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MONSANTO COMPANY

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: ROUNDUP PRODUCTS
LIABILITY LITIGATION

MDL No. 2741
Case No. 3:16-md-02741-VC

This document relates to:

Gebo v. Monsanto Co.,
Case No. 3:17-cv-00168-VC

MONSANTO COMPANY’S ANSWER TO PLAINTIFF’S COMPLAINT

Pursuant to Rule 12 of the Federal Rules of Civil Procedure, Defendant Monsanto Company (“Monsanto”), by and through its counsel, respectfully responds by generally denying all allegations contained in plaintiff Ron Gebo’s Complaint and Jury Demand (“the Complaint”), except as set forth below. As defined in the Complaint and as used in this Answer, Monsanto refers to Monsanto Company, a United States based company incorporated in Delaware, and not to other Monsanto-affiliated companies. Silence as to any allegations shall constitute a denial.

1. The allegations in the Complaint’s first numbered paragraph 1¹ set forth conclusions of law for which no response is required.

2. The allegations in the Complaint’s first numbered paragraph 2 set forth conclusions of law for which no response is required. Monsanto lacks information or knowledge sufficient to form a belief as to the truth of the allegations that plaintiff or other persons or

¹ The Complaint includes two consecutive sets of paragraphs numbered 1-4.

1 entities purchased Roundup[®]-branded products and therefore denies those allegations.

2 3. The allegations in the Complaint's first numbered paragraph 3 set forth
3 conclusions of law for which no response is required.

4 4. The allegations in the Complaint's first numbered paragraph 4 set forth
5 conclusions of law for which no response is required. To the extent that a response is deemed
6 required, Monsanto admits that venue is proper in the Middle District of Florida based upon the
7 allegations in plaintiff's Complaint.

8 1. Monsanto lacks information or knowledge sufficient to form a belief as to the
9 truth of the allegations asserted in the Complaint's second numbered paragraph 1 and therefore
10 denies those allegations.

11 2. Monsanto admits the allegations in the Complaint's second numbered paragraph
12 2.

13 3. In response to the allegations in the Complaint's second numbered paragraph 3,
14 Monsanto admits that it discovered the herbicidal properties of glyphosate; that it has
15 manufactured Roundup[®]-branded herbicides; that certain Roundup[®]-branded herbicides contain
16 POEA and adjuvants; and that the Environmental Protection Agency ("EPA") has classified
17 surfactants and adjuvants as inert. Monsanto notes that EPA has determined that the surfactants
18 used in Roundup[®]-branded herbicides do not pose an unreasonable risk to human health.
19 Monsanto denies the remaining allegations in the Complaint's second numbered paragraph 3.

20 4. Monsanto admits that glyphosate is an herbicide that is used to kill invasive plants
21 and weeds. Monsanto states that the remaining allegations in the Complaint's second numbered
22 paragraph 4 are vague and ambiguous and that it lacks information or knowledge sufficient to
23 form a belief as to the truth of the remaining allegations and therefore denies those allegations.

24 5. Monsanto admits the allegations in the first sentence of paragraph 5. Monsanto
25 denies the allegations in the second sentence of paragraph 5 because the impact of glyphosate on
26 treated plants varies depending upon the amount of glyphosate applied and the type of plant.
27 Monsanto denies the allegations of the third sentence of paragraph 5 to the extent that it suggests
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1 that glyphosate is present in any plants at anything other than *de minimis* amounts well within
2 regulatory safety levels, as determined by EPA.

3 6. In response to the allegations in paragraph 6, Monsanto admits that farmers have
4 safely used Roundup[®]-branded products since the 1970s. Monsanto denies the remaining
5 allegations in paragraph 6.

6 7. Monsanto admits the allegations in the first two sentences of paragraph 7 and
7 admits that it has marketed Roundup[®]-branded products in accord with EPA's regulatory
8 determinations under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").
9 Monsanto otherwise denies the remaining allegations in paragraph 7.

10 8. In response to the allegations in paragraph 8, Monsanto admits that certain
11 Roundup[®]-branded herbicides contain POEA and adjuvants, that EPA has classified surfactants
12 and adjuvants as inert, and that the specific surfactants and adjuvants used in Roundup[®]-branded
13 herbicides – like those in other manufacturers' herbicide products – are protected by EPA as
14 "trade secrets." Monsanto notes that EPA has determined that the surfactants used in Roundup[®]-
15 branded herbicides do not pose an unreasonable risk to human health. Monsanto denies the
16 remaining allegations in paragraph 8.

17 9. The allegations in paragraph 9 set forth conclusions of law for which no response
18 is required. To the extent that a response is deemed required, Monsanto admits the allegations in
19 paragraph 9.

20 10. In response to the allegations in paragraph 10, Monsanto admits that EPA requires
21 registrants of herbicides to submit extensive data in support of the human health and
22 environmental safety of their products and further admits that EPA will not register or approve
23 the labeling of herbicides that do not satisfy the requirements set forth in FIFRA. The remaining
24 allegations in paragraph 10 set forth conclusions of law for which no response is required.

25 11. The allegations in paragraph 11 set forth conclusions of law for which no
26 response is required.

27 12. Monsanto admits that Roundup[®]-branded products are registered by EPA for
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1 manufacture, sale and distribution and are registered by the State of Florida for sale and
2 distribution.

3 13. In response to the allegations in paragraph 13, Monsanto admits that EPA requires
4 registrants of herbicides to submit extensive data in support of the human health and
5 environmental safety of their products and further admits that EPA will not register or approve
6 the labeling of herbicides that do not satisfy the requirements set forth in FIFRA. Monsanto
7 states that the term “the product tests” in the final sentence of paragraph 13 is vague and
8 ambiguous, and Monsanto therefore denies the same. The remaining allegations in paragraph 13
9 set forth conclusions of law for which no answer is required.

10 14. Monsanto denies the allegations in paragraph 14 to the extent that they suggest
11 that EPA only evaluates the safety of pesticide products on the date of their initial registration.
12 Monsanto admits that EPA is in the process of conducting regulatory reviews of various
13 pesticide products, but Monsanto lacks information or knowledge sufficient to form a belief as to
14 the truth of the allegations in paragraph 14 regarding such pesticide products generally and
15 therefore denies those allegations. The remaining allegations in paragraph 14 set forth
16 conclusions of law for which no response is required.

17 15. In response to the allegations in paragraph 15, Monsanto admits that EPA has
18 undertaken a review of glyphosate for purposes of regulatory review and that EPA has not
19 released its findings. Monsanto states, however, that: (a) in September 2016, EPA’s Office of
20 Pesticide Programs (“OPP”) issued a 227-page evaluation of glyphosate’s carcinogenic potential,
21 concluding that “[t]he strongest support is for [the descriptor] ‘not likely to be carcinogenic to
22 humans’ at doses relevant to human health risk assessment”²; and (b) at the same time, EPA
23 posted an October 2015 final report by its standing Cancer Assessment Review Committee
24 (“CARC”), in which CARC endorsed EPA’s existing classification of glyphosate as “Not Likely

25 ² EPA’s Office of Pesticide Programs, *Glyphosate Issue Paper: Evaluation of Carcinogenic*
26 *Potential* at 141 (Sept. 12, 2016) (“EPA OPP Report”), [https://www.regulations.gov/](https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0094)
27 [document?D=EPA-HQ-OPP-2016-0385-0094](https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0094). The EPA OPP Report was prepared in
28 anticipation of an EPA Scientific Advisory Panel meeting on glyphosate’s carcinogenic potential.

1 to be Carcinogenic to Humans.”³ Monsanto lacks information or knowledge sufficient to form a
2 belief as to the truth of the remaining allegations in paragraph 15 and therefore denies those
3 allegations.

4 16. In response to the allegations in paragraph 16, Monsanto admits that an EPA
5 review committee classified glyphosate as Class C in 1985 based on limited data and that EPA
6 changed its classification of glyphosate to Group E based upon a full evaluation of the scientific
7 evidence, including but not limited to three animal carcinogenicity studies. Monsanto admits
8 that plaintiff has accurately quoted from one passage in an EPA document in 1991 with respect
9 to the designation of an agent as Group E, but states that EPA repeatedly has concluded that
10 glyphosate does not pose any cancer risk to humans. In addition to the conclusions in the EPA
11 OPP Report and the EPA CARC Final Report discussed above, other specific findings of safety
12 include:

- 13 • “In June 1991, EPA classified glyphosate as a Group E [carcinogen]—one that
14 shows evidence of non-carcinogenicity for humans—based on the lack of
15 convincing evidence of carcinogenicity in adequate studies.” EPA, *Glyphosate:
16 Reregistration Eligibility Decision (RED) Facts*, 2 (Sept. 1993),
17 <http://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf>.
- 18 • “No evidence of carcinogenicity.” *Glyphosate; Pesticide Tolerances*, 67 Fed.
19 Reg. 60,934, 60,943 (Sept. 27, 2002) (to be codified at 40 C.F.R. pt. 180).
- 20 • “Glyphosate has no carcinogenic potential.” *Glyphosate; Pesticide Tolerance*, 69
21 Fed. Reg. 65,081, 65,086 (Nov. 10, 2004) (to be codified at 40 C.F.R. pt. 180).
- 22 • “There is [an] extensive database available on glyphosate, which indicate[s] that
23 glyphosate is not mutagenic, not a carcinogen, and not a developmental or
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26 ³ Cancer Assessment Review Committee, Health Effects Division, Office of Pesticide Programs,
27 U.S. Environmental Protection Agency, *Cancer Assessment Document – Evaluation of the
28 Carcinogenic Potential of Glyphosate* at 10, 77 (Final Report, Oct. 1, 2015) (“EPA CARC Final
Report”), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0385-0014>.

1 reproductive toxicant.” Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586,
2 73,589 (Dec. 3, 2008) (to be codified at 40 C.F.R. pt. 180).

- 3 • “EPA has concluded that glyphosate does not pose a cancer risk to humans.” 78
4 Fed. Reg. 25,396, 25,398 (May 1, 2013) (to be codified at 40 C.F.R. pt. 180).
- 5 • “In 2014, EPA reviewed over 55 epidemiological studies conducted on the
6 possible cancer and non-cancer effects of [g]lyphosate. Our review concluded
7 that this body of research does not provide evidence to show that [g]lyphosate
8 causes cancer and does not warrant any change in the EPA’s cancer classification
9 for [g]lyphosate.” *Agriculture Biotechnology: A Look at Federal Regulation and*
10 *Stakeholder Perspectives: Hearing Before the S. Comm. on Agr., Nutrition, &*
11 *Forestry*, 114th Cong. (2015) (statement of Dr. William Jordan, Deputy Director
12 of EPA’s Office of Pesticide Programs),
13 [http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-](http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-0e55900753b4)
14 [0e55900753b4](http://www.ag.senate.gov/templates/watch.cfm?id=74793e67-5056-a055-64af-0e55900753b4), at time stamp 55:05 – 56:20.

15 Monsanto denies the remaining allegations in paragraph 16.

16 17. In response to the allegations in paragraph 17, Monsanto admits that it – along
17 with a large number of other companies and governmental agencies – was defrauded by two
18 chemical testing laboratories, and that Monsanto had hired both of these laboratories to conduct
19 testing on glyphosate. Monsanto states that only one of these laboratories was hired to conduct
20 toxicity tests of glyphosate. Monsanto denies that EPA’s registration of glyphosate or any
21 glyphosate-based herbicides is based upon any invalid Industrial Bio-Test (“IBT”) Laboratories
22 studies. To the extent that the allegations in paragraph 17 are intended to suggest that Monsanto
23 was anything other than a victim of this fraud, such allegations are denied.

24 18. In response to the allegations in paragraph 18, Monsanto admits that IBT
25 Laboratories was hired to conduct toxicity studies in connection with the registration of a
26 Roundup[®]-branded product. Monsanto denies that EPA’s regulatory approval of such product is
27 based upon any fraudulent or false IBT studies.

1 Monsanto also admits that the patent for glyphosate expired in the United States in 2000. The
2 remaining allegations in paragraph 23 are vague and conclusory and comprise attorney
3 characterizations, and are accordingly denied.

4 24. In response to the allegations in paragraph 24, Monsanto admits that following the
5 development of Roundup[®] Ready seeds, it began to sell them in the 1990s and that such seeds
6 are now widely used by farmers in the United States and worldwide. Monsanto lacks
7 information or knowledge sufficient to form a belief as to the accuracy of the specific numbers
8 cited in paragraph 24 and accordingly denies those allegations. The remaining allegations in
9 paragraph 24 are vague and conclusory and comprise attorney characterizations, and are
10 accordingly denied.

11 25. In response to the allegations in paragraph 25, Monsanto admits that glyphosate is
12 one of the world's largest herbicides by sales volume, but Monsanto denies any suggestion that it
13 is the only company that sells glyphosate or glyphosate-based herbicides. Monsanto lacks
14 information or knowledge sufficient to form a belief as to the accuracy of the specific numbers
15 cited in paragraph 25 and accordingly denies the same. The remaining allegations in paragraph
16 25 are vague and conclusory and comprise attorney characterizations, and are accordingly
17 denied.

18 26. In response to the allegations in paragraph 26, Monsanto admits that the New
19 York Attorney General filed a lawsuit against Monsanto in 1996 alleging false and misleading
20 advertising of Roundup[®]-branded products. This lawsuit was subsequently resolved without any
21 admission of wrongdoing by Monsanto. Monsanto states that none of the New York Attorney
22 General's allegations related in any way to a purported or alleged risk of cancer. To the extent
23 the subparts purport to quote a document, the document speaks for itself and thus does not
24 require any further answer. The remaining allegations in paragraph 26 are vague and conclusory
25 and comprise attorney characterizations and are accordingly denied.

26 27. In response to the allegations in paragraph 27, Monsanto admits it entered into an
27 assurance of discontinuance with the New York Attorney General. The assurance speaks for
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1 itself and thus does not require any further answer. The remaining allegations in paragraph 27
2 are vague and conclusory and comprise attorney characterizations and are accordingly denied.

3 28. Monsanto denies the allegations in paragraph 28.

4 29. In response to the allegations in paragraph 29, Monsanto admits that the French
5 court ruled that Monsanto had falsely advertised its herbicide Roundup[®] as “biodegradable” and
6 that it “left the soil clean,” but denies the allegations in paragraph 29 to the extent that they
7 suggest that this ruling was in any way related to plaintiff’s claim here that glyphosate can cause
8 cancer. Monsanto denies the remaining allegations in paragraph 29.

9 30. In response to the allegations in paragraph 30, Monsanto denies that IARC
10 follows stringent procedures for the evaluation of a chemical agent. Monsanto lacks information
11 or knowledge sufficient to form a belief as to the accuracy of the specific numbers cited in
12 paragraph 30, which are not limited as of any specified date, and accordingly denies the same.

13 31. In response to the allegations in paragraph 31, Monsanto admits that IARC sets
14 forth in its Preamble the procedures that it claims to follow in its carcinogenicity evaluations.
15 Monsanto denies the remaining allegations in paragraph 31.

16 32. Monsanto denies any suggestion that IARC reviewed the full body of scientific
17 research in conducting its evaluation of glyphosate or that IARC reliably reviewed the studies
18 that it cited in its glyphosate monograph. Monsanto lacks information or knowledge sufficient to
19 form a belief as to the truth of the remaining allegations in paragraph 32 and therefore denies
20 those allegations.

21 33. Monsanto denies any suggestion that IARC reviewed the full body of scientific
22 research in conducting its evaluation of glyphosate or that IARC reliably reviewed the studies
23 that it cited in its glyphosate monograph. Monsanto lacks information or knowledge sufficient to
24 form a belief as to the truth of the remaining allegations in paragraph 33 and therefore denies
25 those allegations.

26 34. Monsanto denies the allegations in paragraph 34 to the extent that they suggest
27 that IARC had previously assessed glyphosate. Monsanto admits that IARC classified
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1 glyphosate as a Group 2A agent in March 2015.

2 35. In response to the allegations in paragraph 35, Monsanto admits that IARC issued
3 its monograph for glyphosate, Monograph 112, on July 29, 2015, and that a draft of the
4 monograph was prepared by a “working group” of individuals selected by IARC who met over a
5 one-week period in March 2015 to consider glyphosate along with a number of other substances.
6 Monsanto denies the allegation that all members of the working groups are “experts.” Monsanto
7 denies that the working group or anyone at IARC conducted a one-year review of the scientific
8 evidence related to glyphosate or that the working group’s findings reflected a comprehensive
9 review of the latest available scientific evidence. Monsanto also denies that the working group
10 considered all information available in the scientific literature and all data from government
11 reports that are publicly available. Monsanto denies the remaining allegations in paragraph 35.

12 36. In response to the allegations in paragraph 36, Monsanto denies that the IARC
13 working group considered all of the data in the numerous studies that have been conducted
14 looking at the safety of glyphosate and glyphosate-containing herbicides in human populations or
15 that it reliably considered the studies that it purports to have reviewed, which frequently reach
16 conclusions directly contrary to those espoused by the IARC working group. To the extent the
17 allegations purport to characterize statements made in the IARC monograph for glyphosate, the
18 statements in that document speak for themselves, but Monsanto lacks information or knowledge
19 sufficient to form a belief as to the accuracy of the source of said information and accordingly
20 denies the allegations.

21 37. The allegations in paragraph 37 are vague and conclusory. To the extent they
22 purport to characterize statements made in the IARC monograph for glyphosate, the statements
23 in that document speak for themselves, but Monsanto lacks information or knowledge sufficient
24 to form a belief as to the accuracy of the source of said information and accordingly denies the
25 allegations.

26 38. In response to the allegations in paragraph 38, to the extent the allegations purport
27 to characterize statements made in the IARC monograph for glyphosate, the statements in that
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1 document speak for themselves, but to the extent that this paragraph means that more than *de*
2 *minimis* amounts of exposure are present, Monsanto denies the allegations in paragraph 38.

3 39. In response to the allegations in paragraph 39, Monsanto admits that the IARC
4 working group identified a number of case control studies of populations with exposures to
5 glyphosate, but Monsanto denies that any of these studies provide any evidence of a human
6 health concern from such exposures.

7 40. Monsanto denies the allegations in paragraph 40. The IARC working group
8 concluded that there was only limited evidence of carcinogenicity in epidemiologic studies,
9 which, per IARC's guidelines, means that the working group could not rule out chance, bias or
10 confounding so as to reach any conclusion of an increased risk.

11 41. In response to the allegations in paragraph 41, Monsanto admits that the working
12 group cited to a study that it concluded provided evidence of chromosomal damage in
13 community residents reported to be exposed to glyphosate, but Monsanto denies that the study
14 supports such a conclusion or that the authors of the study reached such a conclusion.

15 42. In response to the allegations in paragraph 42, Monsanto admits that the IARC
16 working group purported to make these findings, but denies that the animal carcinogenicity
17 studies of glyphosate in the aggregate provide evidence of a positive trend for or increase in any
18 of the identified tumors. Monsanto further states that regulatory agencies around the world have
19 reviewed the same animal studies and concluded that they do not provide evidence that
20 glyphosate can cause cancer. Monsanto denies the remaining allegations in paragraph 42.

21 43. In response to the allegations in paragraph 43, Monsanto admits that the IARC
22 working group purported to make these findings, but denies that the cited studies provide any
23 reliable basis for a finding that any meaningful levels of glyphosate or AMPA are present or
24 persists in human blood or urine. Monsanto denies the remaining allegations in paragraph 43.

25 44. In response to the allegations in paragraph 44, Monsanto admits that the IARC
26 working group interpreted a selected number of experimental studies as evidence that glyphosate
27 can cause genotoxicity, but Monsanto denies that the working group reliably considered the full
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1 body of scientific data on such alleged genotoxic endpoints and denies that the working group
2 reliably interpreted the studies that it selected for consideration. Regulators around the world
3 repeatedly have concluded that glyphosate is not genotoxic. Monsanto denies the remaining
4 allegations in paragraph 44.

5 45. In response to the allegations in paragraph 45, Monsanto admits that the IARC
6 working group purported to find such effects, but denies that there is any reliable scientific basis
7 for such conclusion. Monsanto denies the remaining allegations in paragraph 45.

8 46. In response to the allegations in paragraph 46, Monsanto admits that the working
9 group reviewed the findings of an Agricultural Health Study (“AHS”) published in 2005, but
10 denies that the working group characterized that study as supporting an association between
11 glyphosate and the specified cancers. The AHS cohort study did not find a positive association
12 between glyphosate and any type of cancer. Monsanto denies all other allegations in paragraph
13 46.

14 47. In response to the allegations in paragraph 47, Monsanto admits that EPA has a
15 technical fact sheet, as part of its Drinking Water and Health, National Primary Drinking Water
16 regulations, relating to glyphosate that predates the IARC March 20, 2015 evaluation, which
17 should be read in context of EPA’s precautionary regulatory mandate and EPA’s consistent
18 finding that glyphosate does not pose any cancer risk to humans.

19 48. In response to the allegations in paragraph 48, Monsanto admits that the
20 Northwest Coalition for Alternatives to Pesticides made the identified claims, but denies that the
21 Coalition provides any reliable basis for any conclusions regarding potential health risks from
22 glyphosate. Monsanto notes that a federal district court has characterized this same publication
23 as an “advocacy piece[] published in [a] non-peer-reviewed journal.” *See Arias v. DynCorp*, 928
24 F. Supp. 10, 24 (D.D.C. 2013).

25 49. Monsanto states that the term “toxic” as used in paragraph 49 is vague and
26 ambiguous to the extent it is intended to suggest any evidence of carcinogenicity. Monsanto
27 denies the allegations in paragraph 49.

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1 50. In response to the allegations in paragraph 50, Monsanto admits that Julie Marc
2 published the cited study in 2002 and states that the document speaks for itself and does not
3 require a response. To the extent that a response is deemed required, Monsanto denies the
4 allegations in paragraph 50.

5 51. In response to the allegations in the first sentence of paragraph 51, Monsanto
6 admits that Julie Marc published a study titled “Glyphosate-based pesticides affect cell cycle
7 regulation” in 2004. To the extent that the first sentence of paragraph 51 characterizes the
8 meaning of the cited study, Monsanto denies the allegations in the first sentence of paragraph 51.
9 In response to the remaining allegations in paragraph 51, Monsanto states that the document
10 speaks for itself and does not require a response. To the extent that a response is deemed
11 required, Monsanto denies the remaining allegations in paragraph 51.

12 52. In response to the allegations in paragraph 52, Monsanto states that the cited
13 document speaks for itself and does not require a response. To the extent that paragraph 52
14 characterizes the meaning of the cited study, Monsanto denies the remaining allegations in
15 paragraph 52.

16 53. In response to the allegations in paragraph 53, Monsanto states that the cited
17 document speaks for itself and does not require a response. To the extent that paragraph 53
18 characterizes the meaning of the cited study, Monsanto denies the allegation that the cited studies
19 support the allegation that glyphosate or Roundup[®]-branded products pose any risk to human
20 health and denies the remaining allegations in paragraph 53.

21 54. Monsanto denies the allegations in paragraph 54.

22 55. Monsanto denies the allegations in paragraph 55.

23 56. In response to the allegations in paragraph 56, Monsanto admits that the IARC
24 working group’s classification of glyphosate as a Class 2A carcinogen has resulted in ongoing
25 discussions in certain countries regarding the sale of glyphosate-based herbicides, including the
26 Netherlands. Monsanto denies that any final conclusion has been reached in these countries and
27 denies that there is any scientific basis for the concerns raised by the improper IARC
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1 classification. Monsanto denies the remaining allegations in paragraph 56.

2 57. In response to the allegations in paragraph 57, Monsanto admits that the IARC
3 working group classification led an individual government attorney in Brazil to write a letter to
4 the Brazilian regulatory authorities requesting a reevaluation of glyphosate. Monsanto denies the
5 remaining allegations in paragraph 57.

6 58. In response to the allegations in paragraph 58, Monsanto admits that following the
7 IARC working group classification, in France, all non-professional plant protection products,
8 including but not limited to glyphosate-based products, will be sold behind locked counters (no
9 free sales). Monsanto further admits that the French government has announced that, beginning
10 on January 1, 2019, the sale of non-professional lawn and garden products, including but not
11 limited to non-professional use glyphosate-based products, will be prohibited with certain
12 exceptions. Monsanto denies the remaining allegations in paragraph 58.

13 59. In response to the allegations in paragraph 59, Monsanto admits that some
14 employees of Bermuda's government announced an intention to suspend the importation of
15 glyphosate-based herbicides, but Monsanto lacks information sufficient to form a belief as to the
16 truth of the allegations about whether this suspension took effect and accordingly denies the
17 same. Monsanto denies the remaining allegations in paragraph 59.

18 60. In response to the allegations in paragraph 60, Monsanto admits that the IARC
19 monograph appears to be the alleged basis for the Sri Lankan government's actions, including
20 the allegation that glyphosate can cause kidney disease. Monsanto further states that the
21 allegations regarding kidney disease found in Sri Lanka are unrelated to plaintiff's allegations
22 regarding claimed carcinogenicity. Monsanto denies the remaining allegations in paragraph 60.

23 61. In response to the allegations in paragraph 61, Monsanto denies the alleged basis
24 for Colombia's suspension of aerial spraying of glyphosate. Colombia's attorney general has
25 explained that the ban on aerial spraying of illicit coca plantations was a concession to the FARC
26 ("Fuerzas Armadas Revolucionarias de Colombia"), and had nothing to do with alleged safety
27 concerns. As of April 2016, the government of Colombia has resumed manual application of
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1 glyphosate on illicit coca crops. A federal district court in the United States excluded plaintiffs’
2 expert testimony purporting to link these same aerial eradication operations with cancer as
3 scientifically unreliable. *See Arias v. DynCorp*, 928 F. Supp. 10 (D.D.C. 2013). Monsanto
4 denies the remaining allegations in paragraph 66.

5 62. In response to the allegations in paragraph 62, Monsanto admits that California’s
6 Office of Environmental Health Hazard Assessment (“OEHHA”) published a notice of intent to
7 include glyphosate on its Proposition 65 listing and admits that this notice was not based upon
8 any independent scientific analysis of glyphosate but instead was in response to a section of the
9 Labor Code triggering such action based solely upon the IARC classification. Monsanto further
10 states that OEHHA concluded in 2007, based upon its own independent evaluation of the
11 scientific evidence, that glyphosate is “unlikely to pose a cancer hazard to humans.”⁴ The
12 remaining allegations set forth conclusions of law for which no response is required. To the
13 extent that a response is deemed required, Monsanto denies the allegations in paragraph 62.

14 63. The allegations in paragraph 63 set forth conclusions of law for which no
15 response is required.

16 64. The allegations in paragraph 64 set forth conclusions of law for which no
17 response is required.

18 65. In response to the allegations in paragraph 65, Monsanto admits that it has
19 brought a lawsuit challenging OEHHA’s notice of intent to include glyphosate on its Proposition
20 65 list.

21 66. In response to the allegations in paragraph 66, Monsanto admits that plaintiff
22 accurately quotes from Monsanto’s complaint in the referenced lawsuit, and states that
23 Monsanto’s complaint in that lawsuit speaks for itself. Monsanto further admits that its lawsuit
24 cites to OEHHA’s 2007 determination based upon its own independent evaluation of the
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27 ⁴ OEHHA, *Public Health Goal for Glyphosate in Drinking Water* (June 2007), <http://oehha.ca.gov/media/downloads/water/chemicals/phg/glyphg062907.pdf>.

1 scientific evidence that glyphosate is “unlikely to pose a cancer hazard to humans.”⁵ The
2 remaining allegations in paragraph 66 comprise attorney characterizations and are accordingly
3 denied.

4 67. Monsanto admits the allegations in paragraph 67.

5 68. In response to the allegations in Paragraph 68, Monsanto admits that, on
6 November 12, 2015, the European Food Safety Authority issued its Renewal Assessment Report
7 (RAR) on glyphosate, in which it concluded that “glyphosate is unlikely to pose a carcinogenic
8 hazard to humans.”⁶ Monsanto further admits that this conclusion affirmed a similar finding by
9 the German Federal Institute for Risk Management (BfR). Monsanto admits that the European
10 scientists who reached these determinations were acting independently of Monsanto and were
11 acting to protect the public.

12 69. In response to the allegations in Paragraph 69, Monsanto denies that “industry
13 groups” were afforded any ability to review the RAR beyond that afforded to the public
14 generally. Monsanto otherwise admits the allegations in paragraph 69.

15 70. Monsanto admits the allegations in paragraph 70.

16 71. In response to the allegations in paragraph 71, Monsanto states that the cited
17 document speaks for itself and does not require a response. Monsanto denies the allegations in
18 paragraph 71 to the extent that they purport to set forth all of the distinctions identified by EFSA
19 between its evaluation and the evaluation of the IARC working group. Monsanto states that in
20 the same document cited by plaintiff, EFSA states that, in contrast to IARC, “the EU peer review
21 concluded that no significant increase in tumour incidence could be observed in any of the
22 treated groups of animals in the nine long term rat studies considered” and explains that “[a]s
23 well as reviewing a larger number of studies [than IARC], EFSA for example considered that
24 carcinogenic effects observed at high doses were unreliable as they could be related to general

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26 ⁵ OEHHA, *Public Health Goal for Glyphosate in Drinking Water* (June 2007), <http://oehha.ca.gov/media/downloads/water/chemicals/phg/glyphg062907.pdf>.

27 ⁶ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.
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1 toxicity.”⁷ To the extent that paragraph 71 characterizes the meaning of the cited studies,
2 Monsanto denies the remaining allegations in paragraph 71.

3 72. In response to the allegations in paragraph 72, Monsanto states that the cited
4 document speaks for itself and does not require a response.

5 73. In response to the allegations in paragraph 73, Monsanto admits that EFSA set
6 acceptable exposure thresholds for glyphosate that are orders of magnitude higher than those
7 which occur in the ordinary use of glyphosate-based herbicides. Monsanto denies that these
8 exposure thresholds are based upon any alleged risk of carcinogenicity.

9 74. In response to the allegations in paragraph 74, Monsanto admits that certain
10 individuals, including Dr. Christopher Portier, sent the letter identified in paragraph 74
11 (hereinafter, “the Portier letter”). Monsanto denies that Dr. Portier or the other signatories to his
12 letter are “independent” and “renowned international experts in the field.” Monsanto states that
13 Dr. Portier has subsequently admitted that he is working as a consultant for plaintiff’s counsel in
14 the glyphosate cancer litigation against Monsanto. Monsanto otherwise admits that this letter
15 urged the EU Health Commissioner to disregard the scientific findings reached by EFSA and by
16 the BfR.

17 75. In response to the allegations in paragraph 75, Monsanto admits that Dr. Portier
18 sent the letter identified in paragraph 75. Monsanto denies that Dr. Portier or the other
19 signatories to his letter are “renowned international experts in the field.” Monsanto admits that
20 certain members of the IARC working group assigned to glyphosate signed on to the Portier
21 letter, but states that Monsanto lacks information or knowledge sufficient to form a belief as to
22 whether those individuals or the other signatories were aware at the time that Dr. Portier was
23 working as a consultant for plaintiff’s counsel.

24 76. In response to the allegations in paragraph 76, Monsanto states that the cited
25 Portier letter speaks for itself and does not require a response. Monsanto further admits that Dr.

26 _____
27 ⁷ EFSA, *EFSA Explains Risk Assessment Glyphosate*, http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/efsaexplainsglyphosate151112en.pdf.

1 Portier – who is a consultant for plaintiff’s counsel in the glyphosate cancer litigation against
2 Monsanto – seeks in his letter to challenge the scientific conclusions reached by EFSA in support
3 of its finding that “glyphosate is unlikely to pose a carcinogenic hazard to humans.”⁸ To the
4 extent that paragraph 76 characterizes the meaning of the cited document or of EFSA’s
5 evaluation of glyphosate, Monsanto denies the remaining allegations in paragraph 76.

6 77. In response to the allegations in paragraph 77, Monsanto admits that IARC
7 concluded that the human epidemiologic data provides only “limited evidence of
8 carcinogenicity,” which IARC defines as meaning that “chance, bias, or confounding could not
9 be ruled out with reasonable confidence.”⁹ Monsanto further admits that Dr. Portier – who is a
10 consultant for plaintiff’s counsel in the glyphosate cancer litigation against Monsanto – seeks in
11 his letter to challenge the scientific conclusions reached by EFSA in support of its finding that
12 “glyphosate is unlikely to pose a carcinogenic hazard to humans.”¹⁰ In response to the remaining
13 allegations in paragraph 77, Monsanto states that the cited Portier letter speaks for itself and does
14 not require a response. To the extent that paragraph 77 characterizes the meaning of the cited
15 document or of EFSA’s evaluation of glyphosate, Monsanto denies the remaining allegations in
16 paragraph 77.

17 78. In response to the allegations in paragraph 78, Monsanto states that the cited
18 Portier letter speaks for itself and does not require a response. Monsanto further admits that Dr.
19 Portier – who is a consultant for plaintiff’s counsel in the glyphosate cancer litigation against
20 Monsanto – seeks in his letter to challenge the scientific conclusions reached by EFSA in support
21 of its finding that “glyphosate is unlikely to pose a carcinogenic hazard to humans.”¹¹ To the
22

23 ⁸ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

24 ⁹ <http://monographs.iarc.fr/ENG/Preamble/currentb6evalrationale0706.php>.

25 ¹⁰ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

26 ¹¹ See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

1 extent that paragraph 78 characterizes the meaning of the cited document or of EFSA’s and
2 BfR’s evaluation of glyphosate, Monsanto denies the remaining allegations in paragraph 78.

3 79. In response to the allegations in paragraph 79, Monsanto states that the cited
4 Portier letter speaks for itself and does not require a response. Monsanto further admits that Dr.
5 Portier – who is a consultant for plaintiff’s counsel in the glyphosate cancer litigation against
6 Monsanto – seeks in his letter to challenge the scientific conclusions reached by EFSA in support
7 of its finding that “glyphosate is unlikely to pose a carcinogenic hazard to humans.”¹² To the
8 extent that paragraph 79 characterizes the meaning of the cited document or of EFSA’s and
9 BfR’s evaluation of glyphosate, Monsanto denies the remaining allegations in paragraph 79.

10 80. Monsanto admits the allegations in paragraph 80.

11 81. In response to the allegations in paragraph 81, Monsanto states that the cited
12 document speaks for itself and does not require a response. Monsanto denies that the self-
13 labeled “consensus statement” represents the view of any consensus of scientific opinion. To the
14 extent that paragraph 81 characterizes the scientific evidence regarding the safety of glyphosate-
15 based herbicides, Monsanto denies the remaining allegations in paragraph 81.

16 82. In response to the allegations in paragraph 82, Monsanto states that the cited
17 document speaks for itself and does not require a response. Monsanto denies that the self-
18 labeled “consensus statement” represents the view of any consensus of scientific opinion. To the
19 extent that paragraph 82 characterizes the scientific evidence regarding the safety of glyphosate-
20 based herbicides, Monsanto denies the remaining allegations in paragraph 82.

21 83. In response to the allegations in paragraph 83, Monsanto states that the cited
22 document speaks for itself and does not require a response. Monsanto denies that the self-
23 labeled “consensus statement” represents the view of any consensus of scientific opinion. To the
24 extent that paragraph 83 characterizes the scientific evidence regarding the safety of glyphosate-
25 based herbicides, Monsanto denies the remaining allegations in paragraph 83.

26
27 ¹² See EFSA, *Glyphosate: EFSA updates toxicological profile*, <http://www.efsa.europa.eu/en/press/news/151112>.

1 84. In response to the allegations in paragraph 84, Monsanto states that the cited
2 document speaks for itself and does not require a response. Monsanto denies that the self-
3 labeled “consensus statement” represents the view of any consensus of scientific opinion. To the
4 extent that paragraph 84 characterizes the scientific evidence regarding the safety of glyphosate-
5 based herbicides, Monsanto denies the remaining allegations in paragraph 84.

6 85. In response to the allegations in paragraph 85, Monsanto states that the cited
7 document speaks for itself and does not require a response. Monsanto denies that the self-
8 labeled “consensus statement” represents the view of any consensus of scientific opinion. To the
9 extent that paragraph 85 characterizes the scientific evidence regarding the safety of glyphosate-
10 based herbicides, Monsanto denies the remaining allegations in paragraph 85.

11 86. In response to the allegations in paragraph 86, Monsanto states that the cited
12 document speaks for itself and does not require a response. Monsanto denies that the self-
13 labeled “consensus statement” represents the view of any consensus of scientific opinion. To the
14 extent that paragraph 86 characterizes the scientific evidence regarding the safety of glyphosate-
15 based herbicides, Monsanto denies the remaining allegations in paragraph 86.

16 87. In response to the allegations in paragraph 87, Monsanto states that the cited
17 document speaks for itself and does not require a response. Monsanto denies that the self-
18 labeled “consensus statement” represents the view of any consensus of scientific opinion. To the
19 extent that paragraph 87 characterizes the scientific evidence regarding the safety of glyphosate-
20 based herbicides, Monsanto denies the remaining allegations in paragraph 87.

21 88. In response to the allegations in paragraph 88, Monsanto admits that the FDA has
22 authority to enforce pesticide residues and that the FDA announced it would begin testing certain
23 foods for glyphosate residues. In response to the remaining allegations in paragraph 88,
24 Monsanto states that the cited documents speak for themselves and do not require a response.

25 89. In response to the allegations in paragraph 89, Monsanto admits that the U.S.
26 Government Accounting Office issued the cited report regarding pesticide residue monitoring
27 programs, but Monsanto denies that the GAO report was limited to glyphosate. In response to
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1 the remaining allegations in paragraph 89, Monsanto states that the cited documents speak for
2 themselves and do not require a response. To the extent that paragraph 89 characterizes the
3 meaning of the cited documents, Monsanto denies the remaining allegations in paragraph 89.

4 90. In response to the allegations in paragraph 90, Monsanto admits that the FDA has
5 authority to enforce pesticide residues and that the FDA announced it would begin testing certain
6 foods for glyphosate residues. In response to the remaining allegations in paragraph 90,
7 Monsanto states that the cited documents speak for themselves and do not require a response. To
8 the extent that paragraph 90 characterizes the meaning of the cited documents, Monsanto denies
9 the remaining allegations in paragraph 90.

10 91. In response to the allegations in paragraph 91, Monsanto admits that the FDA has
11 authority to enforce pesticide residues and that the FDA announced it would begin testing certain
12 foods for glyphosate residues. In response to the remaining allegations in paragraph 91,
13 Monsanto states that the cited documents speak for themselves and do not require a response. To
14 the extent that paragraph 91 characterizes the meaning of the cited documents, Monsanto denies
15 the remaining allegations in paragraph 91.

16 92. Monsanto admits the allegations in paragraph 92.

17 93. In response to the allegations in paragraph 93, Monsanto states that the cited
18 document speaks for itself and does not require a response.

19 94. In response to the allegations in paragraph 94, Monsanto lacks information or
20 knowledge sufficient to form a belief as to whether each of the individuals at the referenced
21 meeting were “experts” and therefore denies that allegation. Monsanto admits the remaining
22 allegations in paragraph 94.

23 95. In response to the allegations in paragraph 95, Monsanto states that the cited
24 document speaks for itself and does not require a response. To the extent that paragraph 95
25 characterizes the meaning of the cited document, Monsanto denies the remaining allegations in
26 paragraph 95.

27 96. In response to the allegations in paragraph 96, Monsanto states that the cited
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1 document speaks for itself and does not require a response. To the extent that paragraph 96
2 characterizes the meaning of the cited document, Monsanto denies the remaining allegations in
3 paragraph 96.

4 97. Monsanto admits the allegations in paragraph 97.

5 98. Monsanto admits the allegations in paragraph 98.

6 99. Monsanto admits the allegations in paragraph 99.

7 100. Monsanto admits the allegations in paragraph 100. Monsanto notes that, in March
8 2017, the European Chemical Agency (“ECHA”) announced that its Committee for Risk
9 Assessment concluded that the available scientific evidence did not meet the criteria to classify
10 glyphosate as a carcinogen. *See ECHA, Glyphosate not classified as a carcinogen by ECHA,*
11 <https://echa.europa.eu/-/glyphosate-not-classified-as-a-carcinogen-by-echa>.

12 101. Monsanto lacks information or knowledge sufficient to form a belief as to the
13 truth of the allegations asserted in paragraph 101 and therefore denies those allegations.

14 102. Monsanto lacks information or knowledge sufficient to form a belief as to the
15 truth of the allegations asserted in paragraph 102 and therefore denies those allegations.

16 103. Monsanto lacks information or knowledge sufficient to form a belief as to the
17 truth of the allegations asserted in paragraph 103 and therefore denies those allegations.

18 104. Monsanto lacks information or knowledge sufficient to form a belief as to the
19 truth of the allegations asserted in paragraph 104 and therefore denies those allegations.

20 105. Monsanto lacks information or knowledge sufficient to form a belief as to the
21 truth of the allegations asserted in paragraph 105 and therefore denies those allegations.

22 106. Monsanto lacks information or knowledge sufficient to form a belief as to the
23 truth of the allegations asserted in paragraph 106 and therefore denies those allegations.

24 107. Monsanto lacks information or knowledge sufficient to form a belief as to the
25 truth of the allegations asserted in paragraph 107 and therefore denies those allegations.

26 108. Monsanto denies that any exposure to Roundup[®]-branded products can cause non-
27 Hodgkin’s lymphoma (“NHL”) and other serious illnesses and therefore denies the allegations in
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1 paragraph 108. Monsanto states, however, that the scientific studies upon which IARC
2 purported to base its evaluation of glyphosate were all publicly available before March 2015.

3 109. Monsanto denies that any exposure to Roundup[®]-branded products can cause
4 NHL and other serious illnesses and therefore denies the allegations in paragraph 109. Monsanto
5 states, however, that the scientific studies upon which IARC purported to base its evaluation of
6 glyphosate were all publicly available before March 2015.

7 110. In response to the allegations in paragraph 110, Monsanto denies that there is any
8 risk of serious illness associated with the use of and/or exposure to Roundup[®]-branded products
9 and glyphosate and denies that glyphosate is injurious to human health. Monsanto states,
10 however, that the scientific studies upon which IARC purported to base its classification were all
11 publicly available before March 2015. The final sentence of paragraph 110 sets forth a
12 conclusion of law for which no response is required.

13 111. In response to the allegations in paragraph 111, Monsanto denies that exposure to
14 Roundup[®]-branded products and glyphosate is injurious to human health. Monsanto states,
15 however, that the scientific studies upon which IARC purported to base its cancer classification
16 for glyphosate were all publicly available before March 2015. The allegations in paragraph 111
17 set forth conclusions of law for which no response is required.

18 112. In response to the allegations in paragraph 112, Monsanto denies that there is any
19 risk of NHL or other serious illness associated with the use of and/or exposure to Roundup[®]-
20 branded products and glyphosate. Monsanto states, however, that the scientific studies upon
21 which IARC purported to base its cancer classification for glyphosate were all publicly available
22 before March 2015. Monsanto lacks information or knowledge sufficient to form a belief as to
23 the truth of the remaining allegations in paragraph 112 and therefore denies those allegations.

24 113. Paragraph 113 sets forth conclusions of law for which no response is required.

25 114. In response to the allegations in paragraph 114, Monsanto denies that it concealed
26 any facts related to the human health safety of glyphosate. The remaining allegations in
27 paragraph 114 set forth conclusions of law for which no response is required.
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1 115. Monsanto denies the allegations in paragraph 115.

2 116. Paragraph 116 sets forth conclusions of law for which no response is required.

3 117. Monsanto denies the allegations in paragraph 117.

4 118. Paragraph 118 sets forth conclusions of law for which no response is required.

5 119. Monsanto incorporates by reference its responses to paragraphs 1 through 118 in
6 response to paragraph 119 of plaintiff's Complaint.

7 120. In response to the allegations in paragraph 120, Monsanto admits that plaintiff
8 purports to bring claims for strict liability but denies any liability to plaintiff.

9 121. In response to the allegations in paragraph 121, Monsanto lacks information or
10 knowledge sufficient to form a belief as to the truth of the allegation that plaintiff used or was
11 exposed to Roundup[®]-branded products and therefore denies that allegation. Monsanto denies
12 the remaining allegations in paragraph 121.

13 122. In response to the allegations in paragraph 122, Monsanto lacks information or
14 knowledge sufficient to form a belief as to the truth of the allegation that plaintiff used or was
15 exposed to Roundup[®]-branded products and therefore denies that allegation. Monsanto denies
16 the remaining allegations in paragraph 122.

17 123. Monsanto lacks information or knowledge sufficient to form a belief as to the
18 truth of the allegations in paragraph 123 and therefore denies those allegations.

19 124. Monsanto denies the allegations in paragraph 124.

20 125. Monsanto denies the allegations in paragraph 125.

21 126. Monsanto denies the allegations in paragraph 126 and each of its subparts.

22 127. Monsanto lacks information or knowledge sufficient to form a belief as to the
23 truth of the allegations in paragraph 127 concerning plaintiff's claimed use of or exposure to
24 Roundup[®]-branded products and therefore denies those allegations. Monsanto denies the
25 remaining allegations in paragraph 127, including that Roundup[®]-branded products have
26 "dangerous characteristics."

27 128. Monsanto denies the allegations in paragraph 128.

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1 129. Monsanto denies the allegations in paragraph 129.

2 130. Monsanto denies the allegations in paragraph 130.

3 131. Monsanto denies the allegations in paragraph 131.

4 132. Monsanto denies the allegations in paragraph 132.

5 133. Monsanto denies the allegations in paragraph 133.

6 134. Monsanto denies the allegations in paragraph 134.

7 135. In response to the allegations in paragraph 135, Monsanto demands that judgment
8 be entered in its favor and against plaintiff; that plaintiff's Complaint be dismissed, with
9 prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's fees as allowed
10 by law and such further and additional relief as this Court may deem just and proper.

11 136. Monsanto incorporates by reference its responses to paragraphs 1 through 135 in
12 response to paragraph 136 of plaintiff's Complaint.

13 137. In response to the allegations in paragraph 137, Monsanto admits that plaintiff
14 purports to bring claims for strict liability, but denies any liability to plaintiff.

15 138. Monsanto denies the allegations in paragraph 138.

16 139. In response to the allegations in paragraph 139, Monsanto lacks information or
17 knowledge sufficient to form a belief as to the truth of the allegations that plaintiff or other
18 persons or entities purchased Roundup[®]-branded products and therefore denies those allegations.
19 The allegations in paragraph 139 also set forth conclusions of law for which no response is
20 required. Monsanto denies the remaining allegations in paragraph 139.

21 140. In response to the allegations in paragraph 140, Monsanto denies that there is any
22 risk of NHL or other serious illness associated with the use of and/or exposure to Roundup[®]-
23 branded products and glyphosate. The remaining allegations in paragraph 140 set forth
24 conclusions of law for which no response is required.

25 141. Monsanto denies the allegations in paragraph 141. All labeling of Roundup[®]-
26 branded products has been and remains EPA-approved and in compliance with all federal
27 requirements under FIFRA.

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1 142. Monsanto denies the allegations in paragraph 142.

2 143. Monsanto denies the allegations in paragraph 143.

3 144. Monsanto denies the allegations in paragraph 144.

4 145. Monsanto lacks information or knowledge sufficient to form a belief as to the
5 truth of the allegations in paragraph 145 and therefore denies those allegations.

6 146. Monsanto lacks information or knowledge sufficient to form a belief as to the
7 truth of the allegations in paragraph 146 regarding plaintiff's claimed use of and exposure to
8 Roundup[®]-branded products and therefore denies those allegations. Monsanto denies the
9 remaining allegations in paragraph 146, including that Roundup[®]-branded products have
10 "dangerous characteristics."

11 147. Monsanto lacks information or knowledge sufficient to form a belief as to the
12 truth of the allegations in the second sentence of paragraph 147 and therefore denies those
13 allegations. Monsanto denies the remaining allegations in paragraph 147.

14 148. Monsanto denies the allegations in paragraph 148.

15 149. Monsanto denies the allegations in paragraph 149.

16 150. Monsanto denies the allegations in paragraph 150.

17 151. Monsanto denies the allegations in paragraph 151.

18 152. Monsanto denies the allegations in paragraph 152.

19 153. Monsanto denies the allegations in paragraph 153.

20 154. Monsanto denies the allegations in paragraph 154.

21 155. Monsanto denies the allegations in paragraph 155.

22 156. In response to the allegations in paragraph 156, Monsanto demands that judgment
23 be entered in its favor and against plaintiff; that plaintiff's Complaint be dismissed, with
24 prejudice; and that Monsanto be awarded costs of suit and reasonable attorney's fees as allowed
25 by law and such further and additional relief as this Court may deem just and proper.

26 157. Monsanto incorporates by reference its responses to paragraphs 1 through 156 in
27 response to paragraph 157 of plaintiff's Complaint.

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1 158. Monsanto lacks information or knowledge sufficient to form a belief as to the
2 truth of the allegations in paragraph 158 regarding the specific products allegedly used by
3 plaintiff or any advertising or marketing allegedly seen or considered by plaintiff, and therefore
4 denies the allegations in paragraph 158.

5 159. The allegations in paragraph 159 set forth conclusions of law for which no
6 response is required.

7 160. The allegations in paragraph 160 set forth conclusions of law for which no
8 response is required.

9 161. Monsanto denies the allegations in paragraph 161.

10 162. Monsanto denies the allegations in paragraph 162.

11 163. Monsanto denies the allegations in paragraph 163.

12 164. Monsanto denies the allegations in paragraph 164.

13 165. Monsanto denies the allegations in paragraph 165. All labeling of Roundup[®]-
14 branded products has been and remains EPA-approved and in compliance with all federal
15 requirements under FIFRA.

16 166. Monsanto denies the allegations in paragraph 166.

17 167. Monsanto denies the allegations in paragraph 167.

18 168. Monsanto denies the allegations in paragraph 168.

19 169. Monsanto denies the allegations in paragraph 169, including each of its subparts.

20 170. Monsanto denies the allegations in paragraph 170.

21 171. Monsanto lacks information or knowledge sufficient to form a belief as to the
22 truth of the allegations in paragraph 171 regarding plaintiff's knowledge and therefore denies
23 those allegations. Monsanto denies the remaining allegations in paragraph 171, including that
24 intended use of and/or exposure to Roundup[®]-branded products causes any injuries.

25 172. Monsanto denies the allegations in paragraph 172.

26 173. Monsanto denies the allegations in paragraph 173.

1 and instructions, in accordance with Fla. Stat. §768.1257 the state of the art and the state of
2 scientific and technological knowledge.

3 5. Plaintiff's claims are barred, in whole or in part, because the products at issue
4 were not defective or unreasonably dangerous in that they complied with, at all relevant times,
5 all applicable government safety standards.

6 6. Plaintiff's claims are preempted, in whole or in part, by applicable federal law
7 relating to the design, testing, producing, manufacturing, labeling, distributing, modeling,
8 processing, and supply of Roundup[®]-branded products and/or glyphosate-containing products.

9 7. Plaintiff's claims are preempted, in whole or in part, because of U.S. EPA
10 findings that glyphosate does not cause cancer in humans and/or because of U.S. EPA-approved
11 product labeling.

12 8. Plaintiff's claims are barred, in whole or in part, by the doctrine of primary
13 jurisdiction, including by the authority delegated by Congress to the U.S. EPA.

14 9. Plaintiff's claims are barred, in whole or in part, because plaintiff's injuries, if
15 any, were the result of conduct of plaintiff, independent third parties, and/or events that were
16 extraordinary under the circumstances, not foreseeable in the normal course of events, and/or
17 independent, intervening and superseding causes of the alleged injuries, including but not limited
18 to plaintiff's pre-existing medical conditions.

19 10. The doctrines contained in Restatement (Second) of Torts § 402A, comments j
20 and k, bar plaintiff's claims against Monsanto in whole or in part.

21 11. Applicable statutes of limitations and/or repose bar plaintiff's claims in whole or
22 in part.

23 12. Plaintiffs' claims are barred, in whole or in part, by application of Fla. Stat.
24 §768.1256.

25 13. Plaintiff's misuse or abnormal use of the product or failure to follow instructions
26 bar plaintiff's claims in whole or in part.

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1 14. If plaintiff suffered injury or damages as alleged (no injury or damages being
2 admitted), such injury or damage resulted from acts or omissions of persons or entities for which
3 Monsanto is neither liable nor responsible or resulted from diseases and/or causes that are not
4 related or connected with any product sold, distributed, or manufactured by Monsanto. Such acts
5 or omissions on the part of others or diseases or causes constitute an independent, intervening
6 and sole proximate cause of plaintiff's alleged injury or damages.

7 15. Monsanto had no legal relationship or privity with plaintiff and owed no duty to
8 him by which liability could be attributed to it.

9 16. Monsanto made no warranties of any kind or any representations of any nature
10 whatsoever to plaintiff. If any such warranties were made, which Monsanto specifically denies,
11 then plaintiff failed to give notice of any breach thereof.

12 17. Plaintiff's claims are preempted in whole or part by the Freedom of Speech
13 Clause of the First Amendment of the U.S. Constitution.

14 18. Plaintiff's claims for punitive damages are barred because such an award would
15 violate Monsanto's due process, equal protection and other rights under the United States
16 Constitution, the Florida Constitution, and/or other applicable state constitutions.

17 19. Plaintiff's claims for punitive damages are barred because plaintiff has failed to
18 allege conduct warranting imposition of punitive damages under Florida law and/or other
19 applicable state laws.

20 20. Any recovery of punitive or exemplary damages is limited pursuant to Fla. Stat. §
21 768.73. However, Monsanto would further show that under the facts of this case, an award of
22 punitive damages consistent with the maximum awards permitted under § 768.73 would be a
23 violation of Monsanto's state and federal constitutional rights.

24 21. Any recovery of compensatory damages is limited by operation of Fla. Stat. §
25 768.76.

26 22. Plaintiff's claims are barred in whole or in part by plaintiff's own
27 contributory/comparative negligence.

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