

DEC 05 2016

Sherri R. Carter, Executive Officer/Clerk
By: Jontae M. Alvarez, Deputy

1 Reuben Yeroushalmi (SBN 193981)
2 Ben Yeroushalmi (SBN 232540)
3 Peter T. Sato (SBN 238486)
4 **YEROUSHALMI & YEROUSHALMI**
5 An Association of Independent Law Corporations
6 9100 Wilshire Boulevard, Suite 240W
7 Beverly Hills, California 90212
8 Telephone: 310.623.1926
9 Facsimile: 310.623.1930

10 Attorneys for Plaintiffs,
11 Consumer Advocacy Group, Inc.

12 SUPERIOR COURT OF THE STATE OF CALIFORNIA

13 COUNTY OF LOS ANGELES

14 CONSUMER ADVOCACY GROUP, INC.,
15 in the interest of the Public,

16 Plaintiff,

17 v.

18 BODEGA LATINA CORPORATION, a
19 Delaware Corporation; GRUPO
20 COMERCIAL CHEDRAUI, S.A. DE C.V., a
21 Mexico Corporation; PRODUCTORA Y
22 COMERCIALIZADORA DE PRODUCTOS
23 S.A. DE C.V., a Mexico Corporation; and
24 DOES 1-20;

25 Defendants.

CASE NO. BC575811

26 CONSENT JUDGMENT [PROPOSED]

27 Complaint filed: March 17, 2015

28 Department: 74

Judge: Hon. Teresa Sanchez- Gordon

29 **1. INTRODUCTION**

30 1.1 This Consent Judgment is entered into by and between plaintiff Consumer
31 Advocacy Group, Inc. ("CAG") acting on behalf of itself and in the interest of the public, and
32 defendant PRODUCTORA Y COMERCIALIZADORA DE PRODUCTOS S.A. DE C.V.
33 ("PRODUCTORA" or "Defendant"), in its own right and for the benefit of all other Defendants
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1 named in this action and other unnamed parties involved in the chain of distribution of
2 PRODUCTORA's products, with each a "Party" and collectively referred to as "Parties."

3 1.2 It is alleged that Defendants named in the Complaint employ ten or more persons,
4 are persons in the course of doing business for purposes of the Safe Drinking Water and Toxic
5 Enforcement Act of 1986, California Health & Safety Code §§ 25249.6 et seq. ("Proposition
6 65"), and manufactured, distributed, and/or sold Caramel Coating, which includes but is not
7 limited to "Forritos® CAMEL COATING FOR APPLES ARTIFICIAL TAMARIND
8 FLAVORED; NET WT. 12.8 OZ(0.8Lb)365g; Forritos® CUBRE MANZANAS; MADE BY:
9 PRODUCTORA Y COMERCIALIZADORA DE PRODUCTOS S.A. DE C.V. CALLE ZEUS
10 No. 1105 PARQUE INDUSTRIAL KALOS DEL PONIENTE, SANTA CATARINA, N.L.
11 MÉXCO, C.P. 66370; Barcode: 7 03885 06312 1" before the Effective Date of this Consent
12 Judgment. Defendants specifically deny having ten or more employees.

13 1.3 **Notice of Violation.**

14 1.3.1 On or about September 5, 2014, CAG served Defendants PRODUCTORA,
15 Bodega Latina Corporation, Comercial Chedraui, S.A. De C.V., and various public enforcement
16 agencies with documents entitled "60-Day Notice of Violation" (the "September 5, 2014
17 Notice") that provided the recipients with notice of alleged violations of Health & Safety Code §
18 25249.6 for failing to warn individuals in California of exposures to Lead contained in the
19 Covered Products.

20 1.3.2 No public enforcer has commenced or diligently prosecuted the allegations
21 set forth in the September 5, 2014 Notices.

22 1.4 **Complaint.**

23 1.4.1 On March 17, 2015, CAG filed a Complaint for civil penalties and injunctive
24 relief ("Complaint") in Los Angeles Superior Court, Case No. BC575811. The Complaint
25 alleges, among other things, that the named Defendants violated Proposition 65 by failing to give
26 clear and reasonable warnings of exposure to Lead from the Covered Products.

27 1.5 **Consent to Jurisdiction**

28 While otherwise disputed, for purposes of this Consent Judgment, the Parties consent that

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1 this Court has jurisdiction over the allegations of violations contained in the Complaint and
2 personal jurisdiction over the named Defendants as to the acts alleged in the Complaint, that
3 venue is proper in the City and County of Los Angeles and that this Court has jurisdiction to
4 enter this Consent Judgment as a full settlement and resolution of the allegations contained in the
5 Complaint and of all related claims which were or could have been raised by any person or entity
6 based in whole or in part, directly or indirectly, on the prior conduct of the Parties or on the facts
7 alleged in the Complaint or arising therefrom or related to.

8 **1.6 No Admission**

9 1.6.1 This Consent Judgment resolves claims that are denied and disputed. The Parties
10 enter into this Consent Judgment pursuant to a full and final settlement of any and all claims
11 between the parties for the purpose of avoiding prolonged litigation. This Consent Judgment
12 shall not constitute an admission with respect to any material allegation of the Complaint, each
13 and every allegation of which Defendants deny including jurisdiction, nor may this Consent
14 Judgment or compliance with it be used as evidence of any wrongdoing, misconduct, culpability
15 or liability on the part of Defendants.

16 1.6.2 Nothing in this Consent Judgment shall prejudice, waive or impair any right,
17 remedy, argument, or defense the Parties may have in any other or future legal proceeding,
18 except as expressly provided in this Consent Judgment.

19 1.6.3 This Consent Judgment is the product of negotiation and compromise and is
20 accepted by the Parties, for purposes of settling, compromising, and resolving issues disputed in
21 this Action, including future compliance by Defendants with Section 3 of this Consent Judgment.

22 **2. DEFINITIONS**

23 2.1 "Covered Products" means all Caramel Coating, including but not limited to
24 "Forritos® Zumba Pica® CARAMEL COATING FOR APPLES ARTIFICIAL TAMARIND
25 FLAVORED; NET WT. 12.8 OZ(0.8Lb)365g; Forritos® CUBRE MANZANAS; MADE BY:
26 PRODUCTORA Y COMERCIALIZADORA DE PRODUCTOS S.A. DE C.V. CALLE ZEUS
27 No. 1105 PARQUE INDUSTRIAL KALOS DEL PONIENTE, SANTA CATARINA, N.L.

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1 MÉXCO, C.P. 66370; Barcode: 7 03885 06312 1" sold, distributed, processed, packaged,
2 produced, manufactured, and/or handled by Defendant.

3 2.2 "Compliance Documentation" shall mean (i) the Certifications from the
4 Independent Food Processing Auditor and the Internal Auditor received pursuant to Section 3.2,
5 below; (ii) a résumé or summary showing the qualifications of the Independent Food Processing
6 Auditor who has provided the Auditor's Certification(s) of the required under Section 3.2, below,
7 that establishes that the Auditor has the qualifications specified in Section 2.4, below; and (iii)
8 the results of the laboratory testing required by Section 3.4, below.

9 2.3 "Effective Date" means the date that this Consent Judgment is approved by the
10 Court.

11 2.4 "Independent Food Processing Auditor" or "Independent Auditor" shall mean an
12 independent auditor or auditing company, foreign or domestic, that (i) has extensive knowledge
13 of good manufacturing practices in the food processing industry; (ii) has sufficient experience in
14 inspecting food processing facilities to ensure compliance with good manufacturing practices
15 and with the Hazard Analysis and Critical Control Points ("HACCP") food safety management
16 system; (iii) has qualification sufficient to address the Food Processing Association ("FPA")
17 certification criteria used for the FPA-Safe Program), Safe Quality Foods (SQF), or other Global
18 Food Safety Initiative approved programs¹; and (iv) has submitted a satisfactory résumé or other
19 summary of its qualifications to CAG. Upon request, the Attorney General may provide
20 Defendant with a non-exclusive list of Independent Food Processing Auditors who have
21 previously submitted their qualifications to CAG, whose qualifications are up to date, and who
22 are deemed to meet the criteria set forth in this paragraph. Defendant, however, may select an
23 Independent Food Processing Auditor whose résumé is satisfactory to CAG and who otherwise
24 meets the criteria set forth in this paragraph. For purposes of this Consent Judgment, the Parties
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27 ¹ This includes: (1) certification as an International HACCP Alliance Lead Instructor; or (2) certification
28 as a SQF (Safe Quality Food) HACCP Lead Auditor or SQF Consultant; or (3) holding an NEHA
(National Environmental Health Association) Certified Professional - Food Safety (CP-FS) Credential; or
(4) certification as a Food Scientist by Institute of Food Technology; or (5) equivalent qualifications.

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1 stipulate that, as of the Effective Date of this Consent Judgment, Mario Pineda is an approved
2 Independent Food Processing Auditor.

3 2.5 "Lead" means Lead and Lead Compounds.

4 2.6 "Maximum Lead Level" means 50 parts per billion. A Covered Product satisfies
5 the Maximum Lead Level if testing pursuant to this Consent Judgment demonstrates that it has a
6 lead concentration of no more than 50 parts per billion.

7 2.7 A "Qualified Laboratory" shall mean a laboratory that has demonstrated
8 proficiency to conduct lead analysis on the Covered Products using Inductively Coupled Plasma
9 Mass Spectrometry ("ICP-MS"). A Qualified Laboratory shall meet the standards of the
10 American Association for Laboratory Accreditation for Chemical Testing or another
11 organization with equivalent standards. Laboratories should be experienced in (1) testing
12 methodologies for lead levels in foods (in particular Chili based products) that comply with the
13 Production and Process Control System; and (2) Requirements for Laboratory Operations set
14 forth in 21 Code of Federal Regulations Part 111, Subpart J, including but not limited to the
15 requirements for written procedures, requirements for laboratory control processes, requirements
16 for laboratory methods and examination, record retention policies, and other laboratory
17 requirements. A Qualified Laboratory shall be prepared to implement the Laboratory Standards
18 set forth in Exhibit C, and to share the initial laboratory reports, data and test results that it
19 obtains or generates pursuant to this Consent Judgment with CAG. Upon request, the Attorney
20 General may provide Defendant with a non-exclusive list of laboratories that are deemed to meet
21 the requirements of this section, but Defendant is free to use any other laboratory that meets of
22 this section. Defendant may use laboratory procedures that differ from those set forth in this
23 section and Exhibit C with the advance written approval of the Attorney General. For purposes
24 of this Consent Judgment, the Parties stipulate that, as of the Effective Date of this Consent
25 Judgment, the Covance Lab is a Qualified Laboratory.

26 2.8 "Validation Testing" means testing of randomly selected products in accordance
27 with the requirements of Section 3.4, below, and Exhibit A.

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1 2.9 A "Validation Testing Cycle" is the interval for testing (e.g., quarterly, annually,
2 etc.) required by this Consent Judgment, including any testing interval set by the Independent
3 Auditor selected pursuant to subparagraph 3.4.

4 **3. INJUNCTIVE RELIEF/REFORMULATION**

5 3.1 After the Effective Date, Defendant shall not sell, offer for sale in California, or
6 ship for sale in California any Covered Products unless (1) the Covered Product satisfies the
7 Maximum Lead Level; or (2) Defendant provides a Proposition 65 compliant warning on the
8 Covered Products. Any warning provided pursuant to this section shall be affixed to the
9 packaging of, or directly on, the Covered Products, and be prominently placed with such
10 conspicuousness as compared with other words, statements, designs, or devices as to render it
11 likely to be read and understood by an ordinary individual under customary conditions before
12 purchase or use. The Parties agree that product labeling stating that:

13 **WARNING:** This product contains lead, a chemical known to the State of
14 California to cause cancer, birth defects or other reproductive harm.

15 shall constitute compliance with Proposition 65 with respect to the Lead in the Covered
16 Products distributed and/or sold by the Defendants after the Effective Date. Prior to selling any
17 Covered Product with a warning set forth above, Defendant will make good faith efforts to
18 reduce the lead levels in that Covered Product so that it satisfies the Maximum Lead Level.

19 **3.2 Certification from Independent and Internal Food Processing Auditors:**

20 3.2.1 **Retain Independent Food Processing Auditor:** In the event it has not
21 done so already, within three (3) months following the Effective Date, Defendant will retain an
22 Independent Food Processing Auditor to conduct annual inspections of each of its facilities used
23 to manufacture Covered Products for the purpose of ensuring that each such facility is employing
24 all good manufacturing practices, procedures and purchasing controls/ingredient standards
25 necessary to reduce lead in its products to the lowest level then currently feasible ("GMPs"). In
26 conducting the audit(s) required by this subparagraph, the Independent Food Processing Auditor
27 shall provide the certification set forth in Exhibit A, confirming that each facility has
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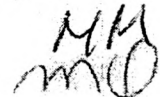
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1 implemented GMPs based on the lead-related GMP checklist attached as Exhibits A and B to
2 this Consent Judgment.

3 **3.2.2 Obtain Written Certification from the Independent Food Processing**

4 **Auditor:** Defendant shall obtain annual certification from an Independent Food Processing
5 Auditor they retain pursuant to subparagraph 3.2.1 above attesting to Defendant's compliance
6 with the requirements for in this Consent Judgment. Defendant shall maintain records
7 documenting their ongoing compliance with the testing requirements set forth in paragraphs 3.2-
8 3.4. These certifications shall be based on the Independent Food Processing Auditor's firsthand
9 review of the Defendant's GMPs and Compliance Documentation. If it has not done so already,
10 the Independent Auditor shall provide the first Auditor's Certification ("Initial Auditor's
11 Certification") within six months after the Effective Date, and the Independent Auditor or the
12 Internal Auditor, as specified below, shall provide subsequent Auditor's Certifications annually
13 thereafter on the anniversary of the submission of the Initial Auditor's Certification. Once
14 Defendant has satisfactorily submitted the Auditor's Certification in accordance with Section
15 3.5.3 of this Consent Judgment, then an employee of Defendant who has received training
16 adequate to conduct and document the audits ("Internal Auditor") may assume the Independent
17 Auditor's responsibility for annual audits set forth in Exhibit A. The Independent Auditor will
18 provide CAG with copies of the Lead Contribution Exercises conducted pursuant to Exhibit A as
19 part of the Initial Auditor's Certification. Upon formal written request (which shall not exceed
20 one every six months), Defendant will provide CAG with information that the Auditor relied on
21 in providing any Auditor's Certification required by this Consent Judgment, including:
22 laboratory reports; other non-confidential documents and information; and subsequent Lead
23 Contribution Exercises.

24 **3.3 Safeguards on Ingredient Chili:** Within six (6) months following the Effective
25 Date, Defendant shall purchase ground chili products for use in the Covered Products from only
26 those suppliers who have done the following: (i) retained an Independent Food Processing
27 Auditor(s) to conduct annual inspections of each of the suppliers' chili grinding/processing
28 facilities which produce chili powder sold for use in Covered Products, for the purpose of



1 ensuring that each such facility is employing GMPs necessary to reduce lead in their chili
2 products sold for use in Covered Products; the inspection shall be based on the lead related GMP
3 checklist set forth in Exhibit B to this Consent Judgment; and (ii) obtained written certification
4 by one or more Independent Food Processing Auditor(s) that the inspection(s) have been
5 completed and that the GMPs have been implemented. Upon request, the Attorney General may
6 provide Defendant with a non-exclusive list of chili suppliers that are deemed to meet the
7 requirements of this section. Alternatively, if none of the listed suppliers are able to provide the
8 required chili products, Defendant may use its own Independent Food Processing Auditor to
9 certify that the chili products purchased from other suppliers are compliant with Proposition 65.

10 **3.4 Validation Testing Requirements for Covered Products:** If it has not begun
11 doing so already, beginning within three (3) months following the Effective Date, Defendant
12 will perform, using Qualified Laboratories employing a limit of quantitation ("LOQ") of 10
13 parts per billion ("ppb") (i.e., 0.010 parts per million ("ppm")) or lower, quarterly lead content
14 testing of Representative Samples (as that term is defined in Exhibit A) of each family of its
15 Covered Products pursuant to the sampling and testing protocol contained in Exhibits A and C
16 to this Judgment. For purposes of this Consent Judgment, a family of Covered Products
17 ("Product Family") is defined as all products made with the same formula or recipe except as
18 to minor variations, which variations do not involve the use of chili, tamarind, imitation
19 tamarind or salt. Validation Testing will be done on Representative Samples of each Product
20 Family. Validation testing will be performed quarterly for a period of one year, and annually
21 thereafter on the anniversary of the entry of this Consent Judgment, but the frequency of
22 Validation Testing may be increased on the request of the Independent Auditor, CAG or the
23 Attorney General to address any violations of this Consent Judgment.

24 **3.4.1 Outlier Limitation:** The Parties recognize that lead levels in Covered
25 Products will have some degree of inherent variability notwithstanding the use of chili from
26 suppliers meeting the requirements of subparagraph 3.3 above and, therefore, individual samples
27 of Covered Products may from time to time contain lead in excess of the Maximum Lead Level
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1 as defined above. Accordingly, the "Outlier Limitation Level" for purposes of this Consent
2 Judgment is 60 ppb (0.060 ppm). In the event an individual sample of any Covered Product as
3 measured by a Qualified Laboratory pursuant to the testing method set forth in contained in
4 Exhibits A and C to this Judgment contains a lead level between the Maximum Lead Level and
5 the Outlier Limitation Level (i.e., between 50 and 60 ppb), the Settling Defendant will consult
6 with its Independent Food Processing Auditor, who will (i) attempt to locate the source of
7 elevated lead seen in the laboratory results, and (ii) provide CAG and Attorney General with (a)
8 a report on this investigation and (b) a proposal to prevent the situation from occurring in the
9 future. Settling Defendant will implement the recommendations of the Independent Auditor.

10 3.4.2 In the event that Defendant's testing shows that the average² lead results
11 from Representative Samples for a Product Family are in excess of the Maximum Lead Level
12 specified by subparagraph 3.1, or that individual samples from that Product Family exceed the
13 Outlier Limitation Level, the Settling Defendant shall not sell the lot(s) which was (were) tested
14 and shall promptly notify CAG and the Attorney General in writing of the laboratory results
15 showing elevated lead levels in the Settling Defendant's Covered Product Family. The Settling
16 Defendant will also: (i) consult with its Independent Food Processing Auditor, (ii) attempt to
17 locate the source of elevated lead seen in the laboratory results, and (iii) provide CAG and the
18 Attorney General with a report on this investigation and a proposal to prevent the situation from
19 occurring in the future. On approval by CAG or the Attorney General, the affected Settling
20 Defendant will implement this proposal. Before it resumes selling caramel coating from the
21 Product Family in question, the Settling Defendant shall re-conduct the testing of the Product
22 Family. Before selling any lots from that Product Family, Defendant shall demonstrate to CAG
23 or Attorney General that the lots of the Product Family which are to be offered for sale do not
24 contain average levels of lead in excess of the Maximum Lead Level and that randomly selected
25 individual samples from those lots do not exceed the Outlier Limitation Level.

26 **3.5 Compliance Documentation – Related Submittals to the Attorney General**
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28 ²² For purposes of this Consent Judgment, "average" means the arithmetic mean.

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1 3.5.1 **Initial Certification:** By no later than six (6) months following the
2 Effective Date, Defendant shall provide CAG and the Attorney General with certification
3 from the Independent Food Processing Auditor(s) demonstrating that the requirements of
4 paragraphs 3.1-3.4 have been fully met.

5 3.5.2 **Annual Recertification:** On the anniversary of the submission of the
6 Initial Auditor's Certification, Defendant shall provide CAG and the Attorney General with
7 annual certification from the Independent Food Processing Auditor retained pursuant to
8 subparagraph 3.2.1, demonstrating that the required annual inspections have been completed,
9 that substantial compliance has been demonstrated, and that the Auditor's recommendations as to
10 non-substantial compliance items (if any) have been satisfactorily addressed within thirty (30)
11 days. For purposes of the preceding sentence, "substantial compliance" shall mean having no
12 "critical deficiencies" (i.e., conditions that result or would likely result in the addition of lead
13 into the product in question); items for which "critical deficiencies" exist are delineated on the
14 lead-related GMP checklists attached as Exhibits A and B to this Consent Judgment.

15 3.5.3 **Reduction in Frequency of Audits:** Once Defendant, or Defendant's
16 chili supplier, has satisfactorily completed three (3) consecutive annual audits in accordance with
17 the terms of this Consent Judgment, then the requirements of paragraphs 3.1.-3.4 may be
18 addressed through a formal, documented internal auditing program ("Internal Auditing
19 Program") that has been approved in advance by an Independent Food Processing Auditor with
20 notification thereof provided to CAG and Attorney General. Once the Internal Auditing Program
21 has been approved, Defendant shall supply CAG and the Attorney General with written annual
22 certifications for an additional three years showing that such internal audits have been completed
23 and GMPs have been met. Thereafter, Defendant shall keep its Internal Auditing Program in
24 effect, but the obligation to submit annual certifications to CAG and the Attorney General shall
25 be suspended. In the event that CAG or the Attorney General thereafter determines that
26 Defendant has sold Covered Products with lead in excess of the levels set forth in paragraphs 3.1
27 or has otherwise violated any provision of this Consent Judgment, CAG or the Attorney General
28 may instruct Defendant to resume conducting audits using an Independent Food Processing

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1 Auditor, and providing certification of such audits, on an annual or biennial basis to the extent
2 and for the duration that CAG or the Attorney General deems necessary.

3 3.5.4 In addition to providing the certifications to CAG and the Attorney
4 General as described above, if Defendant's testing for a Product Family of any Covered Product
5 pursuant to the sampling and testing protocol set forth in Exhibit A results in an exceedance of
6 the Maximum Lead Level or a single result in excess of the Outlier Limitation, the Settling
7 Defendant shall (i) promptly inform CAG and the Attorney General, (ii) upon request, supply
8 CAG and the Attorney General with a copy of the test results, and (iii) follow the protocol set
9 forth in 3.4.2.

10 3.5.5 Defendant is required to keep all Compliance Documentation on file, and
11 available to CAG and the Attorney General upon request, for a period of five years from the date
12 on which it is created.

13 **4. SETTLEMENT PAYMENT**

14 **Total Payment:** After the Effective Date, Defendants shall pay a total of sixty-eight
15 thousand dollars (\$68,000.00) as follows:

16 **4.1 Civil Penalties.** Defendants shall issue two separate checks for a total amount of
17 four thousand dollars (\$4,000.00) as penalties pursuant to Health & Safety Code § 25249.12: (a)
18 one check made payable to the State of California's Office of Environmental Health Hazard
19 Assessment (OEHHA) in the amount of \$3,000.00 representing 75% of the total penalty; and (b)
20 one check to Consumer Advocacy Group, Inc. in the amount of \$1,000.00 representing 25% of
21 the total penalty. Two separate 1099s shall be issued for the above payments: The first 1099
22 shall be issued to OEHHA, P.O. Box 4010, Sacramento, CA 95184 (EIN: 68-0284486) in the
23 amount of \$3,000.00. The second 1099 shall be issued in the amount of \$1,000.00 to CAG and
24 delivered to: Yeroushalmi & Yeroushalmi, 9100 Wilshire Boulevard, Suite 240W, Beverly
25 Hills, California 90212.

26 **4.2 Payments in Lieu of Civil Penalties**

27 Defendants also shall separately pay four thousand dollars (\$4,000.00) to CAG as a
28 payment in lieu of civil penalty pursuant to Health & Safety Code §25249.7(b) and California

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1 Code of Regulations, Title 11 § 3203(b). CAG will use this payment for investigation of the
2 public's exposure to Proposition 65 listed chemicals through various means, laboratory fees for
3 testing for Proposition 65 listed chemicals, expert fees for evaluating exposures through various
4 mediums, including but not limited to consumer product, occupational, and environmental
5 exposures to Proposition 65 listed chemicals, and the cost of hiring consulting and retained
6 experts who assist with the extensive scientific analysis necessary for those files in litigation, as
7 well as administrative costs incurred during the litigation, in order to reduce the public's
8 exposure to Proposition 65 listed chemicals by notifying those persons and/or entities believed to
9 be responsible for such exposures and attempting to persuade those persons and/or entities to
10 reformulate their products or the source of exposure to completely eliminate or lower the level of
11 Proposition 65 listed chemicals, thereby addressing the same public harm as allegedly in the
12 instant Action.

13 **4.3 Reimbursement of Attorneys' Fees and Costs:** Defendants shall pay sixty
14 thousand dollars (\$60,000.00) to "Yeroushalmi & Associates" as reimbursement for the
15 investigation fees and costs, testing costs, expert fees, attorney fees, and other litigation costs and
16 expenses for all work performed through the approval of this Consent Judgment.

17 **4.4** Payments pursuant to 4.1, 4.2 and 4.3 shall be delivered to: Reuben Yeroushalmi,
18 Yeroushalmi & Yeroushalmi, 9100 Wilshire Blvd., Suite 240W, Beverly Hills, CA 90212 within
19 the time agreed upon by the Parties.

20 **5. MATTERS COVERED BY THIS CONSENT JUDGMENT**

21 **5.1** This Consent Judgment is a full, final, and binding resolution between CAG on
22 behalf of itself and in the public interest and Defendants and its officers, directors, insurers,
23 employees, parents, shareholders, divisions, subdivisions, subsidiaries, partners, affiliates, sister
24 companies, agents, contractors, vendors, licensors, including but limited to PRODUCTORA and
25 their successors and assigns ("Defendant Releasees"), and each of their suppliers, customers,
26 distributors, wholesalers, retailers, including but not limited to Bodega Latina Corporation, and
27 the successors and assigns of any of them who may use, maintain, distribute or sell Covered
28 Products ("Downstream Defendant Releasees"), for all conduct of the named Defendants prior to

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1 the Effective Date based on alleged exposure to Lead from Covered Products as set forth in the
2 Notice. Defendants and Defendant Releasees' compliance with this Consent Judgment shall
3 constitute compliance with Proposition 65 with respect to exposure to Lead from Covered
4 Products.

5 **5.2** CAG on behalf of itself, its past and current agents, representatives, attorneys,
6 successors, and/or assignees, hereby waives all rights to institute or participate in, directly or
7 indirectly, any form of legal action and releases all claims, including, without limitation, all
8 actions, and causes of action, in law or in equity, suits, liabilities, demands, obligations,
9 damages, costs, fines, penalties, losses, or expenses (including, but not limited to, investigation
10 fees, expert fees, and attorneys' fees) of any nature whatsoever, whether known or unknown,
11 fixed or contingent (collectively "Claims"), against Defendants, Defendant Releasees, and
12 Downstream Defendant Releasees arising from any allegations of violation of Proposition 65 or
13 any other statutory or common law regarding the failure to warn about exposure to Lead from
14 Covered Products manufactured, distributed, or sold by Defendants and Defendant Releasees. In
15 furtherance of the foregoing, as to alleged exposures to Lead from Covered Products, CAG
16 hereby waives any and all rights and benefits which it now has, or in the future may have,
17 conferred upon it with respect to the Claims arising from any violation of Proposition 65 or any
18 other statutory or common law regarding the failure to warn about exposure to Lead from
19 Covered Products by virtue of the provisions of section 1542 of the California Civil Code, which
20 provides as follows:

21 A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE
22 CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS FAVOR AT
23 THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM,
24 MUST HAVE MATERIALLY AFFECTED HIS SETTLEMENT WITH THE
25 DEBTOR.

26 CAG understands and acknowledges that the significance and consequence of this waiver of
27 California Civil Code section 1542 is that even if CAG suffers future damages arising out of or
28 resulting from, or related directly or indirectly to, in whole or in part, the Claims arising from
any alleged violation of Proposition 65 or any other statutory or common law regarding the
failure to warn about exposure to Lead from Covered Products, including but not limited to any

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1 exposure to, or failure to warn with respect to exposure to Lead from the Covered Products,
2 CAG will not be able to make any claim for those damages against Defendants or the Defendant
3 Releasees or Downstream Defendant Releasees. Furthermore, CAG acknowledges that it intends
4 these consequences for any such Claims arising from any alleged violation of Proposition 65 or
5 any other statutory or common law regarding the failure to warn about exposure to Lead from
6 Covered Products as may exist as of the date of this release but which CAG does not know exist,
7 and which, if known, would materially affect their decision to enter into this Consent Judgment,
8 regardless of whether their lack of knowledge is the result of ignorance, oversight, error,
9 negligence, or any other cause. This Consent Judgment does not constitute a release of the
10 Attorney General's rights and does not waive, limit or restrict the Attorney General's right to
11 seek from Settling Defendant in another action whatever fines, costs, penalties, or remedies are
12 provided for by law for failure to comply with Proposition 65 or other laws.

13 **6. ENFORCEMENT OF JUDGMENT**

14 **6.1** For purposes of this Consent Judgment only, the Parties stipulate that this Court
15 has jurisdiction over Defendants as to the allegations contained in the Complaint, that venue of
16 the action in Los Angeles County is proper, and that this Court has jurisdiction to enter and
17 enforce the provisions of this Consent Judgment, pursuant to Code of Civil Procedure section
18 664.6, as a full and binding resolution of all claims that were or could have been raised in the
19 Complaint against Defendants based on the facts alleged therein and in the Notices.

20 **6.2 Levels Between 51 and 60 Parts Per Billion.** If Plaintiff alleges that Defendant
21 has sold a Covered Product with lead levels between 51 and 60 parts per billion, Plaintiff shall
22 provide notice of the exceedance (Exceedance) to the Settling Defendant. The Settling
23 Defendant must then refer the notice to the appropriate Independent Auditor for review, and the
24 Independent Auditor must take the Exceedance into account in ensuring continuing compliance
25 with the Maximum Lead Level and other provisions of this Judgment. If the Settling Defendant
26 is in compliance with all of the requirements of section 3 of the Consent Judgment, an isolated
27 Exceedance in the 51 to 60 parts per billion range will not be considered a violation of this
28 Consent Judgment and will not require the payment of penalties or the reimbursement of costs.

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1 **6.3 Notice of Violation.** Prior to bringing any motion, order to show cause, or other
2 proceeding to enforce any alleged violation of Section 3 of this Consent Judgment, CAG shall
3 provide a Notice of Violation ("NOV") by certified mail, return receipt requested, to Defendants.
4 The NOV shall include for each of the Newly Alleged Products ("Newly Alleged Products"
5 means any Covered Product for which CAG alleges a violation of the Consent Judgment after
6 the Effective Date): the date(s) the alleged violation(s) was observed and the location at which
7 the Newly Alleged Products were offered for sale, and shall be accompanied by all test data
8 obtained by CAG regarding the Newly Alleged Products, including an identification of the
9 component(s) of the Newly Alleged Products that were tested. Before any destructive testing of
10 any Newly Alleged Products is conducted by or on behalf of CAG, CAG shall give Defendant(s)
11 an opportunity to inspect and verify at reasonable times and places the authenticity of any Newly
12 Alleged Product in violation of this Consent Judgment.

13 **6.3.1 Non-Contested NOV.** CAG shall take no further action regarding the
14 alleged violation if, within 60 days of receiving such NOV, Defendants serve a Notice of
15 Election ("NOE") that meets one of the following conditions:

16 (a) The Newly Alleged Products were shipped by Defendants for sale
17 in California before the Effective Date, or

18 (b) The following conditions are all met:

19 (1) The Notice of Violation does not allege that the Product contained lead
20 levels in excess of 100 parts per billion; (2) Settling Defendant has complied with the
21 provisions of Section 3.2 through 3.4, above, with respect to the Product Family in
22 question; (3) Settling Defendant has referred the matter to the Independent Food Quality
23 Auditor for evaluation and will implement any corrective recommendations that the
24 Auditor makes; (4) Settling Defendant has either (i) requested that its customers in
25 California remove the Newly Alleged Products identified in the NOV from sale in
26 California and destroy or return the Newly Alleged Products to Defendants, or (ii)
27 provided a clear and reasonable warning for the Newly Alleged Products identified in the
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1 NOV pursuant to 27 Cal. Code Regs. § 25603 and Section 3.1 above; and (5) Settling
2 Defendant pays penalties and costs as set forth in the following table:
3

Stipulated Payments of Penalties and Costs	
Number of prior violations alleged by CAG against the Settling Defendant (not including violations that CAG withdrew after consulting with the Settling Defendant):	Penalty and reimbursement of laboratory costs per violation
Zero through two:	Laboratory costs
Three through five	\$ 1,250 penalty plus laboratory costs
Six through nine	\$ 2,500 penalty plus laboratory costs.
Ten or more	\$7,500 penalty plus laboratory costs
Surcharge for violations involving lead levels exceeding 75 parts per billion based on the average of four randomly drawn samples from the same lot.	If the test data provided by CAG in support of the alleged violation exceeded 75 parts per billion, then the applicable penalty set forth above for that violation shall be doubled.

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6.3.2 **Contested NOV.** Defendants may serve an NOE informing CAG of its election to contest the NOV within 60 days of receiving the NOV.

(a) In its election, Defendants may request that the sample(s) of Covered Products tested by CAG be subject to additional confirmatory testing at an independent EPA-accredited laboratory selected by the Defendants.

(b) If the confirmatory testing establishes that the Newly Alleged Products do not contain Lead in excess of the level allowed in Section 3.1, CAG shall take no further action regarding the alleged violation. If the testing does not establish

1 compliance with Section 3.1, Defendants may withdraw its NOE to contest the violation
2 and may serve a new NOE pursuant to Section 6.3.1.

3 (c) If Defendants do not withdraw an NOE to contest the NOV, the
4 Parties shall meet and confer for a period of no less than 30 days before CAG may seek
5 an order enforcing the terms of this Consent Judgment. If a violation is not contested
6 because Defendants have withdrawn the NOE without serving a new NOE, or have not
7 filed an NOE, the parties shall meet and confer for a period of no less than 30 days before
8 CAG may seek an order enforcing the terms of this Consent Judgment with respect to the
9 uncontested violation.

10 6.4 In any proceeding brought by either Party to enforce this Consent Judgment, the
11 prevailing party shall be entitled to recover its proven costs and reasonable attorneys' fees.

12 **7. ENTRY OF CONSENT JUDGMENT**

13 7.1 CAG shall file a motion seeking approval of this Consent Judgment pursuant to
14 California Health & Safety Code § 25249.7(f). Upon entry of the Consent Judgment, CAG and
15 Defendants waive their respective rights to a hearing or trial on the allegations of the Complaint.

16 7.2 If this Consent Judgment is not approved in full by the Court, (a) this Consent
17 Judgment and any and all prior agreements between the parties merged herein shall terminate
18 and become null and void, and the actions shall revert to the status that existed prior to the
19 execution date of this Consent Judgment; (b) no term of this Consent Judgment or any draft
20 thereof, or of the negotiation, documentation, or other part or aspect of the Parties' settlement
21 discussions, shall have any effect, nor shall any such matter be admissible in evidence for any
22 purpose in this Action, or in any other proceeding; and (c) the Parties agree to meet and confer to
23 determine whether to modify the terms of the Consent Judgment and to resubmit it for approval.

24 **8. MODIFICATION OF JUDGMENT AND RIGHTS THEREUNDER**

25 8.1 This Consent Judgment may be modified only upon written agreement of the
26 Parties and upon entry of a modified Consent Judgment by the Court thereon, or upon motion of
27 any Party as provided by law and upon entry of a modified Consent Judgment by the Court. Any
28 Party may waive in writing any right it may have under this Consent Judgment.

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1 8.2 Any Party seeking to modify this Consent Judgment shall attempt in good faith to
2 meet and confer with the other Party prior to filing a motion to modify the Consent Judgment.

3 **9. RETENTION OF JURISDICTION**

4 9.1 This Court shall retain jurisdiction of this matter to implement and enforce the
5 terms of this Consent Judgment under Code of Civil Procedure § 664.6.

6 **10. DUTIES LIMITED TO CALIFORNIA**

7 10.1 This Consent Judgment shall have no effect on Covered Products sold outside the
8 State of California.

9 **11. SERVICE ON THE ATTORNEY GENERAL**

10 11.1 CAG has shared a draft of this Consent Judgment with the Attorney General, and
11 has incorporated the Attorney General's suggested revisions thereto. CAG shall also serve a
12 copy of this Consent Judgment, signed by both parties, on the California Attorney General so
13 that the Attorney General may review this Consent Judgment prior to its submittal to the Court
14 for approval. No sooner than forty-five (45) days after the Attorney General has received the
15 aforementioned copy of this Consent Judgment, and in the absence of any written objection by
16 the Attorney General to the terms of this Consent Judgment, the Parties may then submit it to the
17 Court for approval.

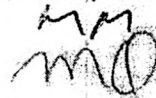
18 **12. ATTORNEY FEES**

19 12.1 Except as specifically provided in Section 4.3 and 6.4, each Party shall bear its
20 own costs and attorney fees in connection with this action.

21 **13. GOVERNING LAW**

22 13.1 The validity, construction and performance of this Consent Judgment shall be
23 governed by the laws of the State of California, without reference to any conflicts of law
24 provisions of California law.

25 13.2 The Parties, including their counsel, have participated in the preparation of this
26 Consent Judgment and this Consent Judgment is the result of the joint efforts of the Parties. This
27 Consent Judgment was subject to revision and modification by the Parties and has been accepted
28 and approved as to its final form by all Parties and their counsel. Accordingly, any uncertainty



1 or ambiguity existing in this Consent Judgment shall not be interpreted against any Party as a
2 result of the manner of the preparation of this Consent Judgment. Each Party to this Consent
3 Judgment agrees that any statute or rule of construction providing that ambiguities are to be
4 resolved against the drafting Party should not be employed in the interpretation of this Consent
5 Judgment and, in this regard, the Parties hereby waive California Civil Code § 1654.

6 **14. EXECUTION AND COUNTERPARTS**

7 **14.1** This Consent Judgment may be executed in counterparts and by means of
8 facsimile or portable document format (PDF), which taken together shall be deemed to constitute
9 one document.

10 **15. NOTICES**

11 **15.1** Any notices under this Consent Judgment shall be by personal delivery or First
12 Class Mail.

13
14 If to CAG:
15 Reuben Yeroushalmi
16 9100 Wilshire Boulevard, Suite 240W
17 Beverly Hills, CA 90212
18 (310) 623-1926

19 If to Productora y Comercializadora de Productos S.A. de C.V.
20 Horacio García Trevino
21 GT&A Servicios Legales
22 Rio Tamesis 666 Norte
23 Col. del Valle
24 Garza García, N.L.
25 Mexico, CP 66220

26 If to Bodega Latina Corporation
27 Jay W. Connolly
28 Sayfarth Shaw LLP
560 Mission Street
Suite 3100
San Francisco, CA 94105-2930

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16. AUTHORITY TO STIPULATE

16.1 Each signatory to this Consent Judgment certifies that he or she is fully authorized by the party he or she represents to enter into this Consent Judgment and to execute it on behalf of the party represented and legally to bind that party.

AGREED TO:

Date: 11/09/, 2016

By: [Signature]

Plaintiff, CONSUMER ADVOCACY GROUP, INC.

AGREED TO:

Date: 11/04/, 2016

By: [Signature]

Defendant, PRODUCTORA Y COMERCIALIZADORA DE PRODUCTOS S.A. DE C.V.

IT IS SO ORDERED.

Date: DEC 05 2016

TERESA SANCHEZ-GORDON
JUDGE OF THE SUPERIOR COURT

EXHIBIT A

AUDITOR'S CERTIFICATION

REQUIRED CERTIFICATION FROM INDEPENDENT FOOD QUALITY AUDITOR RETAINED BY THE
MANUFACTURER OR SUPPLIER OF THE COVERED PRODUCT

[Letterhead of Independent Food Processing Auditor.]

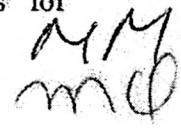
I, _____ [Name] _____, certify as follows with respect to the following Product Families:

INSERT NAMES OF PRODUCT FAMILIES CONSISTENT WITH SECTION 3 OF THE
CONSENT JUDGMENT.

I. DEFINITIONS

For the purposes of that Certification, the following definitions are applicable:

- A. "Consent Judgment" means the Consent Judgment entered into by Consumer Advocacy Group, Inc. ("CAG") and Productora y Comercializadora De Productos S.A. De C.V. ("PRODUCTORA") and approved by the Los Angeles Superior Court with respect to the Covered Products in *Consumer Advocacy Group, Inc. v. Bodega Latina Corporation, et al.* (Case No: BC575811).
- B. "Covered Products" means all Caramel Coating, which includes but is not limited to "Forritos® Zumba Pica® CARAMEL COATING FOR APPLES ARTIFICIAL TAMARIND FLAVORED; NET WT. 12.8 OZ(0.8Lb)365g; Forritos® CUBRE MANZANAS; MADE BY: PRODUCTORA Y COMERCIALIZADORA DE PRODUCTOS S.A. DE C.V. CALLE ZEUS No. 1105 PARQUE INDUSTRIAL KALOS DEL PONIENTE, SANTA CATARINA, N.L. MÉXCO, C.P. 66370; Barcode: 7 03885 06312 1" sold, distributed, processed, packaged, produced, manufactured, and/or handled by PRODUCTORA.
- C. The "Maximum Lead Level" for the finished Covered Product is 50 ppb.
- D. A "Qualified Laboratory" is a laboratory that has demonstrated proficiency to conduct lead analysis on the Covered Products using Inductively Coupled Plasma Mass Spectrometry ("ICP-MS"). A Qualified Laboratory shall meet the standards of the American Association for Laboratory Accreditation for Chemical Testing or another organization with equivalent standards. Laboratories should be experienced in (1) testing methodologies for lead levels in foods (in particular Chili based products) that comply with the Production and Process Control System; and (2) Requirements for Laboratory Operations set forth in 21 Code of Federal Regulations Part 111, Subpart J, including but not limited to the requirements for written procedures, requirements for laboratory control processes, requirements for



laboratory methods and examination, record retention policies, and other laboratory requirements. A Qualified Laboratory shall be prepared to implement the Laboratory Standards set forth in Exhibit C of the Consent Judgment, and to share the initial laboratory reports, data and test results that it obtains or generates pursuant to this Consent Judgment with CAG. Upon request, the Attorney General will provide Defendant with a non-exclusive list of laboratories that are deemed to meet the requirements of this section, but Defendant is free to use any other laboratory that meets of this section. Defendant may use laboratory procedures that differ from those set forth in this section and Exhibit C with the advance written approval of the Attorney General. For purposes of this Consent Judgment, the Parties stipulate that, as of the Effective Date of this Consent Judgment, the Covance Lab is a Qualified Laboratory.

- E. A "Lead Contribution Exercise" is a mass balance exercise that evaluate the contribution of lead from each ingredient used in the manufacture of the Covered Products. The objective of the lead contribution exercise is to determine the potential total amount of lead that will result from the formulation of the product, and then compare this total with the maximum amount of lead allowed. If the formulation of the product results in a lead concentration that exceeds the Maximum Lead Level, then adequate corrective actions must be implemented, (e.g. reformulation and/or the lead content of the ingredients must be changed to meet the maximum lead level).
- F. "Representative Samples" of each Product Family shall mean two samples drawn from the following lots:
1. For purposes of the initial certification of the Maximum Lead Level: Six consecutive lots of the Product Family that were manufactured after the Effective Date.
 2. For subsequent certifications of the Maximum Lead Level: the square root, rounded to the nearest whole number, of the number of lots manufactured during the Validation Testing Cycle, unless a lot fails to satisfy the Maximum Lead Level. In the event of such a failure, PRODUCTORA must re-evaluate its controls, and then show that six consecutive lots satisfy the applicable Maximum Lead Level before reverting to testing the square root of the number of lots sold.
- G. "Effective Date" has the same meaning as in the Consent Judgment, i.e., the date on which the Consent Judgment is approved by the Court.

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CERTIFICATION

1. **Food Safety System.** PRODUCTORA has implemented a Food Safety Management System Hazard Analysis and Critical Control Points ("HACCP") or Preventive Control for Human Food systems that identify "lead" as a "significant hazard or that requires preventive controls" and implemented those preventive controls to minimize the presence of lead in the Covered Products.

2. Based on my review of PRODUCTORA's facilities, I certify that PRODUCTORA satisfies the following requirements ("Lead Reduction Requirements") in its production for the Covered Products
 - 2.1 **Chili Powder Ingredients.** Chili powder used as an ingredient is sourced from (1) chili suppliers which has been approved by the California Attorney General's office in the context of this or other settlement agreements, or (2) chili suppliers that have been certified by an independent auditor to have addressed the lead GMP checklist for manufacturers of chili powder that constitute Exhibit B to the Consent Judgment so that the lead content in its chili products have been minimized. (Evidence of chili powder from a non-approved supplier is considered a critical deficiency.)

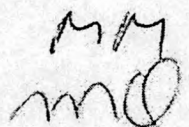
 - 2.2 **Other Ingredients.** Ingredients comply with applicable limits set by Food Chemicals Codex lead specifications, and are consistent with levels necessary for the final product to satisfy the Maximum Lead Level. (Evidence that any ingredient does not comply with applicable specifications is a critical deficiency.) Salt, food colors and additives (e.g. titanium dioxide, silica dioxide, packaging materials) are considered as critical materials and preventive controls must be implemented to ensure that the ingredients do not cause the final product to exceed the Maximum Lead Level.

A. **"Lead Contribution Exercise".**

The manufacturer conducts and documents Lead Contribution Exercises for all new products, for any change of formulation or process, when a new vendor is under approval, where any other condition could result in lead content change, or when necessary to evaluate an exceedance of the Maximum Lead Level. The established lead concentrations for ingredients as part of these Exercises must be designed to result in a finished product that has a lead concentration of no more than 50 ppb.

The Auditor must evaluate the Lead Contribution Exercises for the Covered Products and when applicable, any evidence of documented and implemented corrective actions in case of deviations from to the maximum established limit(s) for lead in an ingredient (lack of exercises and/or failure to implement and ensure effective corrective actions is a Critical deficiency).

- 2.3 **Potable Water Supply.** The potable water supply is monitored for lead levels. The internal distribution system is not a source of lead contamination as verified by point of use testing versus influent lead level. The lead levels in potable water used in processing no more than 0.010 mg/L.



- 2.4 Food Contact Surfaces. All food contact equipment utensils, containers are constructed from lead-free materials as per sanitary design criteria (e.g. 3A-SSI, EHEDG). No brass or bronze components may come in contact with ingredients or the final product. (Evidence of the use of lead-containing materials as verified using a validated testing method (e.g. XRF lead testing device) is considered a critical deficiency).
- 2.5 Non-food chemicals (e.g. Lubricants, paints, sealants, pesticides, cleaning and sanitation chemicals) and similar materials used in direct food contact surfaces, as well as in areas that have the potential to contaminate product, are food grade or for use in food processing plants. This can include storage areas in addition to processing the packing areas (based on the risk assessment).
- 2.6 Preventative devices. Based on risk assessment, preventative devices including screens, filters, magnets, metal detection devices, and manual inspection are used to remove foreign material (metal, wood, plastics, etc.)
- 2.5 Process control. The manufacturer conducts formal validation protocols to validate process controls that must include Lead Testing conducted by a Qualified Laboratory with adequate frequency (once a year minimum). ICP-MS method with Limit of Quantification (LOQ) for the finished products and major ingredients must be equal to or less than 10 ppb.
- 2.6 Lot identification/Traceability. The manufacturer developed and maintained an effective identification and traceability system. The system is effective to describe the history of all related processes and account-for all relevant inbound materials and outbound products, by-products and residues to the first point of contact with vendors and clients.
- 2.7 Current GMPs. PRODUCTORA has established Good Manufacturing Practices for the Covered Products, that include the following, which are continuously in place:
- 2.7.1 Specification are established for controlled manufacturing steps.
- 2.7.2 Master manufacturing records and batch production records are prepared and maintained.
- 2.7.3 Standard Operating Procedures (SOPs) are prepared to cover the quality control operations, including the calibration and control of equipment and instruments used in manufacturing.
- 2.7.4 SOPs are established and reviewed for investigation of product complaints.

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3.8 Annual Audit. PRODUCTORA undergoes an annual audit by an Independent Auditor to verify that its lead prevention program (based on GMPs and HACCP/ Preventive Control for Human Food) is effective with respect to facilities producing the Covered Products.

DATE: _____

SIGNATURE OF INDEPENDENT FOOD QUALITY AUDITOR.

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EXHIBIT B

LEAD GMP CHECKLIST FOR MANUFACTURERS OF CHILI POWDER

Y/N – 1. A cleaning process is in place that effectively removes visible soil and debris from peppers used to produce chili powder for use as an ingredient in confectionery products. (Evidence of soil and/or debris on pepper surfaces, or commingled with peppers, after the cleaning process is considered a critical deficiency.) The auditor will also recommend to the chili processor that, to the extent possible, chili used to produce chili powder to be used as an ingredient in confectionery products is sourced from growers that employ good agricultural practices and which avoid chili drying practices that could result in avoidable contamination.

Comments:

Y/N – 2. Potable water supply is monitored for lead levels. Internal distribution system is not a source of lead contamination as verified by point-of-use testing versus influent lead level. (Evidence that potable water supply is not monitored, or that internal distribution system has not been verified as not being a source of lead by point-of-use testing, is considered a critical deficiency.)

Comments:

Y/N – 3. All food contact equipment, utensils, containers are not constructed from lead containing materials. (Evidence of the use of lead containing materials, as verified by lead surface swab or similar test method, is considered a critical deficiency.)

Comments:

Y/N – 4. Leaded fuel is not used as an energy source in chili dehydration. (Evidence of the use of leaded fuel is considered a critical deficiency.)

Comments:

Y/N – 5. Lubricant, sealants, and similar materials used in direct food contact areas, as well as in areas that have the potential to contaminate product, are food grade. This includes storage areas in addition to processing and packing areas. (Evidence of chili contamination with lead containing material is considered a critical deficiency.)

Comments:

Y/N – 6. Where appropriate, screens, filters, magnets, metal detection devices, and/or manual inspection are used to remove foreign material (e.g. metal, wood, plastics, etc.).

Comments

Y/N – 7. Process control is validated through an audit program whereby ground chili powder is

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periodically tested for lead. (Failure to provide evidence of a testing program is considered a critical deficiency.)

Comments:

Y/N - 8. Lot identification and traceability is maintained for both finished chili powder and unprocessed chili peppers. Manufacturer is able to document chili pepper lots used to produce specific finished chili powder lots, and to trace finished chili powder shipments "one level" forward to the confectionery manufacturer. (Failure to provide documented evidence of compliance is considered a critical deficiency.)

Comments:

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EXHIBIT C

LABORATORY STANDARDS

Analytical guidance for Laboratories:

Laboratories must utilize a method that employs ICP-MS. Laboratories must have the capability of controlling lead contamination throughout the analytical process, including sample compositing, sample digestion, and the lead determination steps. In order to meet the analytical objectives, the use of high purity acids will be required as well as the use of closed-vessel type sample digestion procedures. The conditions and procedures needed to successfully meet the analyses are described in the FDA Elemental Analysis Manual.

<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm20006954.htm>

(see method EAM 4.7)

<http://www.fda.gov/downloads/Food/FoodScienceResearch/LaboratoryMethods/UCM377005.pdf>

Particular attention must be given to recovery information offered to attribute accuracy to these analyses. The level used to fortify products and ingredients for analyte recovery must be in the range of 50-200% of the lead level in the product, if the level of lead in the product is in a quantifiable range. As a measure of accuracy, laboratories are also encouraged to provide recovery information on certified reference materials with lead levels similar to these products or ingredients (including chili based).

Participating laboratories must be accredited, preferably under ISO 17025 to conduct low level lead analyses in foods by ICP-MS.

The analytical objective for lead analysis, i.e., the Limit of Quantification (LOQ), for finished products and for the major ingredients is 10 ppb.

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