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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.

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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 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](mailto: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](mailto: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](mailto: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](mailto: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.

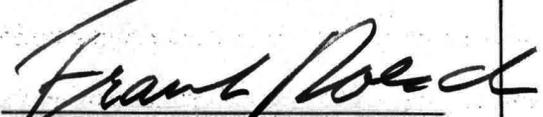
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21. EXECUTION IN COUNTERPARTS

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.

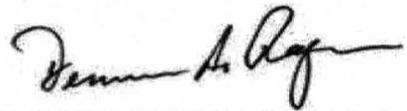
IT IS SO ORDERED and ADJUDGED:

DATED: Jan 27, 2022

  
JUDGE OF THE SUPERIOR COURT

Dated: December 1, 2021

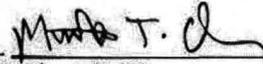
ROB BONTA  
Attorney General of California  
LAURA J. ZUCKERMAN  
Supervising Deputy Attorney General



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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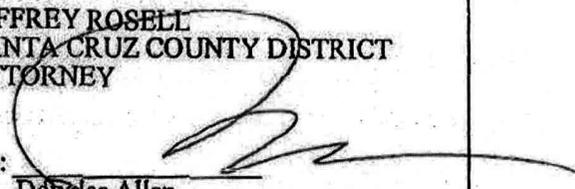
Dated: \_\_\_\_\_, 2021

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

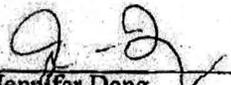
TODD SPITZER  
ORANGE COUNTY DISTRICT ATTORNEY

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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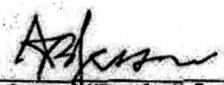
Dated: \_\_\_\_\_, 2021

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  
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 –<br>MS 19-B<br>Office of Environmental Health Hazard Assessment<br>P.O. Box 4010<br>Sacramento, CA 95812-0410 | Civil Penalty | \$54,375.00 |
| Attorney General  | Robert Thomas<br>Legal Analyst<br>1515 Clay St., 20th Floor<br>P.O. Box 70550<br>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<br>Deputy District Attorney<br>1200 Aguajito Road, Room 301,<br>Monterey, CA 93940                                     | Civil Penalty | 72,500.00   |
|   |  | Fees/Costs    | 30,000.00   |
|   |  | Total         | 102,500.00  |
| Community Science Institute   | Rebecca L. Davis<br>Lozeau, Drury LLP<br>1939 Harrison St., Suite 150<br>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