supplied (b) (4) Masks (will be coming soon)

Effective Date: 6-16-20

Below is a list of more serious complaints involving dietary supplements and links to file this mandatory report.

Dietary supplements include vitamins, minerals, herbs, amino acids, whey protein, creatine, and weight loss pills. FDA does not approve dietary supplement products before they are sold to the public. Therefore, it is particularly important for consumers, health professionals, and industry members to report serious health-related reactions or illnesses (also known as adverse events) to FDA, so we can take action to protect the public from unsafe products.

Serious reactions or illnesses may include:

- itching, rash, hives, throat/lip/tongue swelling, wheezing
- low blood pressure, fainting, chest pain, shortness of breath, palpitations, irregular heart beat
- severe, persistent nausea, vomiting, diarrhea, or abdominal pain
- difficulty urinating, decreased urination
- fatigue, appetite loss, yellowing skin/eyes, itching, dark urine
- severe joint/muscle pain
- slurred speech, one-sided weakness of face, arm, leg, vision (stroke)
- abnormal bleeding from nose or gums
- blood in urine, stool, vomit, or sputum
- marked mood, cognitive, or behavioral changes, thoughts of suicide
- visit to Emergency Room or hospitalization

For Industry:

Members of the dietary supplement industry may now use the reporting form on the Safety Reporting Portal to meet the reporting requirements established in section 761 of the FD&C Act. **If You Need Assistance:** If you have any questions about reporting on dietary supplements, please contact DSRSupport@fda.hhs.gov. For technical support with submitting a safety report, please contact SRPSupport@fda.hhs.gov.

How to Report a Problem with Food

- To file a voluntarily report a complaint or adverse event (illness or serious allergic reaction) related to a food product, you have three choices:
  - Call an FDA Consumer Complaint Coordinator if you wish to speak directly to a person about your problem.
  - Complete an electronic Voluntary MedWatch form online.
  - Complete a paper Voluntary MedWatch form that can be mailed to FDA.
- If you are a member of the food industry who needs to submit a Reportable Food Registry report when there is a reasonable probability that an article of food will cause serious adverse health consequences or death to humans or animals, please visit the Reportable Food Registry page.

Effective Date: 6-16-20

How to Report a Problem with Cosmetics

To voluntarily report a complaint or adverse event (illness or serious allergic reaction) related to a cosmetic, you have three choices:

- Call an FDA Consumer Complaint Coordinator if you wish to speak directly to a person about your problem.
- Complete an electronic Voluntary MedWatch form online.
- Complete a paper Voluntary MedWatch form that can be mailed to FDA.

Also, make sure you report this event immediately to the CEO of the company.