

Errata to the FDA Briefing Materials
“Briefing Document - Epidemiology: Evaluation of Anaphylaxis and Pulmonary Oil
Microembolism Reporting Rates”

1. Page 2, Executive Summary, paragraph 4, last sentence,
 from: 32.4 cases per 10,000 treatment years of exposure
 to: 5.5 cases per 10,000 treatment years of exposure

2. Page 2, Executive Summary, paragraph 5, second sentence,
 from: “...the rate seen... is significantly higher than published rates...”
 to: “...the rate seen...is on the high end of published rates...”

3. Page 17, Table 9, 5th row,
 from:

Cases per 10,000 person-years	16.2	19.4	21.3
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to:

Cases per 10,000 person-years	16.2	22.2	21.3
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4. Page 18, Table 10, 3rd row,
 from:

Gu (2009)** (500 mg monthly)	22/1054 (2.1%)	208.1	22/42,876 (<0.01%)	5.1
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to:

Gu (2009)** (500 mg monthly)	22/1054 (2.1%)	208.1	22/42,876 (0.05%)	5.1
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5. Page 18, table 11, 5th row,
 from:

Cases per 10,000 person-years	0.0	32.4	4.7
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to:

Cases per 10,000 person-years	0.0	5.5	4.7
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6. Page 19, section 3.5.3, 3rd paragraph, 5th sentence,
 from: “...(or 32.4 cases per 10,000 person-years) is significantly higher than...”
 to: “...(or 5.5 cases per 10,000 person-years) is on the high end of...”

7. Page 20, section 3.5.3, 4th paragraph, 5th sentence,
from: "...is higher than other published rates."
to: "...is on the high end of other published rates."

8. Page 20, section 4, 4th paragraph, 5th sentence,
from: "...32.4 cases per 10,000 patient-years is higher than published rates..."
to: "...5.5 cases per 10,000 patient-years is on the high end of published rates..."