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13 Attorneys for Defendant
14 PFIZER INC.

15 UNITED STATES DISTRICT COURT
16 NORTHERN DISTRICT OF CALIFORNIA
17 SAN FRANCISCO DIVISION

18 IN RE BEXTRA AND CELEBREX)
19 MARKETING, SALES PRACTICES AND)
PRODUCTS LIABILITY LITIGATION)

20 *This document relates to*)

21 TERESITA FALCON MATOS, et al.,)

22 Plaintiffs,)

23 vs.)

24 ASTRA MERCK, INC., et al.,)

25 Defendants.)
26)
27)
28)

MDL Docket No. 1699

CASE NO. 3:06-cv-2660-CRB

**PFIZER INC.'S ANSWER TO
COMPLAINT**

**JURY DEMAND ENDORSED
HEREIN**

1 NOW COMES Defendant Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as
2 Pfizer Corporation, Pfizer Pharmaceuticals, Inc., Pfizer Pharmaceuticals, LLC, Pfizer Disks,
3 Inc., and Pfizer, Inc.") ("Pfizer" or "Defendant"), and files this Answer to Plaintiffs' Complaint
4 ("Complaint"), and would respectfully show the Court as follows:

5 **I.**

6 **PRELIMINARY STATEMENT**

7 The Complaint does not state in sufficient detail when Plaintiff was prescribed or used
8 Bextra® (valdecoxib) ("Bextra®") and Celebrex® (celecoxib) ("Celebrex®"). Accordingly,
9 this Answer can only be drafted generally. Defendant may seek leave to amend this Answer
10 when discovery reveals the specific time periods in which Plaintiff was prescribed and used
11 Bextra® and Celebrex®.

12 **II.**

13 **ANSWER**

14 **Response to Allegations Regarding Jurisdiction**

15 Answering the first unnumbered paragraph preceding Paragraph 1 of the Complaint,
16 Defendant states that, to the extent that the allegations in this paragraph of the Complaint are
17 not directed toward Defendant, no response is required. Defendant states that Pfizer is a
18 Delaware corporation with its principal place of business in New York. Defendant is without
19 knowledge or information sufficient to form a belief as to the truth of the allegations in this
20 paragraph of the Complaint regarding the amount in controversy, and, therefore, denies the
21 same. However, Defendant admits that Plaintiffs claim that the amount in controversy exceeds
22 \$75,000, exclusive of interests and costs. Defendant denies the remaining allegations in this
23 paragraph of the Complaint.

24 Answering the second unnumbered paragraph preceding Paragraph 1 of the Complaint,
25 Defendant states that the allegations in this paragraph of the Complaint regarding Vioxx® are
26 not directed toward Defendant, and, therefore, no response is required. Defendant is without
27 knowledge or information sufficient to form a belief as to the truth of the allegations in this
28 paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly

1 arose and, therefore, denies the same. Defendant is without knowledge or information
2 sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint
3 regarding whether Plaintiff used Bextra® and Celebrex®, and, therefore, denies the same.
4 Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra®
5 and Celebrex® in the United States to be prescribed by healthcare providers who are by law
6 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant denies
7 any wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

8 **Response to Factual Allegations**

9 1. Defendant is without knowledge or information sufficient to form a belief as to the truth
10 of the allegations in this paragraph of the Complaint regarding Plaintiff's age, level of
11 education, employment history, and citizenship, and, therefore, denies the same. Defendant
12 denies the remaining allegations in this paragraph of the Complaint.

13 2. Defendant is without knowledge or information sufficient to form a belief as to the truth
14 of the allegations in this paragraph of the Complaint regarding Plaintiff's age, marital status,
15 and citizenship, and, therefore, denies the same. Defendant denies the remaining allegations in
16 this paragraph of the Complaint.

17 3. Defendant is without knowledge or information sufficient to form a belief as to the truth
18 of the allegations in this paragraph of the Complaint regarding Plaintiffs' age, familial
19 relationship, and citizenship, and, therefore, denies the same. Defendant denies the remaining
20 allegations in this paragraph of the Complaint.

21 4. Defendant states that the allegations in this paragraph of the Complaint are not directed
22 toward Defendant, and, therefore, no response is required.

23 5. Defendant admits that, during certain periods of time, it marketed and co-promoted
24 Bextra® and Celebrex® in the United States to be prescribed by healthcare providers who are
25 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
26 admits that it is registered to do and does business in Puerto Rico. Defendant denies the
27 remaining allegations in this paragraph of the Complaint.

28 6. Defendant states that the allegations in this paragraph of the Complaint regarding

1 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
2 admits that Bextra® and Celebrex® are in a class of drugs that are, at times, referred to as being
3 non-steroidal anti-inflammatory drugs (“NSAIDs”). Defendant states that, as indicated in the
4 package insert approved by the FDA, Bextra® is indicated for use in the relief of the signs and
5 symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of
6 primary dysmenorrhea. Defendant states that Celebrex® is a prescription medication which is
7 approved by the FDA for the following indications: (1) for relief of the signs and symptoms of
8 osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for
9 the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to
10 reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP)
11 as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and
12 symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile
13 rheumatoid arthritis in patients two years of age and older. Defendant denies the remaining
14 allegations in this paragraph of the Complaint.

15 7. Defendant states that the allegations in this paragraph of the Complaint are not directed
16 toward Defendant, and, therefore, no response is required.

17 8. Defendant states that the allegations in this paragraph of the Complaint are not directed
18 toward Defendant, and, therefore, no response is required.

19 9. Defendant states that the allegations in this paragraph of the Complaint regarding Merck
20 and Vioxx® are not directed toward Defendant, and, therefore, no response is required.
21 Defendant states that Bextra® and Celebrex® were and are safe and effective when used in
22 accordance with their FDA-approved prescribing information. Defendant states that the
23 potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-
24 approved prescribing information, which was at all times adequate and comported with
25 applicable standards of care and law. Defendant denies any wrongful conduct and denies the
26 remaining allegations in this paragraph of the Complaint.

27 10. Defendant states that the allegations in this paragraph of the Complaint regarding
28 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant

1 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
2 with their FDA-approved prescribing information. Defendant states that the potential effects of
3 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
4 information, which was at all times adequate and comported with applicable standards of care
5 and law. Defendant denies any wrongful conduct and denies the remaining allegations in this
6 paragraph of the Complaint.

7 11. Defendant states that the allegations in this paragraph of the Complaint regarding Merck
8 and Vioxx® are not directed toward Defendant, and, therefore, no response is required.
9 Defendant admits that, during certain periods of time, it marketed and co-promoted Bextra®
10 and Celebrex® in the United States to be prescribed by healthcare providers who are by law
11 authorized to prescribe drugs in accordance with their approval by the FDA. Defendant states
12 that Bextra® and Celebrex® were and are safe and effective when used in accordance with
13 their FDA-approved prescribing information. Defendant states that the potential effects of
14 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
15 information, which was at all times adequate and comported with applicable standards of care
16 and law. Defendant denies any wrongful conduct and denies the remaining allegations in this
17 paragraph of the Complaint.

18 12. Defendant states that the allegations in this paragraph of the Complaint regarding Merck
19 and Vioxx® are not directed toward Defendant, and, therefore, no response is required.
20 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
21 allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and
22 Celebrex®, and, therefore, denies the same. Defendant states that Bextra® and Celebrex®
23 were and are safe and effective when used in accordance with their FDA-approved prescribing
24 information. Defendant states that the potential effects of Bextra® and Celebrex® were and are
25 adequately described in their FDA-approved prescribing information, which was at all times
26 adequate and comported with applicable standards of care and law. Defendant denies any
27 wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

28 13. Defendant states that Bextra® and Celebrex® were and are safe and effective when

1 used in accordance with their FDA-approved prescribing information. Defendant states that the
2 potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-
3 approved prescribing information, which was at all times adequate and comported with
4 applicable standards of care and law. Defendant denies any wrongful conduct and denies the
5 remaining allegations in this paragraph of the Complaint.

6 14. Defendant is without knowledge or information sufficient to form a belief as to the truth
7 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®
8 and Celebrex®, and, therefore, denies the same. Defendant states that Bextra® and Celebrex®
9 were and are safe and effective when used in accordance with their FDA-approved prescribing
10 information. Defendant states that the potential effects of Bextra® and Celebrex® were and are
11 adequately described in their FDA-approved prescribing information, which was at all times
12 adequate and comported with applicable standards of care and law. Defendant denies any
13 wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

14 15. Defendant states that the allegations in this paragraph of the Complaint are not directed
15 toward Defendant, and, therefore, no response is required.

16 16. Defendant is without knowledge or information sufficient to form a belief as to the truth
17 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®
18 and Celebrex®, and, therefore, denies the same. Defendant denies the remaining allegations in
19 this paragraph of the Complaint.

20 17. Defendant states that the allegations in this paragraph of the Complaint regarding
21 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
22 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
23 with their FDA-approved prescribing information. Defendant states that the potential effects of
24 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
25 information, which was at all times adequate and comported with applicable standards of care
26 and law. Defendant denies any wrongful conduct, denies that Bextra® or Celebrex® caused
27 Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the
28 Complaint.

1 18. Defendant is without knowledge or information sufficient to form a belief as to the truth
2 of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition,
3 and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph
4 of the Complaint.

5 19. Defendant states that the allegations in this paragraph of the Complaint regarding
6 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
7 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
8 with their FDA-approved prescribing information. Defendant states that the potential effects of
9 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
10 information, which was at all times adequate and comported with applicable standards of care
11 and law. Defendant denies any wrongful conduct, denies that Bextra® or Celebrex® caused
12 Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the
13 Complaint.

14 20. Defendant states that the allegations in this paragraph of the Complaint regarding
15 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
16 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
17 with their FDA-approved prescribing information. Defendant states that the potential effects of
18 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
19 information, which was at all times adequate and comported with applicable standards of care
20 and law. Defendant denies any wrongful conduct, denies that Bextra® or Celebrex® caused
21 Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the
22 Complaint.

23 21. Defendant states that the allegations in this paragraph of the Complaint regarding
24 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
25 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
26 with their FDA-approved prescribing information. Defendant states that the potential effects of
27 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
28 information, which was at all times adequate and comported with applicable standards of care

1 and law. Defendant denies any wrongful conduct, denies that Bextra® or Celebrex® caused
2 Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the
3 Complaint.

4 22. Defendant denies any wrongful conduct, denies that Bextra® or Celebrex® caused
5 Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the
6 Complaint, including all subparts.

7 23. Defendant states that the allegations in this paragraph of the Complaint regarding
8 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
9 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
10 with their FDA-approved prescribing information. Defendant states that the potential effects of
11 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
12 information, which was at all times adequate and comported with applicable standards of care
13 and law. Defendant denies any wrongful conduct, denies that Bextra® or Celebrex® caused
14 Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the
15 Complaint, including all subparts.

16 24. Defendant states that the allegations in this paragraph of the Complaint regarding
17 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
18 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
19 with their FDA-approved prescribing information. Defendant states that the potential effects of
20 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
21 information, which was at all times adequate and comported with applicable standards of care
22 and law. Defendant denies any wrongful conduct, denies that Bextra® or Celebrex® caused
23 Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the
24 Complaint.

25 25. Defendant states that the allegations in this paragraph of the Complaint are not directed
26 toward Defendant, and, therefore, no response is required. To the extent that a response is
27 deemed required, Defendant states that Plaintiffs fail to provide the proper context for the
28 allegations in this paragraph of the Complaint. Defendant therefore lacks knowledge or

1 information sufficient to form a belief as to the truth of such allegations, and, therefore, denies
2 the same.

3 26. Defendant states that the allegations in this paragraph of the Complaint regarding
4 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
5 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
6 with their FDA-approved prescribing information. Defendant states that the potential effects of
7 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
8 information, which was at all times adequate and comported with applicable standards of care
9 and law. Defendant denies any wrongful conduct and denies the remaining allegations in this
10 paragraph of the Complaint.

11 **Response to First Cause of Action: Breach of Implied Warranties**

12 27. Defendant incorporates by reference its responses to each paragraph of Plaintiffs'
13 Complaint as if fully set forth herein.

14 28. Defendant states that the allegations in this paragraph of the Complaint are not directed
15 toward Defendant, and, therefore, no response is required.

16 29. Defendant states that the allegations in this paragraph of the Complaint are not directed
17 toward Defendant, and, therefore, no response is required.

18 30. Defendant admits that, during certain periods of time, it marketed and co-promoted
19 Bextra® and Celebrex® in the United States to be prescribed by healthcare providers who are
20 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
21 denies the remaining allegations in this paragraph of the Complaint.

22 31. Defendant admits that, during certain periods of time, it marketed and co-promoted
23 Bextra® and Celebrex® in the United States to be prescribed by healthcare providers who are
24 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
25 admits that it provided FDA-approved prescribing information regarding Bextra® and
26 Celebrex®. Defendant states that Bextra® and Celebrex® were and are safe and effective
27 when used in accordance with their FDA-approved prescribing information. Defendant states
28 that the potential effects of Bextra® and Celebrex® were and are adequately described in their

1 FDA-approved prescribing information, which was at all times adequate and comported with
2 applicable standards of care and law. Defendant denies the remaining allegations in this
3 paragraph of the Complaint.

4 32. Defendant states that the allegations in this paragraph of the Complaint regarding
5 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
6 is without knowledge or information sufficient to form a belief as to the truth of the allegations
7 in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and Celebrex®,
8 and, therefore, denies the same. Defendant denies the remaining allegations in this paragraph
9 of the Complaint.

10 **Response to Second Cause of Action: Breach of Express Warranty**

11 33. Defendant incorporates by reference its responses to each paragraph of Plaintiffs'
12 Complaint as if fully set forth herein.

13 34. Defendant states that the allegations in this paragraph of the Complaint are not directed
14 toward Defendant, and, therefore, no response is required.

15 35. Defendant admits that, during certain periods of time, it marketed and co-promoted
16 Bextra® and Celebrex® in the United States to be prescribed by healthcare providers who are
17 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
18 admits that it provided FDA-approved prescribing information regarding Bextra® and
19 Celebrex®. Defendant states that Bextra® and Celebrex® were and are safe and effective
20 when used in accordance with their FDA-approved prescribing information. Defendant states
21 that the potential effects of Bextra® and Celebrex® were and are adequately described in their
22 FDA-approved prescribing information, which was at all times adequate and comported with
23 applicable standards of care and law. Defendant denies the remaining allegations in this
24 paragraph of the Complaint.

25 36. Defendant states that the allegations in this paragraph of the Complaint are not directed
26 toward Defendant, and, therefore, no response is required.

27 37. Defendant states that Bextra® and Celebrex® were and are safe and effective when
28 used in accordance with their FDA-approved prescribing information. Defendant states that the

1 potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-
2 approved prescribing information, which was at all times adequate and comported with
3 applicable standards of care and law. Defendant denies any wrongful conduct and denies the
4 remaining allegations in this paragraph of the Complaint.

5 38. Defendant states that the allegations in this paragraph of the Complaint regarding
6 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
7 is without knowledge or information sufficient to form a belief as to the truth of the allegations
8 in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and Celebrex®,
9 and, therefore, denies the same. Defendant states that Bextra® and Celebrex® were and are
10 safe and effective when used in accordance with their FDA-approved prescribing information.
11 Defendant states that the potential effects of Bextra® and Celebrex® were and are adequately
12 described in their FDA-approved prescribing information, which was at all times adequate and
13 comported with applicable standards of care and law. Defendant denies any wrongful conduct,
14 denies that Bextra® or Celebrex® caused Plaintiffs injury or damages, and denies the
15 remaining allegations in this paragraph of the Complaint.

16 **Response to Third Cause of Action: Strict Liability**

17 39. Defendant incorporates by reference its responses to each paragraph of Plaintiffs'
18 Complaint as if fully set forth herein.

19 40. Defendant states that the allegations in this paragraph of the Complaint are not directed
20 toward Defendant, and, therefore, no response is required.

21 41. Defendant admits that, during certain periods of time, it marketed and co-promoted
22 Bextra® and Celebrex® in the United States to be prescribed by healthcare providers who are
23 by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant
24 denies the remaining allegations in this paragraph of the Complaint.

25 42. Defendant states that the allegations in this paragraph of the Complaint regarding Merck
26 and Vioxx® are not directed toward Defendant, and, therefore, no response is required.
27 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
28 allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and

1 Celebrex®, and, therefore, denies the same. Defendant states that, in the ordinary case,
2 Bextra® and Celebrex® were expected to reach users and consumers without substantial
3 change from the time of sale. Defendant denies the remaining allegations in this paragraph of
4 the Complaint.

5 43. Defendant states that the allegations in this paragraph of the Complaint regarding
6 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
7 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
8 with their FDA-approved prescribing information. Defendant states that the potential effects of
9 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
10 information, which was at all times adequate and comported with applicable standards of care
11 and law. Defendant denies any wrongful conduct, denies that Bextra® or Celebrex® are
12 defective or unreasonably dangerous, and denies the remaining allegations in this paragraph of
13 the Complaint.

14 44. Defendant states that the allegations in this paragraph of the Complaint regarding Merck
15 and Vioxx® are not directed toward Defendant, and, therefore, no response is required.
16 Defendant states that Bextra® and Celebrex® were and are safe and effective when used in
17 accordance with their FDA-approved prescribing information. Defendant states that the
18 potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-
19 approved prescribing information, which was at all times adequate and comported with
20 applicable standards of care and law. Defendant denies any wrongful conduct, denies that
21 Bextra® or Celebrex® are defective or unreasonably dangerous, denies that Bextra® or
22 Celebrex® caused Plaintiffs injury or damages, and denies the remaining allegations in this
23 paragraph of the Complaint.

24 45. Defendant states that the allegations in this paragraph of the Complaint regarding Merck
25 and Vioxx® are not directed toward Defendant, and, therefore, no response is required.
26 Defendant is without knowledge or information sufficient to form a belief as to the truth of the
27 allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and
28 Celebrex®, and, therefore, denies the same. Defendant states that Bextra® and Celebrex®

1 were and are safe and effective when used in accordance with their FDA-approved prescribing
2 information. Defendant states that the potential effects of Bextra® and Celebrex® were and are
3 adequately described in their FDA-approved prescribing information, which was at all times
4 adequate and comported with applicable standards of care and law. Defendant denies any
5 wrongful conduct, denies that Bextra® or Celebrex® are defective or unreasonably dangerous,
6 denies that Bextra® or Celebrex® caused Plaintiffs injury or damages, and denies the
7 remaining allegations in this paragraph of the Complaint, including all subparts.

8 **Response to Fourth Cause of Action: Negligence**

9 46. Defendant incorporates by reference its responses to each paragraph of Plaintiffs'
10 Complaint as if fully set forth herein.

11 47. Defendant states that the allegations in this paragraph of the Complaint regarding
12 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
13 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
14 with their FDA-approved prescribing information. Defendant states that the potential effects of
15 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
16 information, which was at all times adequate and comported with applicable standards of care
17 and law. Defendant denies any wrongful conduct and denies the remaining allegations in this
18 paragraph of the Complaint.

19 48. Defendant states that the allegations in this paragraph of the Complaint regarding
20 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
21 states that this paragraph of the Complaint contains legal contentions to which no response is
22 required. To the extent that a response is deemed required, Defendant admits that it had duties
23 as are imposed by law but denies having breached such duties. Defendant states that Bextra®
24 and Celebrex® were and are safe and effective when used in accordance with their FDA-
25 approved prescribing information. Defendant states that the potential effects of Bextra® and
26 Celebrex® were and are adequately described in their FDA-approved prescribing information,
27 which was at all times adequate and comported with applicable standards of care and law.
28 Defendant denies any wrongful conduct and denies the remaining allegations in this paragraph

1 of the Complaint.

2 49. Defendant states that the allegations in this paragraph of the Complaint regarding
3 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
4 states that this paragraph of the Complaint contains legal contentions to which no response is
5 required. To the extent that a response is deemed required, Defendant admits that it had duties
6 as are imposed by law but denies having breached such duties. Defendant is without
7 knowledge or information sufficient to form a belief as to the truth of the allegations in this
8 paragraph of the Complaint regarding whether Plaintiff used Bextra® and Celebrex®, and,
9 therefore, denies the same. Defendant states that Bextra® and Celebrex® were and are safe and
10 effective when used in accordance with their FDA-approved prescribing information.
11 Defendant states that the potential effects of Bextra® and Celebrex® were and are adequately
12 described in their FDA-approved prescribing information, which was at all times adequate and
13 comported with applicable standards of care and law. Defendant denies any wrongful conduct
14 and denies the remaining allegations in this paragraph of the Complaint.

15 50. Defendant states that the allegations in this paragraph of the Complaint regarding
16 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
17 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
18 with their FDA-approved prescribing information. Defendant states that the potential effects of
19 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
20 information, which was at all times adequate and comported with applicable standards of care
21 and law. Defendant denies any wrongful conduct and denies the remaining allegations in this
22 paragraph of the Complaint.

23 51. Defendant states that the allegations in this paragraph of the Complaint regarding
24 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
25 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
26 with their FDA-approved prescribing information. Defendant states that the potential effects of
27 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
28 information, which was at all times adequate and comported with applicable standards of care

1 and law. Defendant denies any wrongful conduct and denies the remaining allegations in this
2 paragraph of the Complaint.

3 52. Defendant states that Bextra® and Celebrex® were and are safe and effective when
4 used in accordance with their FDA-approved prescribing information. Defendant states that the
5 potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-
6 approved prescribing information, which was at all times adequate and comported with
7 applicable standards of care and law. Defendant denies any wrongful conduct and denies the
8 remaining allegations in this paragraph of the Complaint.

9 53. Defendant states that the allegations in this paragraph of the Complaint regarding
10 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
11 is without knowledge or information sufficient to form a belief as to the truth of the allegations
12 in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and Celebrex®,
13 and, therefore, denies the same. Defendant states that Bextra® and Celebrex® were and are
14 safe and effective when used in accordance with their FDA-approved prescribing information.
15 Defendant states that the potential effects of Bextra® and Celebrex® were and are adequately
16 described in their FDA-approved prescribing information, which was at all times adequate and
17 comported with applicable standards of care and law. Defendant denies any wrongful conduct,
18 denies that Bextra® or Celebrex® caused Plaintiffs injury or damages, and denies the
19 remaining allegations in this paragraph of the Complaint.

20 **Response to Fifth Cause of Action: Fraud**

21 54. Defendant incorporates by reference its responses to each paragraph of Plaintiffs'
22 Complaint as if fully set forth herein.

23 55. Defendant states that the allegations in this paragraph of the Complaint regarding
24 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
25 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
26 with their FDA-approved prescribing information. Defendant states that the potential effects of
27 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
28 information, which was at all times adequate and comported with applicable standards of care

1 and law. Defendant denies any wrongful conduct and denies the remaining allegations in this
2 paragraph of the Complaint.

3 56. Defendant is without knowledge or information sufficient to form a belief as to the truth
4 of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra®
5 and Celebrex®, and, therefore, denies the same. Defendant states that Bextra® and Celebrex®
6 were and are safe and effective when used in accordance with their FDA-approved prescribing
7 information. Defendant states that the potential effects of Bextra® and Celebrex® were and are
8 adequately described in their FDA-approved prescribing information, which was at all times
9 adequate and comported with applicable standards of care and law. Defendant denies any
10 wrongful conduct and denies the remaining allegations in this paragraph of the Complaint.

11 57. Defendant states that the allegations in this paragraph of the Complaint regarding
12 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
13 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
14 with their FDA-approved prescribing information. Defendant states that the potential effects of
15 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
16 information, which was at all times adequate and comported with applicable standards of care
17 and law. Defendant denies any wrongful conduct and denies the remaining allegations in this
18 paragraph of the Complaint.

19 58. Defendant states that the allegations in this paragraph of the Complaint regarding
20 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
21 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
22 with their FDA-approved prescribing information. Defendant states that the potential effects of
23 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
24 information, which was at all times adequate and comported with applicable standards of care
25 and law. Defendant denies any wrongful conduct and denies the remaining allegations in this
26 paragraph of the Complaint, including all subparts.

27 59. Defendant states that the allegations in this paragraph of the Complaint regarding
28 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant

1 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
2 with their FDA-approved prescribing information. Defendant states that the potential effects of
3 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
4 information, which was at all times adequate and comported with applicable standards of care
5 and law. Defendant denies any wrongful conduct and denies the remaining allegations in this
6 paragraph of the Complaint.

7 60. Defendant states that the allegations in this paragraph of the Complaint regarding
8 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
9 is without knowledge or information sufficient to form a belief as to the truth of the allegations
10 in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and Celebrex®,
11 and, therefore, denies the same. Defendant states that Bextra® and Celebrex® were and are
12 safe and effective when used in accordance with their FDA-approved prescribing information.
13 Defendant states that the potential effects of Bextra® and Celebrex® were and are adequately
14 described in their FDA-approved prescribing information, which was at all times adequate and
15 comported with applicable standards of care and law. Defendant denies any wrongful conduct
16 and denies the remaining allegations in this paragraph of the Complaint.

17 61. Defendant states that the allegations in this paragraph of the Complaint regarding
18 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
19 states that Bextra® and Celebrex® were and are safe and effective when used in accordance
20 with their FDA-approved prescribing information. Defendant states that the potential effects of
21 Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing
22 information, which was at all times adequate and comported with applicable standards of care
23 and law. Defendant denies any wrongful conduct and denies the remaining allegations in this
24 paragraph of the Complaint.

25 62. Defendant denies the allegations in this paragraph of the Complaint.

26 63. Defendant states that the allegations in this paragraph of the Complaint regarding
27 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
28 is without knowledge or information sufficient to form a belief as to the truth of the allegations

1 in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and Celebrex®,
2 and, therefore, denies the same. Defendant states that Bextra® and Celebrex® were and are
3 safe and effective when used in accordance with their FDA-approved prescribing information.
4 Defendant states that the potential effects of Bextra® and Celebrex® were and are adequately
5 described in their FDA-approved prescribing information, which was at all times adequate and
6 comported with applicable standards of care and law. Defendant denies any wrongful conduct,
7 denies that Bextra® or Celebrex® caused Plaintiffs injury or damages, and denies the
8 remaining allegations in this paragraph of the Complaint.

9 64. Defendant states that the allegations in this paragraph of the Complaint regarding
10 Vioxx® are not directed toward Defendant, and, therefore, no response is required. Defendant
11 is without knowledge or information sufficient to form a belief as to the truth of the allegations
12 in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and Celebrex®,
13 and, therefore, denies the same. Defendant states that Bextra® and Celebrex® were and are
14 safe and effective when used in accordance with their FDA-approved prescribing information.
15 Defendant states that the potential effects of Bextra® and Celebrex® were and are adequately
16 described in their FDA-approved prescribing information, which was at all times adequate and
17 comported with applicable standards of care and law. Defendant denies any wrongful conduct,
18 denies that Bextra® or Celebrex® caused Plaintiffs injury or damages, and denies the
19 remaining allegations in this paragraph of the Complaint.

20 **Response to Sixth Cause of Action: Husband and Offspring Claims**

21 65. Defendant incorporates by reference its responses to each paragraph of Plaintiffs’
22 Complaint as if fully set forth herein.

23 66. Defendant denies any wrongful conduct, denies that Bextra® or Celebrex® caused
24 Plaintiffs injury or damages, and denies the remaining allegations in this paragraph of the
25 Complaint.

26 **Response to Allegations Regarding Obstinate and Temerarious Denial**

27 67. Defendant states that the allegations in this paragraph of the Complaint regarding Merck
28 and Vioxx® are not directed toward Defendant, and, therefore, no response is required.

1 Defendant states that Bextra® and Celebrex® were and are safe and effective when used in
2 accordance with their FDA-approved prescribing information. Defendant states that the
3 potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-
4 approved prescribing information, which was at all times adequate and comported with
5 applicable standards of care and law. Defendant denies any wrongful conduct, denies that
6 Bextra® or Celebrex® caused Plaintiffs injury or damages, and denies the remaining
7 allegations in this paragraph of the Complaint.

8 **Response to Demand for Relief**

9 Answering the unnumbered paragraph of the Complaint headed “Demand for Relief,”
10 Defendant denies any wrongful conduct, denies that Bextra® or Celebrex® caused Plaintiffs
11 injury or damages, and denies the remaining allegations in this paragraph of the Complaint,
12 including all subparts.

13 **III.**

14 **GENERAL DENIAL**

15 Defendant denies all allegations and/or legal conclusions set forth in Plaintiffs’
16 Complaint that have not been previously admitted, denied, or explained.

17 **IV.**

18 **AFFIRMATIVE DEFENSES**

19 Defendant reserves the right to rely upon any of the following or additional defenses to
20 claims asserted by Plaintiffs to the extent that such defenses are supported by information
21 developed through discovery or evidence at trial. Defendant affirmatively shows that:

22 **First Defense**

23 1. The Complaint fails to state a claim upon which relief can be granted.

24 **Second Defense**

25 2. Bextra® and Celebrex® are prescription medical products. The federal government has
26 preempted the field of law applicable to the labeling and warning of prescription medical
27 products. Defendant’s labeling and warning of Bextra® and Celebrex® was at all times in
28 compliance with applicable federal law. Plaintiffs’ causes of action against Defendant,

1 therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would
2 conflict with applicable federal law and violate the Supremacy Clause of the United States
3 Constitution.

4 **Third Defense**

5 3. At all relevant times, Defendant provided proper warnings, information and instructions
6 for the drugs in accordance with generally recognized and prevailing standards in existence at
7 the time.

8 **Fourth Defense**

9 4. At all relevant times, Defendant's warnings and instructions with respect to the use of
10 Bextra® and Celebrex® conformed to the generally recognized, reasonably available, and
11 reliable state of knowledge at the time the drugs were manufactured, marketed and distributed.

12 **Fifth Defense**

13 5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the
14 applicable Statute of Limitations, and same is pleaded in full bar of any liability as to
15 Defendant.

16 **Sixth Defense**

17 6. Plaintiffs' action is barred by the statute of repose.

18 **Seventh Defense**

19 7. Plaintiffs' claims against Defendant are barred to the extent Plaintiffs were
20 contributorily negligent, actively negligent, or otherwise failed to mitigate Plaintiffs' damages,
21 and any recovery by Plaintiffs should be diminished accordingly.

22 **Eighth Defense**

23 8. The proximate cause of the loss complained of by Plaintiffs is not due to any acts or
24 omissions on the part of Defendant. Rather, said loss is due to the acts or omissions on the part
25 of third parties unrelated to Defendant and for whose acts or omissions Defendant is not liable
26 in any way.

27 **Ninth Defense**

28 9. The acts and/or omissions of unrelated third parties as alleged constituted independent,

1 intervening causes for which Defendant cannot be liable.

2 **Tenth Defense**

3 10. Any injuries or expenses incurred by Plaintiffs were not caused by Bextra® or
4 Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction,
5 operation of nature, or act of God.

6 **Eleventh Defense**

7 11. Defendant affirmatively denies that it violated any duty owed to Plaintiffs.

8 **Twelfth Defense**

9 12. A manufacturer has no duty to warn patients or the general public of any risk,
10 contraindication, or adverse effect associated with the use of a prescription medical product.
11 Rather, the law requires that all such warnings and appropriate information be given to the
12 prescribing physician and the medical profession, which act as a “learned intermediary” in
13 determining the use of the product. Bextra® and Celebrex® are prescription medical products,
14 available only on the order of a licensed physician. Bextra® and Celebrex® provided adequate
15 warnings to Plaintiff’s treating and prescribing physicians.

16 **Thirteenth Defense**

17 13. The products at issue were not in a defective condition or unreasonably dangerous at the
18 time they left the control of the manufacturer or seller.

19 **Fourteenth Defense**

20 14. Bextra® and Celebrex® were at all times material to the Complaint reasonably safe and
21 reasonably fit for their intended use and the warnings and instructions accompanying Bextra®
22 and Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally
23 adequate for their approved usages.

24 **Fifteenth Defense**

25 15. Plaintiffs’ causes of action are barred in whole or in part by the lack of a defect as the
26 Bextra® and Celebrex® allegedly ingested by Plaintiff were prepared in accordance with the
27 applicable standard of care.

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Sixteenth Defense

16. Plaintiffs’ alleged injuries/damages, if any, were the result of misuse or abnormal use of the products Bextra® and Celebrex® after the products left the control of Defendant and any liability of Defendant is therefore barred.

Seventeenth Defense

17. Plaintiffs’ alleged damages were not caused by any failure to warn on the part of Defendant.

Eighteenth Defense

18. Plaintiffs’ alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra® and Celebrex®.

Nineteenth Defense

19. Plaintiff knew or should have known of any risk associated with Bextra® and Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiffs are barred from recovering against Defendant because Plaintiffs’ claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiffs’ claims are barred in whole or in part under the applicable state law because the subject pharmaceutical products at issue were subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical products referred to in Plaintiffs’ Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs’ causes of action are preempted.

Twenty-third Defense

23. Plaintiffs’ claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical products at

1 issue under applicable federal laws, regulations, and rules.

2 **Twenty-fourth Defense**

3 24. Plaintiffs’ claims are barred in whole or in part because there is no private right of
4 action concerning matters regulated by the Food and Drug Administration under applicable
5 federal laws, regulations, and rules.

6 **Twenty-fifth Defense**

7 25. Plaintiffs’ claims are barred in whole or in part because Defendant provided adequate
8 “direction or warnings” as to the use of the subject pharmaceutical products within the meaning
9 of Comment j to Section 402A of the Restatement (Second) of Torts.

10 **Twenty-sixth Defense**

11 26. Plaintiffs’ claims are barred or limited to a product liability failure to warn claim
12 because Bextra® and Celebrex® are prescription pharmaceutical drugs and fall within the
13 ambit of Restatement (Second) of Torts § 402A, Comment k.

14 **Twenty-seventh Defense**

15 27. Plaintiffs’ claims are barred in whole or in part because the subject pharmaceutical
16 products at issue “provide[] net benefits for a class of patients” within the meaning of Comment
17 f to § 6 of the Restatement (Third) of Torts: Products Liability.

18 **Twenty-eighth Defense**

19 28. Plaintiffs’ claims are barred under § 4, et seq., of the Restatement (Third) of Torts:
20 Products Liability.

21 **Twenty-ninth Defense**

22 29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs have failed to plead
23 facts sufficient under the law to justify an award of punitive damages.

24 **Thirtieth Defense**

25 30. Defendant affirmatively avers that the imposition of punitive damages in this case
26 would violate Defendant’s rights to procedural due process under the Fourteenth Amendment of
27 the United States Constitution and the Constitutions of the Puerto Rico and California, and
28 would additionally violate Defendant’s rights to substantive due process under the Fourteenth

1 Amendment of the United States Constitution.

2 **Thirty-first Defense**

3 31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and
4 Fourteenth Amendments to the United States Constitution.

5 **Thirty-second Defense**

6 32. The imposition of punitive damages in this case would violate the First Amendment to
7 the United States Constitution.

8 **Thirty-third Defense**

9 33. Plaintiffs' punitive damage claims are preempted by federal law.

10 **Thirty-fourth Defense**

11 34. In the event that reliance was placed upon Defendant's nonconformance to an express
12 representation, this action is barred as there was no reliance upon representations, if any, of
13 Defendant.

14 **Thirty-fifth Defense**

15 35. Plaintiffs failed to provide Defendant with timely notice of any alleged nonconformance
16 to any express representation.

17 **Thirty-sixth Defense**

18 36. To the extent that Plaintiffs' claims are based on a theory providing for liability without
19 proof of causation, the claims violate Defendant's rights under the United States Constitution.

20 **Thirty-seventh Defense**

21 37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and
22 labeling with respect to the subject pharmaceutical products were not false or misleading and,
23 therefore, constitute protected commercial speech under the applicable provisions of the United
24 States Constitution.

25 **Thirty-eighth Defense**

26 38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly
27 caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable
28 law or statute or, in the alternative, are unconstitutional insofar as they violate the due process

1 protections afforded by the United States Constitution, the excessive fines clause of the Eighth
2 Amendment of the United States Constitution, the Commerce Clause of the United States
3 Constitution, and the Full Faith and Credit Clause of the United States Constitution, and
4 applicable provisions of the Constitutions of Puerto Rico and California. Any law, statute, or
5 other authority purporting to permit the recovery of punitive damages in this case is
6 unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks
7 constitutionally sufficient standards to guide and restrain the jury's discretion in determining
8 whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that
9 it failed to provide adequate advance notice as to what conduct will result in punitive damages;
10 (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied
11 with applicable law, or conduct that was not directed, or did not proximately cause harm, to
12 Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable
13 and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of
14 compensatory damages, if any; (5) permits jury consideration of net worth or other financial
15 information relating to Defendant; (6) lacks constitutionally sufficient standards to be applied
16 by the trial court in post-verdict review of any punitive damages awards; (7) lacks
17 constitutionally sufficient standards for appellate review of punitive damages awards; and (8)
18 otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific*
19 *Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources,*
20 *Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State*
21 *Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

22 **Thirty-ninth Defense**

23 39. The methods, standards, and techniques utilized with respect to the manufacture, design,
24 and marketing of Bextra® and Celebrex®, if any, used in this case, included adequate warnings
25 and instructions with respect to the products' use in the package inserts and other literature, and
26 conformed to the generally recognized, reasonably available, and reliable state of the
27 knowledge at the time the products were marketed.

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Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® and Celebrex® were designed, tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendant and over whom Defendant had no control and for whom Defendant may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® and Celebrex® were not unreasonably dangerous or defective, were suitable for the purpose for which they were intended, and were distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiffs' claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendant's conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® and Celebrex® did not proximately cause injuries or damages to Plaintiffs.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendant's conduct.

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Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the products complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Bextra® and Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® and Celebrex® outweighed their risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendant's liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendant seeks an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®

1 and Celebrex® are comprehensively regulated by the FDA pursuant to the Federal Food, Drug
2 & Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under,
3 and Plaintiffs’ claims conflict with the FDCA, with the regulations promulgated by FDA to
4 implement the FDCA, with the purposes and objectives of the FDCA and FDA’s implementing
5 regulations, and with the specific determinations by FDA specifying the language that should
6 be used in the labeling accompanying Bextra® and Celebrex®. Accordingly, Plaintiffs’ claims
7 are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2,
8 and the laws of the United States.

9 **Fifty-fourth Defense**

10 54. Plaintiffs’ misrepresentation allegations are not stated with the degree of particularity
11 required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

12 **Fifty-fifth Defense**

13 55. Defendant states on information and belief that the Complaint and each purported cause
14 of action contained therein is barred by the statutes of limitations contained in California Code
15 of Civil Procedure §§ 335.1 and 338 and former § 340(3), and such other statutes of limitation
16 as may apply.

17 **Fifty-sixth Defense**

18 56. Defendant states on information and belief that any injuries, losses, or damages suffered
19 by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable
20 conduct of persons or entities other than Defendant. Therefore, Plaintiffs’ recovery against
21 Defendant, if any, should be reduced pursuant to California Civil Code § 1431.2.

22 **Fifty-seventh Defense**

23 57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of
24 Defendant, no act or omission was oppressive, fraudulent, or malicious under California Civil
25 Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive
26 damages is also barred under California Civil Code § 3294(b).

27 **Fifty-eighth Defense**

28 58. Defendant reserves the right to supplement its assertion of defenses as it continues with

1 its factual investigation of Plaintiffs' claims.

2 **V.**

3 **PRAYER**

4 WHEREFORE, Defendant prays for judgment as follows:

- 5 1. That Plaintiffs take nothing from Defendant by reason of the Complaint;
- 6 2. That the Complaint be dismissed;
- 7 3. That Defendant be awarded its costs for this lawsuit;
- 8 4. That the trier of fact determine what percentage of the combined fault or other liability
9 of all persons whose fault or other liability proximately caused Plaintiffs' alleged
10 injuries, losses or damages is attributable to each person;
- 11 5. That any judgment for damages against Defendant in favor of Plaintiffs be no greater
12 than an amount which equals its proportionate share, if any, of the total fault or other
13 liability which proximately caused Plaintiffs' injuries and damages; and
- 14 6. That Defendant has such other and further relief as the Court deems appropriate.

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June 11, 2008

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JURY DEMAND

Defendant Pfizer Inc. hereby demands a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

June 11, 2008

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