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14
15 SUPERIOR COURT OF THE STATE OF CALIFORNIA
16 COUNTY OF ALAMEDA

17 **PEOPLE OF THE STATE OF**
18 **CALIFORNIA,**
19 **v.**
20 **MEAD JOHNSON NUTRITION**
21 **COMPANY, a Delaware corporation;**
22 **MEAD JOHNSON & COMPANY, LLC, a**
23 **Delaware limited liability company;**
24 **NURTURE, INC. (dba HAPPY FAMILY),**
25 **a Delaware corporation; PERRIGO**
26 **COMPANY, a Delaware corporation; PBM**
27 **PRODUCTS, LLC, a Delaware limited**
28 **liability company; PBM NUTRITIONALS,**
LLC (dba Perrigo Nutritionals), a Delaware
limited liability company; TARGET
CORPORATION, a Minnesota corporation;
TARGET BRANDS, INC., a Minnesota
corporation; WALMART, INC. (fka WAL-
MART STORES, INC.), a Delaware
corporation; and DOES 1-50, inclusive,

Defendants.

Plaintiff,

Case No. *RG18912553*

CONSENT JUDGMENT

Action filed: June 7, 2018

Dept: 17

Judge: Hon. Frank Roesch

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1. INTRODUCTION

1.1. This stipulation and proposed consent judgment (“Consent Judgment”) is entered into between (1) Plaintiff in this action, the People of the State of California (the “People”), by and through Rob Bonta, Attorney General (“Attorney General”); Nancy E. O’Malley, District Attorney of Alameda County; Lori E. Frugoli, District Attorney of Marin County; Jeannine Pacioni, District Attorney of Monterey County; Allison Haley, District Attorney of Napa County; Todd Spitzer, District Attorney of Orange County; Jeffrey F. Rosen, District Attorney of Santa Clara County; Jeffrey Rosell, District Attorney of Santa Cruz County; Stephanie Bridgett, District Attorney of Shasta County; Krishna Abrams, District Attorney of Solano County; and Jill R. Ravitch, District Attorney of Sonoma County (collectively, “District Attorneys”); (2) Community Science Institute (“CSI”), which is the Plaintiff in the two related actions described in Section 2.3, below; and (3) the following Defendants: Perrigo Company; PBM Products, LLC; and PBM Nutritionals, LLC (collectively, “Settling Defendants”). The Plaintiffs and the Settling Defendants are referred to as the “Parties. Except where otherwise indicated, the term “Plaintiff” refers collectively to the People and CSI.

1.2. The Parties enter into this Consent Judgment without a trial. Nothing in this Consent Judgment constitutes an admission by Settling Defendants regarding any issue of law or fact. This Consent Judgment sets forth the agreement and obligations of the Parties and, except as specifically provided below, it constitutes the complete, final and exclusive agreement among the Parties and supersedes any prior agreements among the Parties.

2. BACKGROUND, JURISDICTION AND PURPOSE.

2.1. On July 12, 2018, the People filed a complaint for civil penalties and injunctive relief, in this action, for violations of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code section 25249.5 et seq. [“Proposition 65”]) and the Unfair Competition Law (Business and Professions Code section 17200 et seq.) This action is entitled *People of the State of California v. Mead Johnson, et al., Alameda County Superior Court Action No. RG18912553* (the People’s “Complaint”). The People’s Complaint names Settling

1 Defendants and three of its retail customers who sold the products, Walmart, Target Corporation
2 and Nurture, Inc. It alleges that Settling Defendants manufactured and sold infant and toddler
3 formula products to customers in California that contained lead; and that the lead was present in
4 concentrations that required Proposition 65 warnings. The People further alleged that the claimed
5 violations of Proposition 65 also constituted violations of the Unfair Competition Law.

6 2.2. Community Science Institute (CSI) is a non-profit organization whose mission is
7 to unite consumers and neighbors to reform government and industry practices for a toxic-free
8 future. CSI's work involves empowering residents and consumers to test their homes and
9 communities for toxic chemical hazards and to take action to hold corporations accountable.

10 2.3. Prior to the People's filing of their Complaint, on January 2, 2018, CSI filed two
11 complaints, in the related actions, seeking civil penalties and injunctive relief against Settling
12 Defendants and two of their retail customers – Target Corporation in one case and Walmart in the
13 other case. Like the People, CSI alleges violations of the Safe Drinking Water and Toxic
14 Enforcement Act of 1986 (Health and Safety Code section 25249.5 et seq. ["Proposition 65"]).
15 The actions are: *Community Science Institute v. Target Corporation, et al., Alameda County*
16 *Superior Court No. RG1887565* and *Community Science Institute v. Wal-Mart Stores, Inc., et al.*,
17 *Alameda County Superior Court No. RG1887567* (collectively the two complaints are referred to
18 as the "CSI Complaint"). The CSI Complaint alleges that infant and toddler formula products
19 manufactured and sold by Settling Defendants to the two retail customers in California contained
20 lead in concentrations causing exposure that required Settling Defendants to provide warnings on
21 the products pursuant to Proposition 65.

22 2.4. The Complaints of the People and of CSI will be referred to collectively as
23 "Complaints."

24 2.5. Settling Defendants manufacture several different infant and toddler formulas,
25 made for a diverse mix of customers nationwide. Their retail customers in turn purchase the
26 formulas and sell them to consumers under their own private labels.

1 sale to, California, either directly, or to a third-party retail customer who Settling Defendants
2 know or reasonably should know will ship for sale directly to California consumers.

3 3.2. The “Effective Date” of this Consent Judgment shall be the date on which the
4 Consent Judgment is entered as a judgment by the Court.

5 3.3. “Formula Product” shall mean a formulation of either milk or soy protein
6 combined with various additional ingredients, all manufactured to create a finished product in
7 powder form and packaged for sale and to be reconstituted with water for consumption by infants
8 or toddlers pursuant to labeling instructions.

9 3.4. “Independent Food Processing Auditor” or “Independent Auditor” shall mean an
10 independent auditing company, foreign or domestic, that: (i) has extensive knowledge of good
11 manufacturing practices in the food processing industry; (ii) has sufficient experience in
12 inspecting food processing facilities to ensure compliance with good manufacturing practices and
13 with the Hazard Analysis and Critical Control Points (“HAACP”) food safety management
14 system; (iii) which is (1) certified as an International HACCP Alliance lead Instructor; (2)
15 certified as a SQF HACCP Lead Auditor or SQF Consultant; (3) holds an NEHA Certified
16 Professional - Food Safety (CP-FS) Credential; (4) is certified as a Food Scientist by Institute of
17 Food Technology; or (5) has equivalent qualifications; and (iv) has submitted a satisfactory
18 resume of its qualifications to the People. Upon request, the People will provide to the Settling
19 Defendants a list of Independent Food Processing Auditors who have previously submitted their
20 qualifications to the Attorney General, whose qualifications are up to date, and who are deemed
21 to meet the criteria set forth in this Paragraph. The Settling Defendants, however, may select any
22 Independent Food Processing Auditor who meets these criteria. If the Independent Food
23 Processing Auditor’s qualifications do not meet these criteria, the People may instruct Perrigo to
24 select a different Independent Food Processing Auditor.

25 3.5. “Internal Auditor” shall mean an employee or other agent of Settling Defendants
26 who has received training adequate to undertake the responsibilities set forth in Section 4 and 5 of
27 this Consent Judgment, including, without limitation, the requirement to provide complete and
28 accurate certifications as required by Section 4 and 5 of this Consent Judgment. The Internal

1 Auditor may be replaced from time to time by another equally qualified employee or agent of
2 Settling Defendants.

3 3.6. "Maximum Lead Level" shall mean 7 parts per billion (ppb) for soy based
4 formulas and 5 ppb for all other Covered Products. A Covered Product satisfies the Maximum
5 Lead Level if testing pursuant to this Consent Judgment as set forth below demonstrates that it
6 has a lead concentration of no more than 7 ppb for soy-based formulas, and 5 ppb for all other
7 Covered Products.

8 3.7. "Target Lead Level" shall mean 4 ppb or such lower lead level as may be set for a
9 Covered Product, or group of similar Covered Products, by the Internal Auditor pursuant to
10 Section 5.1(3) below. The "Target Level" for a Covered Product may be adjusted to a level above
11 4 ppb in the event that : (a) a significant, unavoidable and prolonged disruption occurs in the
12 supply chain of ingredients Settling Defendants use to manufacture that Covered Product; (b) if
13 the lead level in a new ingredient formulation of a Covered Product cannot be feasibly lowered to
14 an amount that would allow that Covered Product to meet the Target Lead Level; or (c) the
15 ingredients supplied for soy-based product are constituted such that, even with Settling
16 Defendants' ongoing best efforts, it produces a result exceeding 4 ppb.

17 3.8. Test results are defined as follows:

18 3.8.1. An "Outlier Result" is a result of laboratory testing for a Covered Product
19 conducted pursuant to Section 4.2.2 or 4.2.3 that exceeds the Maximum Lead Level.

20 3.8.2. A "Final Test Result" is a result of laboratory testing for a Covered Product
21 that is:

22 (1) conducted pursuant to Section 4.2.2 or 4.2.3 and does not exceed the
23 Maximum Lead Level; or

24 (2) becomes the Final Test Result pursuant to the provisions of Section 4.3.1.

25 3.9. For analysis of the Covered Products, "Qualified Laboratory" shall mean a
26 laboratory that has demonstrated proficiency to conduct lead analysis on the Covered Products
27 using Inductively Coupled Plasma Mass Spectrometry ("ICP-MSA). A Qualified Laboratory must
28

1 meet the specifications set forth in Title 27, California Code of Regulations section 25900(b), and
2 the Laboratory Standards set forth in Exhibit B.

3 3.10. "Named Products" shall mean the formula products named in the Complaints filed
4 by the People and by CSI: 1) *Nurture HappyTot Organic Milk Drink*; 2) *Nurture HappyTot Grow*
5 *& Shine Toddler Formula*; 3) *Target Up & Up Toddler Beginnings*; and 4) *Walmart Parent's*
6 *Choice Toddler Beginnings*.

7 **4. INJUNCTIVE RELIEF: LEAD REDUCTION MEASURES**

8 4.1. After the Effective Date, and excluding Covered Products manufactured before
9 that date, Settling Defendants shall not manufacture for sale to, distribute into, or sell in,
10 California, any Formula Products that do not comply with the Maximum Level, either directly, or
11 to a third-party retail customer who Settling Defendants know or reasonably should know will
12 sell the products in, or ship for sale directly to, California.

13 **4.2. Compliance Testing**

14 4.2.1. A Covered Product complies with the Maximum Lead Level if testing by a
15 Qualified Laboratory pursuant to Sections 4.2.2 through 4.2.4 so establishes. Each lot of finished
16 Covered Products shall be placed on hold until the testing is completed and the results show the
17 lot satisfies the Maximum Lead Level; the lot of finished product then can be released for sale.

18 4.2.2. To determine compliance for a production lot, Settling Defendants shall
19 collect six (6) samples within the lot of finished Covered Products. A Covered Product complies
20 with the Maximum Lead Level if the samples, or a composite of those samples, tested have a lead
21 concentration below the Maximum Lead Level.

22 4.2.3. For each newly formulated Covered Product, Settling Defendants shall test
23 the first six (6) commercial production lots on a hold and release basis, using the procedure set
24 forth in Section 4.2.2.

25 4.2.4. Settling Defendants shall then at a minimum conduct surveillance of each
26 Covered Product by annual testing of representative subsequent production lots, using the
27 procedure set forth in Section 4.2.2, in compliance with Exhibit A, Section G.
28

1 **4.3. Outlier Test Results**

2 4.3.1. If the result of the testing pursuant to Paragraphs 4.2.2 to 4.2.4 yields an
3 Outlier Result, Settling Defendants shall have the option to subject this Outlier Result to
4 validation testing before it is considered a Final Test Result. The validation process shall be
5 concluded within thirty (30) days, and shall be made up of two steps:

6 1. The laboratory from which the Outlier Result in question was obtained
7 shall, at the option of Settling Defendants, evaluate and check the instrument, equipment,
8 supplies and environment used during the testing of the samples to evaluate whether
9 factors in connection with the testing of samples could be a factor in the Outlier Result.
10 The laboratory shall further review the testing methods, including areas of potential
11 contamination with testing equipment, testing processes, validation procedures and
12 potential operator error. If the laboratory determines the Outlier Result was caused by a
13 potential error on its part and explains the basis for this determination to Settling
14 Defendant in writing, the result shall not be considered valid for the purposes of this
15 Consent Judgment. It will be discarded and must be replaced with a new test result from
16 sampling conducted pursuant to the requirements of Section 4.2.2 above. This
17 replacement test must be obtained within thirty (30) days of the date that the original
18 erroneous test result is discarded, and the results of this testing shall become the Final Test
19 Result.

20 2. If an evaluation by the laboratory in paragraph 4.3.1(1) does not determine
21 that there was laboratory error with regard to the Outlier Result, Settling Defendants, at
22 their option, may test a minimum of four (4) subsamples within the lot that exceeded the
23 Maximum Lead Level. If such additional testing is performed, the arithmetic mean of all
24 the test results shall be deemed the Final Test Result for the production lot, and this result
25 will become the Final Test Result for purposes of the Consent Judgment.

26 3. If Settling Defendants choose not to exercise the option to retest the original
27 sample, or any additional samples as set forth herein in Section 4.3, then the original
28 Outlier Result shall become the Final Test Result for the production lot.

1 4.4. **Covered Products That Meet or Exceed Maximum Lead Level**

2 4.4.1. If the Final Test Result does not Exceed the Maximum Lead Level, then
3 the Covered Product in the lot in question shall be considered in compliance.

4 4.4.2. If the Final Test Result exceeds the Maximum Lead Level, Settling
5 Defendants shall follow the requirements of Section 4.5 below.

6 4.5. **Final Test Results in excess of the Maximum Lead Level.**

7 4.5.1. If the Final Test Result exceeds the Maximum Lead Level, Settling
8 Defendants shall cure the exceedance as follows:

9 4.5.2. Settling Defendants shall not release any batch of the specific lot of
10 Covered Product for sale to California.

11 4.5.3. Settling Defendants shall have ninety (90) days from the date that a Final
12 Test Result that shows an exceedance of the Maximum Lead Level to investigate the potential
13 causes of the exceedance in the specific lot in question of the Covered Products, to implement
14 corrective action to bring the Covered Product in question into compliance with the Maximum
15 Lead Level, and to produce a written report, as follows:

- 16 (1) The Internal Auditor shall promptly investigate the cause or causes
17 of the Outlier Result;
- 18 (2) Settling Defendants shall contact the Independent Food Quality
19 Auditor and request a meeting with that Auditor, and the
20 Independent Auditor shall review the test results and investigate
21 the source, or sources, of the Outlier Result in conjunction with the
22 Internal Auditor if: (a) the Final Test Result exceeds 7 ppb, (b)
23 within the preceding two (2) years there have been one or more
24 Final Test Results that exceeded the Maximum Lead Level
25 applicable to that Covered Product, or (c) the Internal Auditor
26 determines that consultation with the Independent Auditor is
27 appropriate. Settling Defendants will, in such an instance, comply
28 with the Independent Food Quality Auditor’s recommendations and

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advice to establish compliance with the Consent Judgment for the Covered Product;

- (3) The Internal Auditor shall prepare a report outlining the cause(s) of the Outlier Result and the corrective steps that will be implemented going forward, including the steps recommended by the Internal Auditor and, if applicable, the Independent Auditor, to ensure the Covered Product’s compliance with the Consent Judgment.

4.5.4. The Internal Auditor will also confirm that testing of samples from the first five (5) production lots subsequent to the report required by Section 4.5.3(3) has been conducted pursuant to Sections 4.2 and 4.3 above, and that the results do not exceed the Maximum Lead Level.

4.6. In addition to the requirements of Section 4.5.3(2), as part of its annual certification required by Section 5.2 of this Consent Judgment for Covered Products intended for sale in, or sold in, California, Settling Defendants will consult with the Independent Auditor to review their procedures pertaining to the feasibility of keeping lead levels of soy-based products at 5 ppb or lower. If the results of testing conducted pursuant to the Sections 4.2 through 4.3 or Section 7 of this Consent Judgment confirms the Final Test Result of a soy-based Covered Product has exceeded 5 ppb within the preceding two (2) years, or indicates that the level for a soy-based Covered Product is likely to exceed 5 ppb, Settling Defendants will consult with the Independent Auditor as part of that annual certification process to review those test results and the feasibility of meeting the 5 ppb level, and discuss and implement to the extent feasible his or her recommendations, if any, for minimizing the lead levels in those Covered Products.

5. INTERNAL AUDITOR

5.1. Settling Defendants shall appoint an Internal Auditor. Within sixty (60) days of the Effective Date and annually thereafter on each anniversary of the Effective Date, the Internal Auditor will provide written certification to the People that:

- 1. the Covered Products, when tested pursuant to Sections 4.2.2 through 4.2.4 of this Consent Judgment, do not contain lead in excess of the Maximum Lead Level;

- 1 2. the Auditor has recommended, and Settling Defendants have implemented, procedures
2 for the testing of Representative Product Samples (as that term is defined in Exhibit A)
3 of the Covered Products by a Qualified Laboratory to ensure that they satisfy the
4 Maximum Lead Level;
- 5 3. The Internal Auditor has conducted a lead contribution exercise (that evaluates any
6 product ingredients that can contribute a significant amount of lead to a Covered
7 Product or group of similar Covered Products). Based on this exercise and the Internal
8 Auditor's review of the lowest lead levels than can be achieved by commercially
9 reasonable means, the Internal Auditor has set a Target Lead Level of 4 ppb or less for
10 each Covered Product or group of similar Covered Products.
- 11 4. Settling Defendants' control process is adequate to keep the Covered Products below
12 the Target Lead Level.
- 13 5. All ingredients that may contribute significant amounts of lead to the Covered Product
14 have been sourced to satisfy the applicable Target Lead Level. These ingredients shall
15 be identified in connection with Settling Defendants' regular risk assessment required
16 as part of its Hazard Analysis and Critical Control Points ("HACCP") program.
- 17 6. Good Manufacturing and robust ingredient sourcing practices have been implemented
18 to ensure that the lead content in the Covered Products (i) has been reduced to the
19 lowest level commercially feasible and (ii) does not exceed the applicable Target Lead
20 Level.
- 21 7. The Internal Auditor has reviewed operations every six (6) months to obtain
22 laboratory testing of the Covered Products and to ensure that requirements of this
23 Section 5 are continuously satisfied.
- 24 8. The Internal Auditor has evaluated any commercially feasible ways to further reduce
25 the lead content in the Covered Products, including, without limitation, the selection of
26 appropriate alternative ingredients or ingredient sources, and the resulting
27 recommendations from the Auditor have been implemented. In completing this task,
28 the Internal Auditor shall consult annually with an Independent Food Quality Auditor

1 who shall provide advice on commercially feasible ways, including ingredient
2 sourcing, to further reduce the lead content in the Covered Products and their
3 ingredients.

4 5.2 The certification shall be in the form set forth in Exhibit A.

5 5.3 The first such annual certification will be reviewed by the Independent Auditor,
6 and Settling Defendants will provide the Independent Auditor with site access and data as
7 necessary for the completion of this review.

8 5.4 The Internal Auditor shall continue to provide these annual certifications to the
9 People for a period of five (5) years following the Effective Date of this Consent Judgment. After
10 providing the last of the annual certifications, Settling Defendants may cease providing further
11 certifications. Settling Defendants shall, however, remain in compliance with the requirements of
12 this Consent Judgment, and the Internal Auditor will, on request, provide the People with
13 documentation showing compliance with Sections 4.2, 4.3, 4.5.3, 4.5.4, 4.6 and 5.1, above.

14 **6. PAYMENTS**

15 **6.1 Civil Penalties and Restitution.**

16 6.2 Pursuant to California Health and Safety Code section 25249.12, Settling
17 Defendants agrees to pay civil penalties in the total sum of \$72,500, as set forth in Exhibit C,
18 which is due to be paid within thirty (30) days of the Effective Date. Pursuant to Health and
19 Safety Code sections 25249.12, seventy-five percent (75%) of this penalty shall be paid to the
20 Office of Environmental Health Hazard Assessment and twenty-five percent (25%) of this
21 penalty will be divided evenly between the Attorney General and CSI.

22 6.3 Pursuant to California Business and Professions Code section 17206, Settling
23 Defendant agrees to pay civil penalties in the amount of \$72,500, which is due to be paid within
24 thirty (30) days of the Effective Date, and which shall be payable as set forth in Exhibit C.
25 Pursuant to Government Code section 26506, these penalties shall be distributed in equal amounts
26 among the counties whose District Attorneys appeared for the People in this matter.

27 6.4 Fees and Costs. Within thirty (30) days of the Effective Date, Settling Defendants
28 shall also make the following payments as stipulated attorneys' fees and costs:

1 Unfair Competition Law, the False Advertising Law (Bus. & Prof. Code, § 17500 et seq.), or
2 other laws, independent of this Consent Judgment, the People or CSI may seek in another action
3 whatever fines, costs, penalties, or remedies are provided for by law for failure to comply with
4 Proposition 65 (assuming that Settling Defendants, at the relevant time, employ enough persons
5 to qualify as a “[p]erson in the course of doing business” within the meaning of Health and Safety
6 Code section 25249.11(a)), the Unfair Competition Law, the False Advertising Law, or any other
7 laws. In any new action brought by the People or CSI or another enforcer alleging subsequent
8 violations of law, Settling Defendants may assert any and all available defenses.

9 **8 AUTHORITY TO STIPULATE TO CONSENT JUDGMENT**

10 8.1 Each signatory to the Stipulation portion of this Consent Judgment certifies that he
11 or she is fully authorized by the Party he or she represents to stipulate to this Consent Judgment
12 and to enter into the Consent Judgment on behalf of the Party he or she represents, respectively,
13 and to legally bind that Party.

14 **9 CLAIMS COVERED**

15 9.1 Full and Binding Resolution. This Consent Judgment is a full, final, and binding
16 resolution between both the People and CSI on the one hand, and on the other, Settling
17 Defendants, their parents, shareholders, divisions, subdivisions, subsidiaries, sister companies,
18 and cooperative members (collectively, the “Covered Entities”), and the officers, directors,
19 employees, attorneys, consultants, agents, representatives, predecessors, successors, and assigns
20 of any of the above, of any Causes of Action currently alleged in the Complaints. This Consent
21 Judgment resolves the claims applicable to the failure to warn for the presence of lead in the
22 Covered Products pled in the Complaints (i.e., the violation of Proposition 65 pled in the
23 Complaints by both the People and by CSI, and the violations of the Unfair Competition Law
24 pled by the People.)

25 9.2 Downstream Entities. This Consent Judgment also resolves the liability of all
26 entities who have purchased or received Covered Products sold or distributed by Settling
27 Defendants (“Downstream Entities”), including those Downstream Entities named as defendants
28 in the Complaints, for violations of Proposition 65 or the Unfair Competition Law for failure to

1 warn about alleged exposure to lead from use of the Covered Products that the Downstream
2 Entities purchased from Settling Defendants prior to the Effective Date, including any exposure
3 to lead from use of the Covered Products manufactured by Settling Defendants prior to the
4 Effective Date. Downstream Entities include all such retail customers of Settling Defendants,
5 including but not limited to, Target Corporation, Target Brands, Inc., Nurture, Inc., and Walmart,
6 Inc.

7 9.3 Following the Effective Date of this Consent Judgment, Compliance by Settling
8 Defendants with all of the requirements of this Consent Judgment, and Settling Defendants' full
9 cooperation in the implementation of this Consent Judgment, shall constitute compliance by
10 Settling Defendants with those provisions of Proposition 65 and the Unfair Competition law with
11 respect to any obligation to give warnings as to the lead content in any Covered Product.
12 Compliance by Settling Defendants with all of the requirements of this Consent Judgment
13 following the Effective Date constitutes compliance with Proposition 65 and the Unfair
14 Competition Law with respect to any obligation of Downstream Entities to provide a warning
15 under Proposition 65 as to the lead content of any Covered Product, provided that: Perrigo and
16 each Downstream Entity must provide any reasonably necessary cooperation in the
17 implementation of this Consent Judgment and they may not frustrate or interfere with the
18 implementation of any provision of this Consent Judgment.

19 9.4 Except as expressly provided herein, nothing in this Consent Judgment is intended
20 to, nor shall it be construed to, preclude the People, or any federal, state, or local agency,
21 department, board, or other entity, from exercising its authority or rights under any federal, state,
22 or local law, statute, or regulation. In any subsequent action that may be brought by the People or
23 CSI, Settling Defendants agree that they will not assert that failing to pursue such claim,
24 violation, or cause of action as part of this action constitutes claim-splitting.

25 9.5 This Consent Judgment resolves all claims relating to the failure to warn of the
26 presence of lead in the Covered Products. The People and CSI expressly retain the right to assert
27 any claims, whether under the Unfair Competition Law, the False Advertising Law, Proposition
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1 65, or any other law or regulation, that do not arise from the failure to warn about the presence of
2 lead in the Covered Products.

3 **10 NOTICE**

4 When any Party is entitled to receive any notice under this Consent Judgment, the notice
5 shall be sent to the person and address set forth below:

6 To Settling Defendants:

7 Dennis Raglin
8 Steptoe & Johnson LLP
9 633 W, Fifth Street, Suite 1900
10 Los Angeles, CA 90017
11 draglin@steptoe.com

12 Office of the General Counsel
13 Perrigo Company
14 515 Eastern Avenue
15 Allegan, MI 49010

16 To the People:

17 Megan Hey, Deputy Attorney General
18 California Department of Justice
19 300 South Spring Street, Suite 1702
20 Los Angeles, CA 90013
21 Megan.Hey@doj.ca.gov

22 Matthew Beltramo, Deputy District Attorney
23 Alameda County District Attorney's Office
24 7677 Oakport Street, Suite 650
25 Oakland, CA 94621
26 matt.beltamo@acgov.org

27 Caroline L. Fowler, Deputy District Attorney
28 Sonoma County District Attorney's Office
Environmental Consumer Law Division
2300 County Center Drive, Suite B-170
Santa Rosa, Ca 95403

To CSI:

Rebecca Davis
Lozeau Drury LLP
1939 Harrison Street, Suite 150
Oakland, CA 94612
rebecca@lozeaudrury.com

1 Any Party may modify the person and address to whom the notice is to be sent by sending each
2 other Party notice by e-mail or certified mail, return receipt requested. Said change shall take
3 effect five days after the date the return receipt is signed by the Party receiving the notice, or
4 immediately upon confirmation by e-mail from the Party receiving the notice.

5 **11. WRITTEN CERTIFICATION.**

6 11.1. Within fifteen (15) court days of the People's or CSI's written request, Settling
7 Defendants will provide the People or CSI with written certification that any required action
8 under this Consent Judgment has been taken or completed pursuant to the terms set forth herein.

9 **12. MODIFICATION OF CONSENT JUDGMENT**

10 12.1. After the Effective Date, this Consent Judgment may be modified from time to
11 time by: 1) express written agreement of the Parties with the approval of the Court; 2) an order of
12 this Court on noticed motion from the People, CSI, or Settling Defendants in accordance with
13 law, for good cause shown; or 3) the Court, pursuant to its inherent authority upon considering a
14 motion or request from a Party or the Parties.

15 12.2. Before filing an application with the Court for a modification to this Consent
16 Judgment, the Party seeking modification shall meet and confer with the other Parties to
17 determine whether the modification may be achieved by consent. If a proposed modification is
18 agreed upon, then Settling Defendants and the People, or Settling Defendants, the People and
19 CSI, or Settling Defendants and CSI, will present the modification to the Court by means of a
20 stipulated modification to the Consent Judgment.

21 **13. REEVALUATION OF MAXIMUM LEAD LEVEL.**

22 13.1. The Maximum Lead Level set forth in Section 3.6, above, as it applies to the
23 Covered Products, shall be subject to reevaluation if the People or CSI determine: (i) that it is
24 feasible, through good manufacturing or good agricultural practices, to achieve lower levels of
25 lead; or (ii) that it is otherwise necessary to comply with the requirements of Proposition 65. If
26 the People determine that the Maximum Lead Level should be lowered, they shall meet and
27 confer with Settling Defendants in order to agree by stipulation on a revised level and to other
28 changes to this Consent Judgment that result from lowering the Maximum Lead Level. If that

1 process is not successful, the People or CSI may seek to revise the Maximum Lead Level and
2 make related changes by making a noticed motion in this Court.

3 13.2. Such a motion shall contain evidence from a qualified expert supporting the
4 People's (and/or CSI's) claim that a lower level is available and feasible. In response to such a
5 motion, Settling Defendants will have the opportunity to request that the Court permit limited
6 written and deposition discovery of the People's expert(s). Settling Defendants may base their
7 opposition to Plaintiff's motion on (i) this limited discovery; (ii) any other admissible evidence
8 supporting its claim that a lower level is available and commercially feasible; and (iii) any
9 applicable affirmative defenses.

10 **14. NO EFFECT ON OTHER PRODUCTS**

11 The Maximum Lead Level defined herein is not applicable to products that are not subject
12 to this Consent Judgment, and it is not intended to establish applicable or unacceptable lead levels
13 for any such products. The People, and CSI, without limitation, expressly reserve the right to
14 take action, seek penalties and injunctive relief, and exercise their authority or rights under any
15 federal, state, or local law, statute, or regulation with regard to any products other than the
16 Covered Products.

17 **15. NO WAIVER OF THE RIGHT TO ENFORCE**

18 The failure of the People, or of CSI, to enforce any provision of the Consent Judgment
19 shall neither be deemed a waiver of such provision, nor in any way affect the validity of the
20 Consent Judgment or enforcement authority of either the People or CSI. The failure of the
21 People or CSI to enforce any such provision in the Consent Judgment shall not preclude them
22 from later enforcing the same or other provisions. No oral advice, guidance, suggestions, or
23 comments by the People, or CSI, or Settling Defendants, or by people or entities acting on behalf
24 of any of them, regarding matters covered in this Consent Judgment, shall be construed to relieve
25 Settlement Defendants of their obligations under this Consent Judgment.

26 **16. COURT APPROVAL**

27 This Consent Judgment shall be submitted to the Court for entry by the Court. If this
28 Consent Judgment is not entered by the Court, it shall be of no force or effect, and may not be

1 used by the People or Settling Defendants for any purpose. If the Court does not approve this
2 Consent Judgment, any money paid by Settling Defendants pursuant to Section 6 and held in trust
3 by the People and/or CSI will be returned to Settling Defendants.

4 **17. ENTIRE AGREEMENT**

5 This Consent Judgment contains the sole and entire agreement and understanding of the
6 Parties with respect to the entire subject matter hereof, and any and all prior discussions,
7 negotiations, commitments and understandings related hereto. No representations, oral or
8 otherwise, express or implied, other than those contained herein have been made by any Party
9 hereto. No other agreements not specifically referred to herein, oral or otherwise, shall be deemed
10 to exist or to bind any of the Parties.

11 **18. RETENTION OF JURISDICTION**

12 This Court shall retain jurisdiction of this matter to implement and enforce the Consent
13 Judgment, and to resolve any disputes that may arise as to the implementation of this Consent
14 Judgment. Should a dispute arise as to the implementation of this Consent Judgment, any Party
15 may, by noticed motion, request that the Court resolve the dispute. If the dispute involves a
16 determination made by the People pursuant to Section 7 of this Consent Judgment, the Party
17 objecting to that determination will have the burden of challenging it.

18 **19. SEVERABILITY**

19 If, subsequent to the entry of this Consent Judgment, any of its provisions are held by any
20 court to be unenforceable, the validity of the enforceable provisions remaining shall not be
21 adversely affected.

22 **20. EQUAL AUTHORSHIP**

23 This Consent Judgment shall be deemed to have been drafted equally by the Parties
24 hereto. The Parties agree that the rule of construction holding that ambiguity is construed against
25 the drafting Party shall not apply to the interpretation of this Consent Judgment.
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21. EXECUTION IN COUNTERPARTS

The stipulations to this Consent Judgment may be executed in counterparts and by means of facsimile, which taken together shall be deemed to constitute one document.

IT IS SO ORDERED and ADJUDGED:

DATED:

JUDGE OF THE SUPERIOR COURT

Dated: December 1, 2021


ROB BONTA
Attorney General of California
LAURA J. ZUCKERMAN
Supervising Deputy Attorney General



DENNIS A. RAGEN
MEGAN HEY
Deputy Attorney General
Attorneys for the People of the State of California


Dated: 10/28, 2021

JILL R. RAVITCH
SONOMA COUNTY DISTRICT
ATTORNEY

By: 
Matthew T. Cheever
Deputy District Attorney
Attorneys for the People of the State of California

Dated: October 28, 2021


NANCY E. O'MALLEY
ALAMEDA COUNTY DISTRICT
ATTORNEY

By: 
Matthew Beltramo
Assistant District Attorney
Attorneys for the People of the State of California

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Dated: 10/29, 2021

ALLISON HALEY
NAPA COUNTY DISTRICT ATTORNEY

By: 
Patrick Collins
Deputy District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

JEFFREY ROSELL
SANTA CRUZ COUNTY DISTRICT ATTORNEY

By: _____
Douglas Allen
Deputy Assistant District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

LORI FRUGOLI
MARIN COUNTY DISTRICT ATTORNEY

By: _____
Andres Perez
Deputy District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

JEANNINE PACIONI
MONTEREY COUNTY DISTRICT ATTORNEY

By: _____
Christopher Judge
Deputy District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

TODD SPITZER
ORANGE COUNTY DISTRICT ATTORNEY

By: _____
Jennifer Malone
Deputy District Attorney
Attorneys for the People of the State of California

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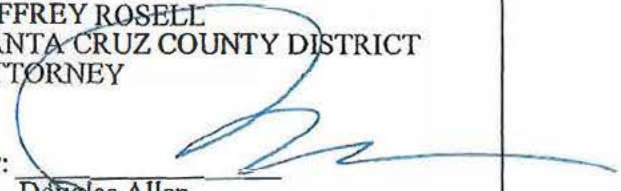
Dated: _____, 2021

ALLISON HALEY
NAPA COUNTY DISTRICT ATTORNEY

By: _____
Patrick Collins
Deputy District Attorney
Attorneys for the People of the State of California

Dated: Oct. 29, 2021

JEFFREY ROSELL
SANTA CRUZ COUNTY DISTRICT ATTORNEY

By: 
Douglas Allen
Deputy Assistant District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

LORI FRUGOLI
MARIN COUNTY DISTRICT ATTORNEY

By: _____
Andres Perez
Deputy District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

JEANNINE PACIONI
MONTEREY COUNTY DISTRICT ATTORNEY

By: _____
Christopher Judge
Deputy District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

TODD SPITZER
ORANGE COUNTY DISTRICT ATTORNEY

By: _____
Jennifer Malone
Deputy District Attorney
Attorneys for the People of the State of California

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Dated: _____, 2021

ALLISON HALEY
NAPA COUNTY DISTRICT ATTORNEY

By: _____
Patrick Collins
Deputy District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

JEFFREY ROSELL
SANTA CRUZ COUNTY DISTRICT ATTORNEY

By: _____
Douglas Allen
Deputy Assistant District Attorney
Attorneys for the People of the State of California

Dated: 10-29, 2021

LORI FRUGOLI
MARIN COUNTY DISTRICT ATTORNEY

By: Andres H. Perez
Andres Perez
Deputy District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

JEANNINE PACIONI
MONTEREY COUNTY DISTRICT ATTORNEY

By: _____
Christopher Judge
Deputy District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

TODD SPITZER
ORANGE COUNTY DISTRICT ATTORNEY

By: _____
Jennifer Malone
Deputy District Attorney
Attorneys for the People of the State of California

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Dated: _____, 2021

ALLISON HALEY
NAPA COUNTY DISTRICT ATTORNEY

By: _____
Patrick Collins
Deputy District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

JEFFREY ROSELL
SANTA CRUZ COUNTY DISTRICT ATTORNEY

By: _____
Douglas Allen
Deputy Assistant District Attorney
Attorneys for the People of the State of California


Dated: _____, 2021

LORI FRUGOLI
MARIN COUNTY DISTRICT ATTORNEY

By: _____
Andres Perez
Deputy District Attorney
Attorneys for the People of the State of California

Dated: 10/31/21, 2021

JEANNINE PACIONI
MONTEREY COUNTY DISTRICT ATTORNEY

By: 
Christopher Judge
Deputy District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

TODD SPITZER
ORANGE COUNTY DISTRICT ATTORNEY

By: _____
Jennifer Malone
Deputy District Attorney
Attorneys for the People of the State of California

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Dated: _____, 2021

ALLISON HALEY
NAPA COUNTY DISTRICT ATTORNEY

By: _____
Patrick Collins
Deputy District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

JEFFREY ROSELL
SANTA CRUZ COUNTY DISTRICT ATTORNEY

By: _____
Douglas Allen
Deputy Assistant District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

LORI FRUGOLI
MARIN COUNTY DISTRICT ATTORNEY

By: _____
Andres Perez
Deputy District Attorney
Attorneys for the People of the State of California


Dated: _____, 2021

JEANNINE PACIONI
MONTEREY COUNTY DISTRICT ATTORNEY

By: _____
Christopher Judge
Deputy District Attorney
Attorneys for the People of the State of California

Dated: _____, 2021

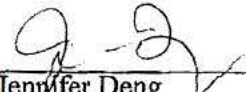
TODD SPITZER
ORANGE COUNTY DISTRICT ATTORNEY

By: 
~~Jennifer Malone~~ Alicia Berry
Deputy District Attorney
Attorneys for the People of the State of California

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Dated: 10-29, 2021

JEFFREY F. ROSEN
SANTA CLARA COUNTY DISTRICT
ATTORNEY

By: 
Jennifer Deng
Deputy District Attorney
*Attorneys for the People of the State of
California*

Dated: _____, 2021

STEPHANIE BRIDGETT
SHASTA COUNTY DISTRICT
ATTORNEY

By: _____
Anand "Lucky" Jesrani
Senior Deputy District Attorney
*Attorneys for the People of the State of
California*

Dated: _____, 2021

KRISHNA ADAMS
SOLANO COUNTY DISTRICT
ATTORNEY

By: _____
Diane Newman
Deputy District Attorney
*Attorneys for the People of the State of
California*

Dated: _____, 2021

LOZEAU DRURY LLP

REBECCA L. DAVIS
Attorneys for CSI

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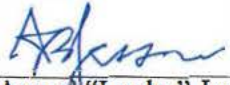
Dated: _____, 2021

JEFFREY F. ROSEN
SANTA CLARA COUNTY DISTRICT
ATTORNEY

By: _____
Jennifer Deng
Deputy District Attorney
*Attorneys for the People of the State of
California*

Dated: November 4, 2021

STEPHANIE BRIDGETT
SHASTA COUNTY DISTRICT
ATTORNEY

By: 
Anand "Lucky" Jesrani
Senior Deputy District Attorney
*Attorneys for the People of the State of
California*

Dated: _____, 2021

KRISHNA ADAMS
SOLANO COUNTY DISTRICT
ATTORNEY

By: _____
Diane Newman
Deputy District Attorney
*Attorneys for the People of the State of
California*

Dated: _____, 2021

LOZEAU DRURY LLP

REBECCA L. DAVIS
Attorneys for CSI

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Dated: _____, 2021

JEFFREY F. ROSEN
SANTA CLARA COUNTY DISTRICT
ATTORNEY

By: _____
Jennifer Deng
Deputy District Attorney
*Attorneys for the People of the State of
California*


Dated: _____, 2021

STEPHANIE BRIDGETT
SHASTA COUNTY DISTRICT
ATTORNEY

By: _____
Anand "Lucky" Jesrani
Senior Deputy District Attorney
*Attorneys for the People of the State of
California*

Dated: October 28, 2021

KRISHNA ADAMS
SOLANO COUNTY DISTRICT
ATTORNEY

By: 
Diane Newman
Deputy District Attorney
*Attorneys for the People of the State of
California*

Dated: _____, 2021

LOZEAU DRURY LLP

REBECCA L. DAVIS
Attorneys for CSI

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Dated: _____, 2021

JEFFREY F. ROSEN
SANTA CLARA COUNTY DISTRICT
ATTORNEY

By: _____
Jennifer Deng
Deputy District Attorney
*Attorneys for the People of the State of
California*

Dated: _____, 2021

STEPHANIE BRIDGETT
SHASTA COUNTY DISTRICT
ATTORNEY

By: _____
Anand "Lucky" Jesrani
Senior Deputy District Attorney
*Attorneys for the People of the State of
California*

Dated: _____, 2021

KRISHNA ADAMS
SOLANO COUNTY DISTRICT
ATTORNEY

By: _____
Diane Newman
Deputy District Attorney
*Attorneys for the People of the State of
California*

Dated: Oct. 30 _____, 2021

LOZEAU DRURY LLP


REBECCA L. DAVIS
Attorneys for CSI

SIGNATURES CONTIUTED ON NEXT PAGE

Dated: October 27, 2021

PERRIGO CO., PBM PRODUCTS, LLC
and PBM NUTRITIONALS, LLC

DocuSigned by:
By: Todd Kingma
Todd Kingma
Executive Vice President and
General Counsel
PERRIGO COMPANY

Dated: October 28, 2021

STEPTOE & JOHNSON, LLP

By: Dennis E. Raglin
Dennis E. Raglin
Attorneys for Defendants Perrigo
Company, PBM Products, LLC and
PBM Nutritionals, LLP

EXHIBIT A

EXHIBIT A
AUDITOR’S CERTIFICATION

I, _____[Name]_____, certify as follows with respect to the following Covered Products:

INSERT NAMES OF PRODUCTS

I. DEFINITIONS

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

- A. “Consent Judgment” means the Consent Judgment entered into by the People and Perrigo Company (Perrigo) in Alameda County Superior Court, Case No. RG18407841, on [DATE].
- B. “Covered Products” means the Products identified in Section 3.1 of the Consent Judgment that were manufactured after the Effective Date.
- C. The “Maximum Lead Level(s)” shall mean 7 parts per billion (ppb) for soy-based formulas and 5 ppb for all other Covered Products.
- D. The “Target Lead Level” -shall mean-the lead level set for each Covered Product, or group of similar Covered Products, based on the Lead Contribution Exercise and the Internal Auditor’s review of the lowest lead levels that can be achieved by commercially reasonable means, pursuant to Sections 3.7 and 5.1(3) of the Consent Judgment.
- E. A “Qualified Laboratory” is a laboratory that meets the requirements, and follows the procedures, set forth in Exhibit B to the Consent Judgment.
- F. A “Lead Contribution Exercise” is a mass balance exercise that evaluates the contribution of lead from each ingredient that has the potential to contribute a significant amount of lead to the Covered Products pursuant to the risk assessment analysis conducted by Settling Defendants as part of its Hazard Analysis and Critical Control Points (“HACCP”) program. The objective of the Lead Contribution Exercise is to calculate the potential total amount of lead that will result from the formulation of the product, considering: (1) the amount of each ingredient present in the finished product, and (2) the amount of lead present in each such ingredient, based on laboratory testing or other reliable information or evidence regarding the lead levels in each such ingredient. The resulting calculation of the total lead concentration in the product is then compared with the maximum amount of lead allowed. If the formulation of the product results in a lead concentration that exceeds the Target

Lead Level, then the formulation and/or the lead content of the ingredients must be changed to meet the Target Lead Level.

The Auditor will conduct the Lead Contribution Exercise for the Covered Products. Based on the Lead Contribution Exercise, the Auditor will establish maximum lead concentrations for each ingredient that has the potential to cause the finished Covered Product, or group of similar Covered Products, to exceed the Target Lead Level. The lead concentrations that the Auditor establishes as part of the Lead Concentration Exercise must be designed to result in finished Covered Products that have lead concentrations that satisfy the applicable Target Lead Level.

G. “Representative Samples” shall mean six (6) samples, as described in Section 4.2 of the Consent Judgment, from at least the following manufacturing lots:

1. For purposes of the initial certification that a Covered Product complies with the Maximum Lead Level: six (6) consecutive lots of the Covered Product that were manufactured after the Effective Date or after the date that a new Covered Product is initially sold.
2. For subsequent certifications of the Maximum Lead Level for each Covered Product: the greater of
 - (i) six (6) lots of that Covered Product that are manufactured during the annual validation testing cycle, or
 - (ii) either (A) a number of lots equal to the square root, rounded up to the nearest whole number, of the total number of lots that are manufactured during the annual validation testing cycle, or (B) at least the first three lots of that Covered Product manufactured during that cycle, followed by testing of every fourth lot thereafter.

If a lot fails to satisfy the Maximum Lead Level, Settling Defendants must re-evaluate their controls, and then show that the following number of lots satisfy the Maximum Lead Level before reverting to testing the lots as specified in sections 2(i) and (ii) above:

- (a) Where more than six (6) lots of a Covered Product are manufactured during the annual validation cycle, Settling Defendants shall test at least the first two lots and then every second lot thereafter until a total of six (6) lots have been tested;
- (b) Where six (6) or fewer lots of a Covered Product are manufactured during than cycle, each lot shall be tested.

H. “Effective Date” has the same meaning as in the Consent Judgment, i.e., the date on which the Consent Judgment is entered as a judgment by the Court.

II. CERTIFICATION

1. **HAACP Program.** Perrigo has implemented a Hazard Analysis and Critical Control Points (“HACCP”) program that identifies lead as a hazard and implements prevention steps to minimize the presence of lead in the Covered Products.

2. **Certifications.** Based on my review of Perrigo’s facilities, I certify that Perrigo satisfies the following requirements (“Lead Reduction Requirements”) in its production of the Covered Products:
 - 2.1. **Potable Water Supply.** The potable water supply is monitored for lead levels. The internal distribution system is not a source of lead contamination.

 - 2.2. **Food Contact Surfaces.** All food and ingredient contact equipment, utensils and containers are constructed from lead-free materials. 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 LeadCheck Swab, XRF lead testing device, or a similar test method, is considered a critical deficiency).

 - 2.3. **Lubricants/Sealants, etc.** Lubricants, 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 included storage areas in addition to processing and packing areas.

 - 2.4. **Preventative devices.** Preventative devices including screens, filters, magnets, metal detection devices, and manual inspection are used to remove foreign material (metal, wood, plastic, etc).

 - 2.5. **Process control.** Process control is validated through an audit program whereby processes and finished product is periodically tested for total lead content. The Limit of Quantification (LOQ) for the finished products and major ingredients must be equal to or less than 0.001 mg/kg.

 - 2.6. **Lot identification/Traceability.** Lot identification and traceability is maintained for major and minor ingredients and processing aids. The manufacturer is able to document the major and minor ingredients lots used to produce specific finished product lots and to trace finished product shipments one level forward to the customer.

 - 2.7. **Standard GMPs.** Perrigo has established Good Manufacturing Practices for the Covered Products, that include the following, which are continuously in place:
 - 2.7.1. Specifications 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.
 - 2.7.5. Annual Audit. Perrigo undergoes an annual audit by a third party auditor to verify that its GMP and HACCP programs are effectuated with respect to facilities producing the Covered Products.
3. **Target Lead Levels.** I set the following Target Lead Levels for each Covered Product or group of similar Covered Products.
[Insert Target Lead Levels]
4. **Testing and Follow-Up for Covered Products.** In order to ensure that lead levels in the Covered Products do not exceed the applicable Maximum Lead Levels, I have taken the following steps:
 - 4.1. **Testing Representative Samples.** Representative samples of the Covered Product have been tested in compliance with Section 4.2.2 of the Consent Judgment, and the Analytical Guidance for Laboratories set forth in Exhibit B.
 - 4.2. **Results Exceeding Maximum Lead Level [If Applicable Pursuant to Section 4.5 of the Consent Judgment].** This testing indicated that the lead levels in the following products exceeded the applicable Maximum Lead Level. [Insert Product Names, if any]
 - 4.2.1. **Follow Up Measures.** [If Applicable] With respect to these products, Perrigo has complied with, or is currently in the process of complying with, the requirements set forth in Section 4.5 of the Consent Judgment, as follows: [Describe steps taken to comply with Section 4.3.1 of the Consent Judgment.]
 - 4.2.2. **Follow-Up Measures.** For soy-based formulas that have lead concentrations that exceed or are likely to exceed 5 ppb, Perrigo has taken the following steps: [Describe steps taken to comply with Section 4.6 of the Consent Judgment.]
5. **Lead Contribution Exercise.** I have conducted Perrigo’s Lead Contribution Exercise for existing and newly-created Covered Products. Based on the Lead Contribution Exercise described in Section F above, and the Target Lead Levels described in Section 3.7 and 5.1(3) of the Consent Judgment and in section 3, above, I established maximum lead concentrations for the following ingredients: [Insert ingredients and maximum lead concentrations]. The lead concentrations that I established as part of the Lead Concentration Exercise are designed to result in finished Covered Products with lead concentrations of no more than the applicable Target Lead Level.
6. **Ingredient Certification or Testing.** With respect to ingredients that are likely to contribute lead in amounts that that can cause the finished product to exceed the applicable Target Lead

Level, Perrigo has taken the following steps to ensure that those ingredients do not contain lead in excess of the applicable maximum lead concentrations established pursuant to Sections F, 3 and 5, above: [Describe steps which include Perrigo's testing of ingredients, or reliable testing, or certification of the ingredients by the suppliers.]

7. Independent Food Quality Auditor. [For the First Annual Certification:] This certification has been reviewed by a qualified Independent Food Quality Auditor who has been given site access and data necessary for that review.

DATE: _____

SIGNATURE OF PERRIGO INTERNAL AUDITOR.

EXHIBIT B

Exhibit B

Analytical Guidance for Laboratories.

Analyses 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 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, EAM 4.7.

<https://www.fda.gov/food/laboratory-methods-food/elemental-analysis-manual-eam-food-and-related-products>

<https://www.fda.gov/media/87509/download>

Particular attention must be given to the specifications for recovery determinations offered to attribute accuracy to these analyses. The levels of lead used to fortify products and ingredients for analyte recovery must be in the range of 50-200% of the lead level found 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 for Certified Reference Materials with a matrix like that of the sample and with similar lead levels.

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 0.001 mg/kg, or less.

Test results shall be the average of the triplicate analysis conducted by the laboratory.

The analytical results from the laboratory shall include the: limit of detection; limit of quantitation; spike recovery; blanks; method validation and other quality control parameters; and the statistical variance within the method (typically 10% or one sigma of the results).

The laboratory must participate in a valid check sample program.

EXHIBIT C

Exhibit C
Payment Detail

Payee	Address	Description	Amount
Office of Environmental Health Hazard Assessment	Senior Accounting Officer – MS 19-B Office of Environmental Health Hazard Assessment P.O. Box 4010 Sacramento, CA 95812-0410	Civil Penalty	\$54,375.00
Attorney General	Robert Thomas Legal Analyst 1515 Clay St., 20th Floor P.O. Box 70550 Oakland, CA 94612-0550	Civil Penalty	9,062.50
		Fees/Costs	45,000.00
		Total	54,062.50
Monterey County District Attorney to be distributed to California FDMD Task Force	Christopher Judge Deputy District Attorney 1200 Aguajito Road, Room 301, Monterey, CA 93940	Civil Penalty	72,500.00
		Fees/Costs	30,000.00
		Total	102,500.00
Community Science Institute	Rebecca L. Davis Lozeau, Drury LLP 1939 Harrison St., Suite 150 Oakland, CA 94612	Civil Penalty	9,062.50
		Fees/Costs	140,000.00
		Total	149,062.50

Copies of all checks will be sent to:

Megan Hey
Deputy Attorney General
Office of the CA Attorney General
300 South Spring Street
Los Angeles, CA 90013