

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 7. Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>		<i>Treatment (ug/kg)</i>					
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
<b>Alimentary System</b>							
Liver * Basophilic Focus	Simple Incidence	0/20 ( 0.0%)	1/22 ( 4.5%)	1/20 ( 5.0%)	2/22 ( 9.1%)	3/20 ( 15.0%)	2/22 ( 9.1%)
	Terminal Incidence	0/20 ( 0.0%)	1/22 ( 4.5%)	1/20 ( 5.0%)	2/22 ( 9.1%)	3/20 ( 15.0%)	2/20 ( 10.0%)
	Time-to-First	----	363 (T)	363 (T)	364 (T)	363 (T)	363 (T)
	CAFE P-Value	0.058	0.524	0.500	0.268	0.115	0.268
Liver * Eosinophilic Focus	Simple Incidence	0/20 ( 0.0%)	0/22 ( 0.0%)	1/20 ( 5.0%)	1/22 ( 4.5%)	1/20 ( 5.0%)	2/22 ( 9.1%)
	Terminal Incidence	0/20 ( 0.0%)	0/22 ( 0.0%)	1/20 ( 5.0%)	1/22 ( 4.5%)	1/20 ( 5.0%)	2/20 ( 10.0%)
	Time-to-First	----	----	365 (T)	366 (T)	365 (T)	363 (T)
	CAFE P-Value	0.059		0.500	0.524	0.500	0.268
Liver * Fatty Change	Simple Incidence	1/20 ( 5.0%)	2/22 ( 9.1%)	2/20 ( 10.0%)	4/22 ( 18.2%)	1/20 ( 5.0%)	0/22 ( 0.0%)
	Terminal Incidence	1/20 ( 5.0%)	2/22 ( 9.1%)	2/20 ( 10.0%)	4/22 ( 18.2%)	1/20 ( 5.0%)	0/20 ( 0.0%)
	Time-to-First	365 (T)	364 (T)	364 (T)	363 (T)	363 (T)	----
	CAFE P-Value	0.302N	0.537	0.500	0.203	0.756	0.476N
	Severity Profile	0 1 0 0	0 2 0 0	0 0 2 0	2 2 0 0	1 0 0 0	---
	JT/SW P-Value	0.245N	0.694N	0.793N	0.885N	0.618N	0.371N
	RTE P-Value	0.264N	0.312	0.198	0.087	0.485N	0.274N
Liver * Hepatodiaphragmatic Nodule	Simple Incidence	1/20 ( 5.0%)	2/22 ( 9.1%)	1/20 ( 5.0%)	1/22 ( 4.5%)	2/20 ( 10.0%)	5/22 ( 22.7%)
	Terminal Incidence	1/20 ( 5.0%)	2/22 ( 9.1%)	1/20 ( 5.0%)	1/22 ( 4.5%)	2/20 ( 10.0%)	5/20 ( 25.0%)
	Time-to-First	363 (T)	361 (T)	364 (T)	363 (T)	363 (T)	362 (T)
	CAFE P-Value	0.051	0.537	0.756	0.732N	0.500	0.115
Liver * Hyperplasia,Bile Duct	Simple Incidence	4/20 ( 20.0%)	2/22 ( 9.1%)	4/20 ( 20.0%)	3/22 ( 13.6%)	3/20 ( 15.0%)	8/22 ( 36.4%)
	Terminal Incidence	4/20 ( 20.0%)	2/22 ( 9.1%)	4/20 ( 20.0%)	3/22 ( 13.6%)	3/20 ( 15.0%)	7/20 ( 35.0%)
	Time-to-First	361 (T)	363 (T)	364 (T)	362 (T)	363 (T)	255
	CAFE P-Value	0.095	0.286N	0.653	0.444N	0.500N	0.204
	Severity Profile	3 1 0 0	0 1 1 0	3 1 0 0	2 1 0 0	3 0 0 0	7 1 0 0
	JT/SW P-Value	0.108	0.802	0.583	0.733	0.775	0.136
	RTE P-Value	0.121	0.221N	0.500	0.308N	0.325N	0.099
Liver * Infiltration Cellular,Mononuclear Cell	Simple Incidence	2/20 ( 10.0%)	10/22 ( 45.5%)	7/20 ( 35.0%)	7/22 ( 31.8%)	2/20 ( 10.0%)	8/22 ( 36.4%)
	Terminal Incidence	2/20 ( 10.0%)	10/22 ( 45.5%)	7/20 ( 35.0%)	7/22 ( 31.8%)	2/20 ( 10.0%)	8/20 ( 40.0%)
	Time-to-First	364 (T)	359 (T)	363 (T)	363 (T)	363 (T)	362 (T)
	CAFE P-Value	0.425	0.012 *	0.064	0.088	0.698	0.048 *
	Severity Profile	1 1 0 0	10 0 0 0	7 0 0 0	7 0 0 0	2 0 0 0	8 0 0 0
	JT/SW P-Value	0.439	0.010 ** <sup>1</sup>	0.031 * <sup>1</sup>	0.046 * <sup>1</sup>	0.109	0.049 *
	RTE P-Value	0.427	0.009 **	0.053	0.081	0.460N	0.038 *

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 7. Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>		<i>Treatment (ug/kg)</i>					
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Liver * Tension Lipidosis	Simple Incidence	1/20 ( 5.0%)	2/22 ( 9.1%)	2/20 ( 10.0%)	1/22 ( 4.5%)	4/20 ( 20.0%)	4/22 ( 18.2%)
	Terminal Incidence	1/20 ( 5.0%)	2/22 ( 9.1%)	2/20 ( 10.0%)	1/22 ( 4.5%)	4/20 ( 20.0%)	4/20 ( 20.0%)
	Time-to-First	366 (T)	361 (T)	365 (T)	363 (T)	363 (T)	362 (T)
	CAFE P-Value	0.065	0.537	0.500	0.732N	0.171	0.203
	Severity Profile	0 1 0 0	0 1 1 0	0 0 1 1	0 1 0 0	1 2 1 0	2 0 1 1
	JT/SW P-Value	0.060	0.296	0.308	0.446	0.075	0.102
	RTE P-Value	0.060	0.330	0.281	0.482N	0.083	0.098
Liver * Vacuolization Cytoplasmic	Simple Incidence	2/20 ( 10.0%)	1/22 ( 4.5%)	3/20 ( 15.0%)	4/22 ( 18.2%)	0/20 ( 0.0%)	0/22 ( 0.0%)
	Terminal Incidence	2/20 ( 10.0%)	1/22 ( 4.5%)	3/20 ( 15.0%)	4/22 ( 18.2%)	0/20 ( 0.0%)	0/20 ( 0.0%)
	Time-to-First	363 (T)	359 (T)	363 (T)	363 (T)	----	----
	CAFE P-Value	0.137N	0.463N	0.500	0.380	0.244N	0.221N
	Severity Profile	2 0 0 0	1 0 0 0	3 0 0 0	3 1 0 0	---	---
	JT/SW P-Value	0.121N	0.249N	0.562N	0.727N	0.191N	0.158N
	RTE P-Value	0.116N	0.257N	0.279	0.169	0.105N	0.137N
Pancreas * Degeneration,Acinus	Simple Incidence	16/20 ( 80.0%)	14/22 ( 63.6%)	13/20 ( 65.0%)	14/22 ( 63.6%)	17/20 ( 85.0%)	17/22 ( 77.3%)
	Terminal Incidence	16/20 ( 80.0%)	14/22 ( 63.6%)	13/20 ( 65.0%)	14/22 ( 63.6%)	17/20 ( 85.0%)	16/20 ( 80.0%)
	Time-to-First	361 (T)	361 (T)	363 (T)	362 (T)	362 (T)	255
	CAFE P-Value	0.288	0.204N	0.240N	0.204N	0.500	0.565N
	Severity Profile	1 8 6 1	3 7 4 0	4 8 1 0	4 5 4 1	6 7 3 1	8 8 1 0
	JT/SW P-Value	0.120N	0.047N* <sup>1</sup>	0.015N* <sup>1</sup>	0.035N* <sup>1</sup>	0.069N	0.023N*
	RTE P-Value	0.108N	0.041N*	0.014N*	0.041N*	0.183N	0.020N*
Pancreas * Pigmentation	Simple Incidence	4/20 ( 20.0%)	1/22 ( 4.5%)	1/20 ( 5.0%)	0/22 ( 0.0%)	4/20 ( 20.0%)	2/22 ( 9.1%)
	Terminal Incidence	4/20 ( 20.0%)	1/22 ( 4.5%)	1/20 ( 5.0%)	0/22 ( 0.0%)	4/20 ( 20.0%)	2/20 ( 10.0%)
	Time-to-First	364 (T)	365 (T)	364 (T)	----	363 (T)	363 (T)
	CAFE P-Value	0.445N	0.144N	0.171N	0.043N*	0.653	0.286N
	Severity Profile	4 0 0 0	1 0 0 0	1 0 0 0	---	4 0 0 0	2 0 0 0
	JT/SW P-Value	0.410N	0.063N	0.062N	0.007N** <sup>1</sup>	0.110N	0.113N
	RTE P-Value	0.402N	0.033N*	0.038N*	0.017N*	0.500	0.082N

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<i>Table 7. Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
<b>Cardiovascular System</b>							
Heart * Cardiomyopathy	Simple Incidence	6/20 ( 30.0%)	8/22 ( 36.4%)	7/20 ( 35.0%)	7/22 ( 31.8%)	6/20 ( 30.0%)	7/22 ( 31.8%)
	Terminal Incidence	6/20 ( 30.0%)	8/22 ( 36.4%)	7/20 ( 35.0%)	7/22 ( 31.8%)	6/20 ( 30.0%)	7/20 ( 35.0%)
	Time-to-First	362 (T)	364 (T)	363 (T)	362 (T)	362 (T)	362 (T)
	CAFE P-Value	0.457N	0.457	0.500	0.582	0.634	0.582
	Severity Profile	6 0 0 0	8 0 0 0	6 1 0 0	5 2 0 0	6 0 0 0	5 2 0 0
	JT/SW P-Value	0.483	0.333	0.394	0.441	0.502	0.500
	RTE P-Value	0.484	0.342	0.337	0.377	0.500	0.377
<b>Endocrine System</b>							
Adrenal Cortex * Degeneration,Cystic	Simple Incidence	0/20 ( 0.0%)	1/22 ( 4.5%)	0/20 ( 0.0%)	2/22 ( 9.1%)	0/20 ( 0.0%)	0/22 ( 0.0%)
	Terminal Incidence	0/20 ( 0.0%)	1/22 ( 4.5%)	0/20 ( 0.0%)	2/22 ( 9.1%)	0/20 ( 0.0%)	0/20 ( 0.0%)
	Time-to-First	----	363 (T)	----	364 (T)	----	----
	CAFE P-Value	0.491N	0.524		0.268		
	Severity Profile	---	0 0 1 0	---	1 0 0 1	---	---
	JT/SW P-Value	0.423N	0.830N	0.583N	0.893N	0.636N	0.648N
	RTE P-Value	0.435N	0.149	0.500	0.037 *	0.500	0.500
Parathyroid Gland * Hyperplasia	Simple Incidence	1/20 ( 5.0%)	1/21 ( 4.8%)	0/20 ( 0.0%)	2/22 ( 9.1%)	2/19 ( 10.5%)	0/22 ( 0.0%)
	Terminal Incidence	1/20 ( 5.0%)	1/21 ( 4.8%)	0/20 ( 0.0%)	2/22 ( 9.1%)	2/19 ( 10.5%)	0/20 ( 0.0%)
	Time-to-First	365 (T)	364 (T)	----	364 (T)	363 (T)	----
	CAFE P-Value	0.534N	0.744N	0.500N	0.537	0.480	0.476N
	Severity Profile	1 0 0 0	0 1 0 0	---	0 2 0 0	1 1 0 0	---
	JT/SW P-Value	0.491N	0.500N	0.231N	0.618N	0.712N	0.317N
	RTE P-Value	0.481	0.500	0.240N	0.256	0.152	0.235N
Pituitary Gland * Angiectasis	Simple Incidence	0/20 ( 0.0%)	2/22 ( 9.1%)	1/20 ( 5.0%)	0/22 ( 0.0%)	0/20 ( 0.0%)	0/22 ( 0.0%)
	Terminal Incidence	0/20 ( 0.0%)	2/22 ( 9.1%)	1/20 ( 5.0%)	0/22 ( 0.0%)	0/20 ( 0.0%)	0/20 ( 0.0%)
	Time-to-First	----	363 (T)	365 (T)	----	----	----
	CAFE P-Value	0.154N	0.268	0.500			
	Severity Profile	---	0 1 1 0	0 1 0 0	---	---	---
	JT/SW P-Value	0.110N	0.914N	0.843N	0.618N	0.636N	0.648N
	RTE P-Value	0.145N	0.015 *	0.161	0.500	0.500	0.500
Pituitary Gland * Cyst,Pars Distalis	Simple Incidence	3/20 ( 15.0%)	0/22 ( 0.0%)	0/20 ( 0.0%)	0/22 ( 0.0%)	0/20 ( 0.0%)	2/22 ( 9.1%)
	Terminal Incidence	3/20 ( 15.0%)	0/22 ( 0.0%)	0/20 ( 0.0%)	0/22 ( 0.0%)	0/20 ( 0.0%)	2/20 ( 10.0%)
	Time-to-First	363 (T)	----	----	----	----	362 (T)
	CAFE P-Value	0.291N	0.099N	0.115N	0.099N	0.115N	0.453N

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<i>Table 7. Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Pituitary Gland * Hyperplasia,Pars Distalis	Simple Incidence	18/20 ( 90.0%)	16/22 ( 72.7%)	14/20 ( 70.0%)	20/22 ( 90.9%)	16/20 ( 80.0%)	18/22 ( 81.8%)
	Terminal Incidence	18/20 ( 90.0%)	16/22 ( 72.7%)	14/20 ( 70.0%)	20/22 ( 90.9%)	16/20 ( 80.0%)	18/20 ( 90.0%)
	Time-to-First	361 (T)	361 (T)	363 (T)	362 (T)	362 (T)	362 (T)
	CAFE P-Value	0.496	0.152N	0.118N	0.659	0.331N	0.380N
	Severity Profile	10 8 0 0	10 4 2 0	5 5 4 0	10 9 1 0	6 7 3 0	9 8 1 0
	JT/SW P-Value	0.273	0.861	0.626	0.450	0.440	0.546
	RTE P-Value	0.264	0.179N	0.497	0.356	0.334	0.447N
Thyroid Gland * Hyperplasia,C-Cell	Simple Incidence	10/20 ( 50.0%)	16/22 ( 72.7%)	11/20 ( 55.0%)	12/22 ( 54.5%)	13/20 ( 65.0%)	9/22 ( 40.9%)
	Terminal Incidence	10/20 ( 50.0%)	16/22 ( 72.7%)	11/20 ( 55.0%)	12/22 ( 54.5%)	13/20 ( 65.0%)	9/20 ( 45.0%)
	Time-to-First	361 (T)	359 (T)	363 (T)	363 (T)	362 (T)	362 (T)
	CAFE P-Value	0.211N	0.116	0.500	0.506	0.262	0.390N
	Severity Profile	10 0 0 0	11 4 1 0	8 3 0 0	8 4 0 0	11 2 0 0	8 1 0 0
	JT/SW P-Value	0.204N	0.982N	0.859N	0.896N	0.927N	0.492N
	RTE P-Value	0.235N	0.024 *	0.221	0.194	0.126	0.367N
Thyroid Gland * Ultimobranchial Cyst	Simple Incidence	4/20 ( 20.0%)	6/22 ( 27.3%)	7/20 ( 35.0%)	4/22 ( 18.2%)	6/20 ( 30.0%)	6/22 ( 27.3%)
	Terminal Incidence	4/20 ( 20.0%)	6/22 ( 27.3%)	7/20 ( 35.0%)	4/22 ( 18.2%)	6/20 ( 30.0%)	6/20 ( 30.0%)
	Time-to-First	363 (T)	359 (T)	363 (T)	363 (T)	363 (T)	362 (T)
	CAFE P-Value	0.397	0.426	0.240	0.594N	0.358	0.426
<b>Genital System</b>							
Ovary * Atrophy	Simple Incidence	10/20 ( 50.0%)	9/22 ( 40.9%)	11/20 ( 55.0%)	6/22 ( 27.3%)	12/20 ( 60.0%)	15/22 ( 68.2%)
	Terminal Incidence	10/20 ( 50.0%)	9/22 ( 40.9%)	11/20 ( 55.0%)	6/22 ( 27.3%)	12/20 ( 60.0%)	14/20 ( 70.0%)
	Time-to-First	361 (T)	363 (T)	363 (T)	363 (T)	363 (T)	255
	CAFE P-Value	0.097	0.390N	0.500	0.116N	0.376	0.188
	Severity Profile	2 6 0 2	1 4 0 4	8 1 0 2	1 3 0 2	5 4 0 3	4 5 0 6
	JT/SW P-Value	0.094	0.588	0.709	0.856	0.449	0.131
	RTE P-Value	0.100	0.390N	0.374N	0.095N	0.348	0.099
Ovary * Cyst	Simple Incidence	0/20 ( 0.0%)	2/22 ( 9.1%)	0/20 ( 0.0%)	0/22 ( 0.0%)	0/20 ( 0.0%)	0/22 ( 0.0%)
	Terminal Incidence	0/20 ( 0.0%)	2/22 ( 9.1%)	0/20 ( 0.0%)	0/22 ( 0.0%)	0/20 ( 0.0%)	0/20 ( 0.0%)
	Time-to-First	----	364 (T)	----	----	----	----
	CAFE P-Value	0.160N	0.268				
Ovary * Cyst,Corpus Luteum	Simple Incidence	2/20 ( 10.0%)	2/22 ( 9.1%)	2/20 ( 10.0%)	5/22 ( 22.7%)	1/20 ( 5.0%)	0/22 ( 0.0%)
	Terminal Incidence	2/20 ( 10.0%)	2/22 ( 9.1%)	2/20 ( 10.0%)	5/22 ( 22.7%)	1/20 ( 5.0%)	0/20 ( 0.0%)
	Time-to-First	365 (T)	363 (T)	364 (T)	362 (T)	363 (T)	----
	CAFE P-Value	0.201N	0.659N	0.698	0.247	0.500N	0.221N

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<i>Table 7. Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>		<i>Treatment (ug/kg)</i>					
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Ovary * Cyst,Follicle	Simple Incidence	5/20 ( 25.0%)	6/22 ( 27.3%)	4/20 ( 20.0%)	7/22 ( 31.8%)	11/20 ( 55.0%)	18/22 ( 81.8%)
	Terminal Incidence	5/20 ( 25.0%)	6/22 ( 27.3%)	4/20 ( 20.0%)	7/22 ( 31.8%)	11/20 ( 55.0%)	17/20 ( 85.0%)
	Time-to-First	362 (T)	363 (T)	364 (T)	364 (T)	363 (T)	255
	CAFE P-Value	<.001 ***	0.574	0.500N	0.443	0.053	<.001 ***
Ovary * Cyst,Periovarian Tissue	Simple Incidence	0/20 ( 0.0%)	0/22 ( 0.0%)	0/20 ( 0.0%)	2/22 ( 9.1%)	0/20 ( 0.0%)	0/22 ( 0.0%)
	Terminal Incidence	0/20 ( 0.0%)	0/22 ( 0.0%)	0/20 ( 0.0%)	2/22 ( 9.1%)	0/20 ( 0.0%)	0/20 ( 0.0%)
	Time-to-First	----	----	----	365 (T)	----	----
	CAFE P-Value	0.424			0.268		
Ovary * Depletion,Corpus Luteum	Simple Incidence	2/20 ( 10.0%)	4/22 ( 18.2%)	2/20 ( 10.0%)	2/22 ( 9.1%)	3/20 ( 15.0%)	6/22 ( 27.3%)
	Terminal Incidence	2/20 ( 10.0%)	4/22 ( 18.2%)	2/20 ( 10.0%)	2/22 ( 9.1%)	3/20 ( 15.0%)	6/20 ( 30.0%)
	Time-to-First	362 (T)	363 (T)	364 (T)	365 (T)	363 (T)	363 (T)
	CAFE P-Value	0.138	0.380	0.698	0.659N	0.500	0.152
Ovary * Diestrus	Simple Incidence	10/20 ( 50.0%)	11/22 ( 50.0%)	9/20 ( 45.0%)	12/22 ( 54.5%)	11/20 ( 55.0%)	13/22 ( 59.1%)
	Terminal Incidence	10/20 ( 50.0%)	11/22 ( 50.0%)	9/20 ( 45.0%)	12/22 ( 54.5%)	11/20 ( 55.0%)	11/20 ( 55.0%)
	Time-to-First	361 (T)	359 (T)	364 (T)	362 (T)	362 (T)	43
	CAFE P-Value	0.236	0.621	0.500N	0.506	0.500	0.390
Ovary * Hypertrophy,Interstitial Cell	Simple Incidence	4/20 ( 20.0%)	3/22 ( 13.6%)	1/20 ( 5.0%)	2/22 ( 9.1%)	3/20 ( 15.0%)	5/22 ( 22.7%)
	Terminal Incidence	4/20 ( 20.0%)	3/22 ( 13.6%)	1/20 ( 5.0%)	2/22 ( 9.1%)	3/20 ( 15.0%)	5/20 ( 25.0%)
	Time-to-First	363 (T)	363 (T)	364 (T)	365 (T)	363 (T)	363 (T)
	CAFE P-Value	0.380	0.444N	0.171N	0.286N	0.500N	0.565
	Severity Profile	0 1 3 0	0 2 1 0	0 1 0 0	0 2 0 0	0 3 0 0	0 4 1 0
	JT/SW P-Value	0.400	0.739	0.919	0.951	0.865	0.601
	RTE P-Value	0.429	0.244N	0.061N	0.117N	0.268N	0.459
Ovary * Metestrus	Simple Incidence	7/20 ( 35.0%)	5/22 ( 22.7%)	4/20 ( 20.0%)	4/22 ( 18.2%)	5/20 ( 25.0%)	2/22 ( 9.1%)
	Terminal Incidence	7/20 ( 35.0%)	5/22 ( 22.7%)	4/20 ( 20.0%)	4/22 ( 18.2%)	5/20 ( 25.0%)	2/20 ( 10.0%)
	Time-to-First	362 (T)	361 (T)	363 (T)	363 (T)	363 (T)	365 (T)
	CAFE P-Value	0.055N	0.296N	0.240N	0.188N	0.366N	0.047N*
Ovary * Proestrus	Simple Incidence	1/20 ( 5.0%)	2/22 ( 9.1%)	5/20 ( 25.0%)	4/22 ( 18.2%)	1/20 ( 5.0%)	1/22 ( 4.5%)
	Terminal Incidence	1/20 ( 5.0%)	2/22 ( 9.1%)	5/20 ( 25.0%)	4/22 ( 18.2%)	1/20 ( 5.0%)	1/20 ( 5.0%)
	Time-to-First	364 (T)	363 (T)	363 (T)	363 (T)	366 (T)	364 (T)
	CAFE P-Value	0.382N	0.537	0.091	0.203	0.756	0.732N

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<b>Table 7. Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Stop Dose Arm</b>							
<b>System and Nonneoplasm</b>	<b>Treatment (ug/kg)</b>						
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>2.5</b>	<b>25</b>	<b>250</b>	<b>2500</b>	<b>25000</b>
Uterus * Apoptosis	Simple Incidence	2/20 ( 10.0%)	3/22 ( 13.6%)	2/20 ( 10.0%)	2/22 ( 9.1%)	1/20 ( 5.0%)	6/22 ( 27.3%)
	Terminal Incidence	2/20 ( 10.0%)	3/22 ( 13.6%)	2/20 ( 10.0%)	2/22 ( 9.1%)	1/20 ( 5.0%)	6/20 ( 30.0%)
	Time-to-First	362 (T)	363 (T)	364 (T)	365 (T)	363 (T)	363 (T)
	CAFE P-Value	0.171	0.547	0.698	0.659N	0.500N	0.152
	Severity Profile	0 0 0 2	0 1 0 2	0 0 1 1	0 0 2 0	0 0 0 1	0 1 0 5
	JT/SW P-Value	0.149	0.377	0.522	0.603	0.680	0.061
	RTE P-Value	0.161	0.382	0.479N	0.425N	0.312N	0.055
Uterus * Cyst,Endometrium	Simple Incidence	0/20 ( 0.0%)	1/22 ( 4.5%)	2/20 ( 10.0%)	2/22 ( 9.1%)	3/20 ( 15.0%)	0/22 ( 0.0%)
	Terminal Incidence	0/20 ( 0.0%)	1/22 ( 4.5%)	2/20 ( 10.0%)	2/22 ( 9.1%)	3/20 ( 15.0%)	0/20 ( 0.0%)
	Time-to-First	----	363 (T)	365 (T)	364 (T)	363 (T)	----
	CAFE P-Value	0.314	0.524	0.244	0.268	0.115	
Uterus * Diestrus	Simple Incidence	7/20 ( 35.0%)	10/22 ( 45.5%)	7/20 ( 35.0%)	7/22 ( 31.8%)	9/20 ( 45.0%)	10/22 ( 45.5%)
	Terminal Incidence	7/20 ( 35.0%)	10/22 ( 45.5%)	7/20 ( 35.0%)	7/22 ( 31.8%)	9/20 ( 45.0%)	9/20 ( 45.0%)
	Time-to-First	361 (T)	361 (T)	364 (T)	363 (T)	362 (T)	255
	CAFE P-Value	0.324	0.355	0.629	0.543N	0.374	0.355
Uterus * Dilatation,Lumen	Simple Incidence	1/20 ( 5.0%)	0/22 ( 0.0%)	1/20 ( 5.0%)	4/22 ( 18.2%)	1/20 ( 5.0%)	0/22 ( 0.0%)
	Terminal Incidence	1/20 ( 5.0%)	0/22 ( 0.0%)	1/20 ( 5.0%)	4/22 ( 18.2%)	1/20 ( 5.0%)	0/20 ( 0.0%)
	Time-to-First	363 (T)	----	363 (T)	363 (T)	366 (T)	----
	CAFE P-Value	0.515	0.476N	0.756	0.203	0.756	0.476N
	Severity Profile	0 0 0 1	---	0 0 0 1	0 0 1 3	0 0 1 0	---
	JT/SW P-Value	0.485	0.853	0.583	0.064	0.264	0.473
	RTE P-Value	0.479	0.234N	0.500	0.045 *	0.485N	0.234N
Uterus * Estrus	Simple Incidence	2/20 ( 10.0%)	4/22 ( 18.2%)	2/20 ( 10.0%)	2/22 ( 9.1%)	2/20 ( 10.0%)	6/22 ( 27.3%)
	Terminal Incidence	2/20 ( 10.0%)	4/22 ( 18.2%)	2/20 ( 10.0%)	2/22 ( 9.1%)	2/20 ( 10.0%)	6/20 ( 30.0%)
	Time-to-First	362 (T)	363 (T)	364 (T)	365 (T)	363 (T)	363 (T)
	CAFE P-Value	0.185	0.380	0.698	0.659N	0.698	0.152
Uterus * Hyperplasia,Cystic,Endometrium	Simple Incidence	2/20 ( 10.0%)	4/22 ( 18.2%)	2/20 ( 10.0%)	2/22 ( 9.1%)	1/20 ( 5.0%)	7/22 ( 31.8%)
	Terminal Incidence	2/20 ( 10.0%)	4/22 ( 18.2%)	2/20 ( 10.0%)	2/22 ( 9.1%)	1/20 ( 5.0%)	7/20 ( 35.0%)
	Time-to-First	362 (T)	359 (T)	364 (T)	365 (T)	363 (T)	363 (T)
	CAFE P-Value	0.148	0.380	0.698	0.659N	0.500N	0.088
	Severity Profile	0 1 0 1	0 2 2 0	0 2 0 0	0 2 0 0	0 0 0 1	2 4 0 1
	JT/SW P-Value	0.158	0.241	0.429	0.527	0.617	0.039 *
	RTE P-Value	0.173	0.224	0.474N	0.441N	0.329N	0.030 *

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

**Table 7. Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Stop Dose Arm**

System and Nonneoplasm	Lesion	Statistic	Treatment (ug/kg)				
			Control	2.5	25	250	2500
Uterus * Hyperplasia,Endometrial Glands	Simple Incidence	1/20 ( 5.0%)	0/22 ( 0.0%)	1/20 ( 5.0%)	1/22 ( 4.5%)	0/20 ( 0.0%)	2/22 ( 9.1%)
	Terminal Incidence	1/20 ( 5.0%)	0/22 ( 0.0%)	1/20 ( 5.0%)	1/22 ( 4.5%)	0/20 ( 0.0%)	2/20 ( 10.0%)
	Time-to-First	362 (T)	----	364 (T)	366 (T)	----	362 (T)
	CAFE P-Value	0.313	0.476N	0.756	0.732N	0.500N	0.537
	Severity Profile	0 1 0 0	---	0 1 0 0	0 1 0 0	---	0 2 0 0
	JT/SW P-Value	0.263	0.853	0.583	0.636	0.771	0.338
	RTE P-Value	0.290	0.207N	0.500	0.470N	0.212N	0.252
Uterus * Hyperplasia,Endometrium	Simple Incidence	6/20 ( 30.0%)	9/22 ( 40.9%)	5/20 ( 25.0%)	7/22 ( 31.8%)	6/20 ( 30.0%)	9/22 ( 40.9%)
	Terminal Incidence	6/20 ( 30.0%)	9/22 ( 40.9%)	5/20 ( 25.0%)	7/22 ( 31.8%)	6/20 ( 30.0%)	9/20 ( 45.0%)
	Time-to-First	361 (T)	361 (T)	364 (T)	363 (T)	363 (T)	362 (T)
	CAFE P-Value	0.392	0.340	0.500N	0.582	0.634	0.340
	Severity Profile	1 4 1 0	1 6 2 0	2 2 1 0	2 4 1 0	0 6 0 0	0 7 2 0
	JT/SW P-Value	0.333	0.216	0.488	0.544	0.581	0.249
	RTE P-Value	0.338	0.211	0.340N	0.486	0.499N	0.190
Uterus * Metaplasia,Squamous	Simple Incidence	0/20 ( 0.0%)	2/22 ( 9.1%)	1/20 ( 5.0%)	1/22 ( 4.5%)	0/20 ( 0.0%)	4/22 ( 18.2%)
	Terminal Incidence	0/20 ( 0.0%)	2/22 ( 9.1%)	1/20 ( 5.0%)	1/22 ( 4.5%)	0/20 ( 0.0%)	4/20 ( 20.0%)
	Time-to-First	----	364 (T)	365 (T)	365 (T)	----	363 (T)
	CAFE P-Value	0.091	0.268	0.500	0.524	----	0.065
	Severity Profile	---	2 0 0 0	0 1 0 0	1 0 0 0	---	1 3 0 0
	JT/SW P-Value	0.067	0.086	0.177	0.220	0.289	0.009 **
	RTE P-Value	0.067	0.134	0.190	0.278	0.500	0.005 **
Uterus * Metestrus	Simple Incidence	8/20 ( 40.0%)	7/22 ( 31.8%)	6/20 ( 30.0%)	8/22 ( 36.4%)	7/20 ( 35.0%)	4/22 ( 18.2%)
	Terminal Incidence	8/20 ( 40.0%)	7/22 ( 31.8%)	6/20 ( 30.0%)	8/22 ( 36.4%)	7/20 ( 35.0%)	3/20 ( 15.0%)
	Time-to-First	362 (T)	359 (T)	363 (T)	363 (T)	362 (T)	43
	CAFE P-Value	0.146N	0.409N	0.371N	0.530N	0.500N	0.111N
Uterus * Proestrus	Simple Incidence	2/20 ( 10.0%)	1/22 ( 4.5%)	5/20 ( 25.0%)	5/22 ( 22.7%)	2/20 ( 10.0%)	2/22 ( 9.1%)
	Terminal Incidence	2/20 ( 10.0%)	1/22 ( 4.5%)	5/20 ( 25.0%)	5/22 ( 22.7%)	2/20 ( 10.0%)	2/20 ( 10.0%)
	Time-to-First	363 (T)	365 (T)	363 (T)	362 (T)	365 (T)	362 (T)
	CAFE P-Value	0.464	0.463N	0.204	0.247	0.698	0.659N
Vagina * Diestrus	Simple Incidence	6/20 ( 30.0%)	11/22 ( 50.0%)	9/20 ( 45.0%)	10/22 ( 45.5%)	9/20 ( 45.0%)	10/22 ( 45.5%)
	Terminal Incidence	6/20 ( 30.0%)	11/22 ( 50.0%)	9/20 ( 45.0%)	10/22 ( 45.5%)	9/20 ( 45.0%)	9/20 ( 45.0%)
	Time-to-First	361 (T)	359 (T)	364 (T)	363 (T)	362 (T)	255
	CAFE P-Value	0.276	0.158	0.257	0.239	0.257	0.239

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 7. Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Vagina * Estrus	Simple Incidence	2/20 ( 10.0%)	3/22 ( 13.6%)	2/20 ( 10.0%)	2/22 ( 9.1%)	2/20 ( 10.0%)	6/22 ( 27.3%)
	Terminal Incidence	2/20 ( 10.0%)	3/22 ( 13.6%)	2/20 ( 10.0%)	2/22 ( 9.1%)	2/20 ( 10.0%)	6/20 ( 30.0%)
	Time-to-First	362 (T)	363 (T)	364 (T)	365 (T)	363 (T)	363 (T)
	CAFE P-Value	0.125	0.547	0.698	0.659N	0.698	0.152
Vagina * Hyperplasia,Epithelium	Simple Incidence	2/20 ( 10.0%)	4/22 ( 18.2%)	2/20 ( 10.0%)	1/22 ( 4.5%)	2/20 ( 10.0%)	6/22 ( 27.3%)
	Terminal Incidence	2/20 ( 10.0%)	4/22 ( 18.2%)	2/20 ( 10.0%)	1/22 ( 4.5%)	2/20 ( 10.0%)	6/20 ( 30.0%)
	Time-to-First	362 (T)	363 (T)	364 (T)	365 (T)	363 (T)	363 (T)
	CAFE P-Value	0.199	0.380	0.698	0.463N	0.698	0.152
	Severity Profile	0 0 2 0	0 0 4 0	0 0 2 0	0 0 0 1	0 1 1 0	0 1 5 0
	JT/SW P-Value	0.189	0.227	0.409	0.567	0.604	0.073
	RTE P-Value	0.201	0.219	0.500	0.320N	0.477N	0.064
Vagina * Metestrus	Simple Incidence	9/20 ( 45.0%)	6/22 ( 27.3%)	4/20 ( 20.0%)	5/22 ( 22.7%)	7/20 ( 35.0%)	4/22 ( 18.2%)
	Terminal Incidence	9/20 ( 45.0%)	6/22 ( 27.3%)	4/20 ( 20.0%)	5/22 ( 22.7%)	7/20 ( 35.0%)	3/20 ( 15.0%)
	Time-to-First	362 (T)	361 (T)	363 (T)	363 (T)	362 (T)	43
	CAFE P-Value	0.105N	0.191N	0.088N	0.115N	0.374N	0.061N
Vagina * Mucification,Epithelium	Simple Incidence	8/20 ( 40.0%)	11/22 ( 50.0%)	9/20 ( 45.0%)	11/22 ( 50.0%)	8/20 ( 40.0%)	10/22 ( 45.5%)
	Terminal Incidence	8/20 ( 40.0%)	11/22 ( 50.0%)	9/20 ( 45.0%)	11/22 ( 50.0%)	8/20 ( 40.0%)	9/20 ( 45.0%)
	Time-to-First	361 (T)	361 (T)	364 (T)	363 (T)	363 (T)	255
	CAFE P-Value	0.515	0.367	0.500	0.367	0.626	0.483
	Severity Profile	1 2 1 4	0 3 4 4	0 3 4 2	0 6 2 3	0 1 3 4	0 2 3 5
	JT/SW P-Value	0.405	0.271	0.410	0.433	0.481	0.408
	RTE P-Value	0.402	0.270	0.442	0.379	0.420	0.306
Vagina * Proestrus	Simple Incidence	2/20 ( 10.0%)	2/22 ( 9.1%)	5/20 ( 25.0%)	5/22 ( 22.7%)	2/20 ( 10.0%)	2/22 ( 9.1%)
	Terminal Incidence	2/20 ( 10.0%)	2/22 ( 9.1%)	5/20 ( 25.0%)	5/22 ( 22.7%)	2/20 ( 10.0%)	2/20 ( 10.0%)
	Time-to-First	363 (T)	363 (T)	363 (T)	362 (T)	365 (T)	362 (T)
	CAFE P-Value	0.504N	0.659N	0.204	0.247	0.698	0.659N
<b>Hematopoietic System</b>							
Spleen * Hematopoietic Cell Proliferation	Simple Incidence	2/20 ( 10.0%)	0/22 ( 0.0%)	1/20 ( 5.0%)	3/22 ( 13.6%)	3/20 ( 15.0%)	2/22 ( 9.1%)
	Terminal Incidence	2/20 ( 10.0%)	0/22 ( 0.0%)	1/20 ( 5.0%)	3/22 ( 13.6%)	3/20 ( 15.0%)	1/20 ( 5.0%)
	Time-to-First	366 (T)	---	365 (T)	364 (T)	362 (T)	43
	CAFE P-Value	0.194	0.221N	0.500N	0.547	0.500	0.659N
	Severity Profile	0 2 0 0	---	0 1 0 0	0 2 1 0	1 1 1 0	1 0 1 0
	JT/SW P-Value	0.168	0.933	0.846	0.398	0.381	0.510
	RTE P-Value	0.176	0.165N	0.291N	0.328	0.290	0.461N



RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 7. Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Stop Dose Arm</b>										
<b>System and Nonneoplasm</b>		<b>Treatment (ug/kg)</b>								
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>2.5</b>	<b>25</b>	<b>250</b>	<b>2500</b>	<b>25000</b>			
Spleen * Pigmentation	Simple Incidence	20/20 (100.0%)	22/22 (100.0%)	20/20 (100.0%)	22/22 (100.0%)	20/20 (100.0%)	20/22 (90.9%)			
	Terminal Incidence	20/20 (100.0%)	22/22 (100.0%)	20/20 (100.0%)	22/22 (100.0%)	20/20 (100.0%)	19/20 (95.0%)			
	Time-to-First	361 (T)	359 (T)	363 (T)	362 (T)	362 (T)	255			
	CAFE P-Value	0.029N*						0.268N		
	Severity Profile	6 6 5 3	2 7 10 3	5 8 3 4	5 7 9 1	0 9 10 1	1 6 10 3			
	JT/SW P-Value	0.183	0.096	0.279	0.370	0.137	0.160			
	RTE P-Value	0.192	0.085	0.469	0.446	0.122	0.132			
Thymus * Atrophy	Simple Incidence	18/20 (90.0%)	19/22 (86.4%)	18/20 (90.0%)	17/22 (77.3%)	18/20 (90.0%)	16/22 (72.7%)			
	Terminal Incidence	18/20 (90.0%)	19/22 (86.4%)	18/20 (90.0%)	17/22 (77.3%)	18/20 (90.0%)	16/20 (80.0%)			
	Time-to-First	361 (T)	359 (T)	363 (T)	362 (T)	362 (T)	362 (T)			
	CAFE P-Value	0.100N	0.547N	0.698N	0.247N	0.698N	0.152N			
	Severity Profile	0 8 5 5	0 8 2 9	0 2 4 12	0 5 6 6	0 5 5 8	0 4 4 8			
	JT/SW P-Value	0.464N	0.640N	0.938N	0.571N	0.792N	0.690N			
	RTE P-Value	0.483N	0.323	0.024 *	0.457N	0.189	0.462			
<b>Integumentary System</b>										
Mammary Gland * Dilatation,Duct	Simple Incidence	4/20 (20.0%)	2/22 (9.1%)	1/20 (5.0%)	1/22 (4.5%)	1/20 (5.0%)	1/22 (4.5%)			
	Terminal Incidence	4/20 (20.0%)	2/22 (9.1%)	1/20 (5.0%)	1/22 (4.5%)	1/20 (5.0%)	1/20 (5.0%)			
	Time-to-First	363 (T)	364 (T)	364 (T)	365 (T)	363 (T)	364 (T)			
	CAFE P-Value	0.046N*	0.286N	0.171N	0.144N	0.171N	0.144N			
	Severity Profile	2 1 1 0	1 1 0 0	0 1 0 0	1 0 0 0	0 1 0 0	1 0 0 0			
	JT/SW P-Value	0.036N*	0.155N	0.084N	0.051N	0.054N	0.038N*			
	RTE P-Value	0.035N*	0.073N	0.053N	0.026N*	0.050N	0.026N*			
Mammary Gland * Hyperplasia,Lobular	Simple Incidence	15/20 (75.0%)	12/22 (54.5%)	8/20 (40.0%)	12/22 (54.5%)	7/20 (35.0%)	12/22 (54.5%)			
	Terminal Incidence	15/20 (75.0%)	12/22 (54.5%)	8/20 (40.0%)	12/22 (54.5%)	7/20 (35.0%)	11/20 (55.0%)			
	Time-to-First	361 (T)	361 (T)	363 (T)	362 (T)	363 (T)	255			
	CAFE P-Value	0.072N	0.145N	0.027N*	0.145N	0.012N*	0.145N			
	Severity Profile	10 4 1 0	8 3 1 0	5 1 2 0	8 3 1 0	4 3 0 0	6 4 2 0			
	JT/SW P-Value	0.133N	0.115N	0.034N* <sup>1</sup>	0.074N	0.014N* <sup>1</sup>	0.079N			
	RTE P-Value	0.118N	0.119N	0.031N*	0.119N	0.015N*	0.189N			

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

**Table 7. Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Stop Dose Arm**

System and Nonneoplasm	Lesion	Statistic	Treatment (ug/kg)				
			Control	2.5	25	250	2500
<b>Urinary System</b>							
Kidney * Casts Protein	Simple Incidence	3/20 ( 15.0%)	1/22 ( 4.5%)	1/20 ( 5.0%)	0/22 ( 0.0%)	1/20 ( 5.0%)	1/22 ( 4.5%)
	Terminal Incidence	3/20 ( 15.0%)	1/22 ( 4.5%)	1/20 ( 5.0%)	0/22 ( 0.0%)	1/20 ( 5.0%)	1/20 ( 5.0%)
	Time-to-First	362 (T)	365 (T)	365 (T)	----	363 (T)	365 (T)
	CAFE P-Value	0.123N	0.267N	0.302N	0.099N	0.302N	0.267N
	Severity Profile	3 0 0 0	1 0 0 0	1 0 0 0	---	1 0 0 0	1 0 0 0
	JT/SW P-Value	0.099N	0.127N	0.142N	0.025N* <sup>1</sup>	0.055N	0.060N
	RTE P-Value	0.094N	0.061N	0.094N	0.037N*	0.094N	0.061N
Kidney * Cyst,Cortex	Simple Incidence	3/20 ( 15.0%)	2/22 ( 9.1%)	6/20 ( 30.0%)	4/22 ( 18.2%)	7/20 ( 35.0%)	3/22 ( 13.6%)
	Terminal Incidence	3/20 ( 15.0%)	2/22 ( 9.1%)	6/20 ( 30.0%)	4/22 ( 18.2%)	7/20 ( 35.0%)	3/20 ( 15.0%)
	Time-to-First	364 (T)	359 (T)	364 (T)	363 (T)	363 (T)	364 (T)
	CAFE P-Value	0.242	0.453N	0.225	0.556	0.137	0.620N
Kidney * Cyst,Renal Tubule	Simple Incidence	4/20 ( 20.0%)	3/22 ( 13.6%)	4/20 ( 20.0%)	4/22 ( 18.2%)	6/20 ( 30.0%)	5/22 ( 22.7%)
	Terminal Incidence	4/20 ( 20.0%)	3/22 ( 13.6%)	4/20 ( 20.0%)	4/22 ( 18.2%)	6/20 ( 30.0%)	5/20 ( 25.0%)
	Time-to-First	362 (T)	363 (T)	364 (T)	364 (T)	362 (T)	363 (T)
	CAFE P-Value	0.226	0.444N	0.653	0.594N	0.358	0.565
Kidney * Mineralization	Simple Incidence	13/20 ( 65.0%)	11/22 ( 50.0%)	11/20 ( 55.0%)	14/22 ( 63.6%)	13/20 ( 65.0%)	11/22 ( 50.0%)
	Terminal Incidence	13/20 ( 65.0%)	11/22 ( 50.0%)	11/20 ( 55.0%)	14/22 ( 63.6%)	13/20 ( 65.0%)	11/20 ( 55.0%)
	Time-to-First	361 (T)	359 (T)	363 (T)	362 (T)	362 (T)	363 (T)
	CAFE P-Value	0.428N	0.252N	0.374N	0.591N	0.629N	0.252N
	Severity Profile	8 4 0 1	9 2 0 0	6 4 0 1	8 6 0 0	6 6 1 0	8 3 0 0
	JT/SW P-Value	0.466N	0.093N	0.225N	0.346N	0.465N	0.169N
	RTE P-Value	0.470N	0.100N	0.326N	0.477N	0.376	0.128N
Kidney * Nephropathy	Simple Incidence	10/20 ( 50.0%)	10/22 ( 45.5%)	10/20 ( 50.0%)	11/22 ( 50.0%)	12/20 ( 60.0%)	13/22 ( 59.1%)
	Terminal Incidence	10/20 ( 50.0%)	10/22 ( 45.5%)	10/20 ( 50.0%)	11/22 ( 50.0%)	12/20 ( 60.0%)	12/20 ( 60.0%)
	Time-to-First	361 (T)	361 (T)	363 (T)	363 (T)	362 (T)	43
	CAFE P-Value	0.177	0.506N	0.624N	0.621	0.376	0.390
	Severity Profile	7 2 1 0	7 2 1 0	9 1 0 0	7 3 1 0	7 5 0 0	10 1 1 1
	JT/SW P-Value	0.157	0.610	0.704	0.580	0.302	0.364
	RTE P-Value	0.169	0.392N	0.372N	0.465	0.230	0.319

P-values for dose trend are presented in the "Control" column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

<sup>1</sup> Nonsignificant SW test due to the assumption of monotonicity.

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 8. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
<b>Alimentary System</b>							
Liver * Basophilic Focus	Simple Incidence	1/20 ( 5.0%)	2/20 ( 10.0%)	0/20 ( 0.0%)	0/19 ( 0.0%)	0/20 ( 0.0%)	1/22 ( 4.5%)
	Terminal Incidence	1/20 ( 5.0%)	2/20 ( 10.0%)	0/19 ( 0.0%)	0/19 ( 0.0%)	0/20 ( 0.0%)	1/22 ( 4.5%)
	Time-to-First	364 (T)	363 (T)	----	----	----	365 (T)
	CAFE P-Value	0.226N	0.500	0.500N	0.513N	0.500N	0.732N
Liver * Degeneration,Cystic	Simple Incidence	4/20 ( 20.0%)	4/20 ( 20.0%)	3/20 ( 15.0%)	1/19 ( 5.3%)	0/20 ( 0.0%)	0/22 ( 0.0%)
	Terminal Incidence	4/20 ( 20.0%)	4/20 ( 20.0%)	3/19 ( 15.8%)	1/19 ( 5.3%)	0/20 ( 0.0%)	0/22 ( 0.0%)
	Time-to-First	364 (T)	364 (T)	364 (T)	365 (T)	----	----
	CAFE P-Value	0.001N**	0.653	0.500N	0.187N	0.053N	0.043N*
	Severity Profile	3 1 0 0	4 0 0 0	3 0 0 0	1 0 0 0	---	---
	JT/SW P-Value	0.001N**	0.469N	0.379N	0.117N	0.030N*	0.017N*
	RTE P-Value	0.001N**	0.479N	0.279N	0.039N*	0.010N*	0.013N*
Liver * Fatty Change	Simple Incidence	0/20 ( 0.0%)	1/20 ( 5.0%)	1/20 ( 5.0%)	0/19 ( 0.0%)	2/20 ( 10.0%)	1/22 ( 4.5%)
	Terminal Incidence	0/20 ( 0.0%)	1/20 ( 5.0%)	1/19 ( 5.3%)	0/19 ( 0.0%)	2/20 ( 10.0%)	1/22 ( 4.5%)
	Time-to-First	----	363 (T)	365 (T)	----	363 (T)	364 (T)
	CAFE P-Value	0.235	0.500	0.500	----	0.244	0.524
	Severity Profile	---	0 1 0 0	0 0 1 0	---	0 0 2 0	0 0 1 0
	JT/SW P-Value	0.186	0.159	0.224	0.322	0.067	0.163
	RTE P-Value	0.179	0.224	0.215	0.500	0.082	0.231
Liver * Hepatodiaphragmatic Nodule	Simple Incidence	1/20 ( 5.0%)	2/20 ( 10.0%)	3/20 ( 15.0%)	3/19 ( 15.8%)	2/20 ( 10.0%)	1/22 ( 4.5%)
	Terminal Incidence	1/20 ( 5.0%)	2/20 ( 10.0%)	2/19 ( 10.5%)	3/19 ( 15.8%)	2/20 ( 10.0%)	1/22 ( 4.5%)
	Time-to-First	363 (T)	363 (T)	131	364 (T)	363 (T)	364 (T)
	CAFE P-Value	0.503N	0.500	0.302	0.283	0.500	0.732N
Liver * Hyperplasia,Bile Duct	Simple Incidence	8/20 ( 40.0%)	9/20 ( 45.0%)	5/20 ( 25.0%)	5/19 ( 26.3%)	5/20 ( 25.0%)	5/22 ( 22.7%)
	Terminal Incidence	8/20 ( 40.0%)	9/20 ( 45.0%)	5/19 ( 26.3%)	5/19 ( 26.3%)	5/20 ( 25.0%)	5/22 ( 22.7%)
	Time-to-First	361 (T)	361 (T)	364 (T)	363 (T)	365 (T)	363 (T)
	CAFE P-Value	0.051N	0.500	0.250N	0.286N	0.250N	0.191N
	Severity Profile	7 1 0 0	8 1 0 0	4 1 0 0	3 2 0 0	4 1 0 0	5 0 0 0
	JT/SW P-Value	0.049N*	0.616N	0.215N	0.268N	0.231N	0.142N
	RTE P-Value	0.049N*	0.375	0.168N	0.227N	0.171N	0.110N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 8. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Liver * Infiltration Cellular, Mononuclear Cell	Simple Incidence	11/20 ( 55.0%)	13/20 ( 65.0%)	9/20 ( 45.0%)	13/19 ( 68.4%)	11/20 ( 55.0%)	15/22 ( 68.2%)
	Terminal Incidence	11/20 ( 55.0%)	13/20 ( 65.0%)	9/19 ( 47.4%)	13/19 ( 68.4%)	11/20 ( 55.0%)	15/22 ( 68.2%)
	Time-to-First	364 (T)	361 (T)	363 (T)	363 (T)	362 (T)	362 (T)
	CAFE P-Value	0.268	0.374	0.376N	0.298	0.624N	0.288
	Severity Profile	11 0 0 0	13 0 0 0	9 0 0 0	13 0 0 0	11 0 0 0	15 0 0 0
	JT/SW P-Value	0.249	0.262	0.583	0.255	0.445	0.262
	RTE P-Value	0.259	0.262	0.262N	0.192	0.500	0.201
Liver * Tension Lipidosis	Simple Incidence	1/20 ( 5.0%)	0/20 ( 0.0%)	3/20 ( 15.0%)	2/19 ( 10.5%)	1/20 ( 5.0%)	2/22 ( 9.1%)
	Terminal Incidence	1/20 ( 5.0%)	0/20 ( 0.0%)	3/19 ( 15.8%)	2/19 ( 10.5%)	1/20 ( 5.0%)	2/22 ( 9.1%)
	Time-to-First	365 (T)	----	363 (T)	364 (T)	363 (T)	364 (T)
	CAFE P-Value	0.300	0.500N	0.302	0.480	0.756	0.537
	Severity Profile	0 1 0 0	---	0 1 1 1	0 0 2 0	0 0 1 0	0 0 2 0
	JT/SW P-Value	0.251	0.841	0.115	0.215	0.331	0.352
	RTE P-Value	0.250	0.287N	0.087	0.186	0.484	0.294
Liver * Vacuolization Cytoplasmic	Simple Incidence	6/20 ( 30.0%)	5/20 ( 25.0%)	10/20 ( 50.0%)	5/19 ( 26.3%)	4/20 ( 20.0%)	8/22 ( 36.4%)
	Terminal Incidence	6/20 ( 30.0%)	5/20 ( 25.0%)	10/19 ( 52.6%)	5/19 ( 26.3%)	4/20 ( 20.0%)	8/22 ( 36.4%)
	Time-to-First	360 (T)	364 (T)	363 (T)	364 (T)	365 (T)	363 (T)
	CAFE P-Value	0.504N	0.500N	0.167	0.540N	0.358N	0.457
	Severity Profile	4 2 0 0	3 2 0 0	5 5 0 0	3 2 0 0	3 1 0 0	6 2 0 0
	JT/SW P-Value	0.444N	0.378N	0.803N	0.531N	0.323N	0.572N
	RTE P-Value	0.424N	0.384N	0.064	0.419N	0.243N	0.357
Pancreas * Degeneration, Acinus	Simple Incidence	18/20 ( 90.0%)	19/20 ( 95.0%)	12/20 ( 60.0%)	17/19 ( 89.5%)	18/20 ( 90.0%)	20/22 ( 90.9%)
	Terminal Incidence	18/20 ( 90.0%)	19/20 ( 95.0%)	12/19 ( 63.2%)	17/19 ( 89.5%)	18/20 ( 90.0%)	20/22 ( 90.9%)
	Time-to-First	360 (T)	361 (T)	363 (T)	363 (T)	363 (T)	363 (T)
	CAFE P-Value	0.404	0.500	0.032N*	0.678N	0.698N	0.659
	Severity Profile	2 9 5 2	3 9 4 3	3 5 3 1	5 6 4 2	3 8 7 0	8 8 3 1
	JT/SW P-Value	0.109N	0.563N	0.019N* <sup>1</sup>	0.102N	0.191N	0.089N
	RTE P-Value	0.102N	0.428	0.009N**	0.255N	0.371N	0.065N
Pancreas * Pigmentation	Simple Incidence	11/20 ( 55.0%)	8/20 ( 40.0%)	9/20 ( 45.0%)	8/19 ( 42.1%)	8/20 ( 40.0%)	10/22 ( 45.5%)
	Terminal Incidence	11/20 ( 55.0%)	8/20 ( 40.0%)	9/19 ( 47.4%)	8/19 ( 42.1%)	8/20 ( 40.0%)	10/22 ( 45.5%)
	Time-to-First	360 (T)	363 (T)	363 (T)	363 (T)	363 (T)	364 (T)
	CAFE P-Value	0.318N	0.264N	0.376N	0.314N	0.264N	0.379N
	Severity Profile	5 6 0 0	8 0 0 0	6 3 0 0	6 2 0 0	8 0 0 0	7 3 0 0
	JT/SW P-Value	0.203N	0.053N	0.120N	0.136N	0.064N	0.125N
	RTE P-Value	0.196N	0.058N	0.175N	0.122N	0.057N	0.163N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 8. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
<b>Cardiovascular System</b>							
Heart * Cardiomyopathy	Simple Incidence	17/20 ( 85.0%)	20/20 (100.0%)	19/20 ( 95.0%)	13/19 ( 68.4%)	18/20 ( 90.0%)	19/22 ( 86.4%)
	Terminal Incidence	17/20 ( 85.0%)	20/20 (100.0%)	19/19 (100.0%)	13/19 ( 68.4%)	18/20 ( 90.0%)	19/22 ( 86.4%)
	Time-to-First	360 (T)	361 (T)	363 (T)	363 (T)	362 (T)	362 (T)
	CAFE P-Value	0.242N	0.115	0.302	0.199N	0.500	0.620
	Severity Profile	12 3 2 0	10 7 2 1	7 7 3 2	10 3 0 0	14 3 1 0	9 8 2 0
	JT/SW P-Value	0.258N	0.971N	0.994N	0.148N	0.329N	0.609N
	RTE P-Value	0.201N	0.027 *	0.006 **	0.098N	0.441N	0.150
<b>Endocrine System</b>							
Adrenal Cortex * Vacuolization Cytoplasmic	Simple Incidence	2/20 ( 10.0%)	3/20 ( 15.0%)	3/20 ( 15.0%)	3/19 ( 15.8%)	3/20 ( 15.0%)	2/22 ( 9.1%)
	Terminal Incidence	2/20 ( 10.0%)	3/20 ( 15.0%)	3/19 ( 15.8%)	3/19 ( 15.8%)	3/20 ( 15.0%)	2/22 ( 9.1%)
	Time-to-First	365 (T)	364 (T)	364 (T)	365 (T)	363 (T)	365 (T)
	CAFE P-Value	0.494N	0.500	0.500	0.475	0.500	0.659N
	Severity Profile	0 2 0 0	0 3 0 0	0 3 0 0	2 1 0 0	1 2 0 0	0 1 1 0
	JT/SW P-Value	0.455N	0.682N	0.764N	0.777N	0.795N	0.630N
	RTE P-Value	0.472N	0.322	0.322	0.341	0.343	0.484N
Parathyroid Gland * Hyperplasia	Simple Incidence	4/20 ( 20.0%)	9/20 ( 45.0%)	3/19 ( 15.8%)	7/19 ( 36.8%)	4/19 ( 21.1%)	8/22 ( 36.4%)
	Terminal Incidence	4/20 ( 20.0%)	9/20 ( 45.0%)	3/18 ( 16.7%)	7/19 ( 36.8%)	4/19 ( 21.1%)	8/22 ( 36.4%)
	Time-to-First	364 (T)	361 (T)	363 (T)	363 (T)	364 (T)	364 (T)
	CAFE P-Value	0.367	0.088	0.531N	0.209	0.622	0.204
	Severity Profile	1 2 1 0	7 1 1 0	1 2 0 0	5 2 0 0	4 0 0 0	1 6 1 0
	JT/SW P-Value	0.297	0.090	0.345	0.243	0.424	0.129
	RTE P-Value	0.324	0.084	0.355N	0.199	0.399N	0.098
Pituitary Gland * Cyst,Pars Distalis	Simple Incidence	1/20 ( 5.0%)	2/20 ( 10.0%)	0/20 ( 0.0%)	1/19 ( 5.3%)	0/20 ( 0.0%)	2/22 ( 9.1%)
	Terminal Incidence	1/20 ( 5.0%)	2/20 ( 10.0%)	0/19 ( 0.0%)	1/19 ( 5.3%)	0/20 ( 0.0%)	2/22 ( 9.1%)
	Time-to-First	364 (T)	364 (T)	----	364 (T)	----	365 (T)
	CAFE P-Value	0.526N	0.500	0.500N	0.744	0.500N	0.537
Pituitary Gland * Hyperplasia,Pars Distalis	Simple Incidence	8/20 ( 40.0%)	9/20 ( 45.0%)	3/20 ( 15.0%)	4/19 ( 21.1%)	4/20 ( 20.0%)	7/22 ( 31.8%)
	Terminal Incidence	8/20 ( 40.0%)	9/20 ( 45.0%)	3/19 ( 15.8%)	4/19 ( 21.1%)	4/20 ( 20.0%)	7/22 ( 31.8%)
	Time-to-First	361 (T)	361 (T)	363 (T)	364 (T)	364 (T)	364 (T)
	CAFE P-Value	0.118N	0.500	0.078N	0.175N	0.150N	0.409N
	Severity Profile	8 0 0 0	7 1 0 1	0 3 0 0	4 0 0 0	4 0 0 0	6 1 0 0
	JT/SW P-Value	0.115N	0.712N	0.139N	0.139N	0.122N	0.184N
	RTE P-Value	0.093N	0.295	0.089N	0.105N	0.093N	0.323N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 8. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Thyroid Gland * Hyperplasia,C-Cell	Simple Incidence	13/20 ( 65.0%)	9/20 ( 45.0%)	10/20 ( 50.0%)	11/19 ( 57.9%)	10/20 ( 50.0%)	12/22 ( 54.5%)
	Terminal Incidence	13/20 ( 65.0%)	9/20 ( 45.0%)	10/19 ( 52.6%)	11/19 ( 57.9%)	10/20 ( 50.0%)	12/22 ( 54.5%)
	Time-to-First	360 (T)	363 (T)	364 (T)	363 (T)	363 (T)	363 (T)
	CAFE P-Value	0.400N	0.170N	0.262N	0.450N	0.262N	0.355N
	Severity Profile	5 7 1 0	1 4 4 0	6 2 2 0	3 7 1 0	7 2 1 0	5 5 2 0
	JT/SW P-Value	0.257N	0.365N	0.200N	0.354N	0.139N	0.247N
	RTE P-Value	0.242N	0.303N	0.159N	0.414N	0.111N	0.288N
Thyroid Gland * Hyperplasia,Follicular Cell	Simple Incidence	1/20 ( 5.0%)	1/20 ( 5.0%)	4/20 ( 20.0%)	1/19 ( 5.3%)	0/20 ( 0.0%)	3/22 ( 13.6%)
	Terminal Incidence	1/20 ( 5.0%)	1/20 ( 5.0%)	4/19 ( 21.1%)	1/19 ( 5.3%)	0/20 ( 0.0%)	3/22 ( 13.6%)
	Time-to-First	364 (T)	365 (T)	364 (T)	364 (T)	----	362 (T)
	CAFE P-Value	0.417	0.756	0.171	0.744	0.500N	0.341
	Severity Profile	0 0 1 0	0 0 1 0	0 1 3 0	0 0 1 0	---	0 0 3 0
	JT/SW P-Value	0.367	0.500	0.072	0.257	0.445	0.208
	RTE P-Value	0.391	0.500	0.061	0.488	0.281N	0.153
Thyroid Gland * Ultimobranchial Cyst	Simple Incidence	6/20 ( 30.0%)	3/20 ( 15.0%)	9/20 ( 45.0%)	5/19 ( 26.3%)	4/20 ( 20.0%)	5/22 ( 22.7%)
	Terminal Incidence	6/20 ( 30.0%)	3/20 ( 15.0%)	9/19 ( 47.4%)	5/19 ( 26.3%)	4/20 ( 20.0%)	5/22 ( 22.7%)
	Time-to-First	360 (T)	363 (T)	363 (T)	364 (T)	362 (T)	364 (T)
	CAFE P-Value	0.331N	0.225N	0.257	0.540N	0.358N	0.426N
<b>Genital System</b>							
Epididymis * Exfoliated Germ Cell	Simple Incidence	0/20 ( 0.0%)	3/20 ( 15.0%)	1/20 ( 5.0%)	2/19 ( 10.5%)	1/20 ( 5.0%)	1/22 ( 4.5%)
	Terminal Incidence	0/20 ( 0.0%)	3/20 ( 15.0%)	1/19 ( 5.3%)	2/19 ( 10.5%)	1/20 ( 5.0%)	1/22 ( 4.5%)
	Time-to-First	----	361 (T)	364 (T)	363 (T)	365 (T)	365 (T)
	CAFE P-Value	0.516N	0.115	0.500	0.231	0.500	0.524
	Severity Profile	---	1 2 0 0	0 1 0 0	2 0 0 0	0 1 0 0	1 0 0 0
	JT/SW P-Value	0.462N	0.962N	0.821N	0.908N	0.864N	0.857N
	RTE P-Value	0.474N	0.034 *	0.258	0.150	0.258	0.285
Epididymis * Hypospermia	Simple Incidence	1/20 ( 5.0%)	4/20 ( 20.0%)	2/20 ( 10.0%)	1/19 ( 5.3%)	3/20 ( 15.0%)	1/22 ( 4.5%)
	Terminal Incidence	1/20 ( 5.0%)	4/20 ( 20.0%)	2/19 ( 10.5%)	1/19 ( 5.3%)	3/20 ( 15.0%)	1/22 ( 4.5%)
	Time-to-First	360 (T)	361 (T)	364 (T)	365 (T)	362 (T)	364 (T)
	CAFE P-Value	0.368N	0.171	0.500	0.744	0.302	0.732N
	Severity Profile	0 0 0 1	0 0 0 4	0 0 0 2	0 0 0 1	0 0 0 3	0 0 0 1
	JT/SW P-Value	0.332N	0.922N	0.774N	0.629N	0.832N	0.626N
	RTE P-Value	0.346N	0.076	0.300	0.489	0.157	0.481N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 8. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Epididymis * Infiltration Cellular,Lymphocyte	Simple Incidence	1/20 ( 5.0%)	1/20 ( 5.0%)	4/20 ( 20.0%)	1/19 ( 5.3%)	2/20 ( 10.0%)	2/22 ( 9.1%)
	Terminal Incidence	1/20 ( 5.0%)	1/20 ( 5.0%)	4/19 ( 21.1%)	1/19 ( 5.3%)	2/20 ( 10.0%)	2/22 ( 9.1%)
	Time-to-First	365 (T)	364 (T)	364 (T)	364 (T)	365 (T)	363 (T)
	CAFE P-Value	0.388	0.756	0.171	0.744	0.500	0.537
	Severity Profile	1 0 0 0	1 0 0 0	4 0 0 0	1 0 0 0	2 0 0 0	2 0 0 0
	JT/SW P-Value	0.350	0.500	0.068	0.252	0.300	0.334
	RTE P-Value	0.349	0.500	0.079	0.489	0.293	0.324
Prostate, Dorsal/Lateral Lobe * Infiltration Cellular,Lymphocyte	Simple Incidence	9/20 ( 45.0%)	5/20 ( 25.0%)	4/20 ( 20.0%)	8/18 ( 44.4%)	8/20 ( 40.0%)	6/22 ( 27.3%)
	Terminal Incidence	9/20 ( 45.0%)	5/20 ( 25.0%)	3/19 ( 15.8%)	8/18 ( 44.4%)	8/20 ( 40.0%)	6/22 ( 27.3%)
	Time-to-First	363 (T)	361 (T)	131	363 (T)	364 (T)	364 (T)
	CAFE P-Value	0.420N	0.160N	0.088N	0.615N	0.500N	0.191N
	Severity Profile	9 0 0 0	4 1 0 0	3 1 0 0	8 0 0 0	5 3 0 0	6 0 0 0
	JT/SW P-Value	0.428N	0.124N	0.072N	0.231N	0.338N	0.167N
	RTE P-Value	0.455N	0.128N	0.076N	0.486N	0.495	0.124N
Prostate, Dorsal/Lateral Lobe * Inflammation,Suppurative	Simple Incidence	18/20 ( 90.0%)	19/20 ( 95.0%)	16/20 ( 80.0%)	16/18 ( 88.9%)	19/20 ( 95.0%)	18/22 ( 81.8%)
	Terminal Incidence	18/20 ( 90.0%)	19/20 ( 95.0%)	16/19 ( 84.2%)	16/18 ( 88.9%)	19/20 ( 95.0%)	18/22 ( 81.8%)
	Time-to-First	360 (T)	361 (T)	363 (T)	363 (T)	362 (T)	362 (T)
	CAFE P-Value	0.312N	0.500	0.331N	0.656N	0.500	0.380N
	Severity Profile	5 13 0 0	12 7 0 0	6 10 0 0	7 9 0 0	9 10 0 0	5 12 1 0
	JT/SW P-Value	0.457	0.937	0.923	0.892	0.872	0.812
	RTE P-Value	0.460	0.083N	0.146N	0.215N	0.262N	0.340N
Prostate, Ventral Lobe * Hyperplasia,Epithelium	Simple Incidence	1/20 ( 5.0%)	1/20 ( 5.0%)	0/20 ( 0.0%)	2/18 ( 11.1%)	0/20 ( 0.0%)	0/22 ( 0.0%)
	Terminal Incidence	1/20 ( 5.0%)	1/20 ( 5.0%)	0/19 ( 0.0%)	2/18 ( 11.1%)	0/20 ( 0.0%)	0/22 ( 0.0%)
	Time-to-First	361 (T)	364 (T)	----	364 (T)	----	----
	CAFE P-Value	0.229N	0.756	0.500N	0.459	0.500N	0.476N
	Severity Profile	0 1 0 0	0 1 0 0	---	2 0 0 0	---	---
	JT/SW P-Value	0.171N	0.500N	0.229N	0.618N	0.277N	0.244N
	RTE P-Value	0.194N	0.500	0.104N	0.101	0.105N	0.140N
Prostate, Ventral Lobe * Infiltration Cellular,Lymphocyte	Simple Incidence	9/20 ( 45.0%)	8/20 ( 40.0%)	9/20 ( 45.0%)	9/18 ( 50.0%)	8/20 ( 40.0%)	9/22 ( 40.9%)
	Terminal Incidence	9/20 ( 45.0%)	8/20 ( 40.0%)	8/19 ( 42.1%)	9/18 ( 50.0%)	8/20 ( 40.0%)	9/22 ( 40.9%)
	Time-to-First	360 (T)	361 (T)	131	363 (T)	362 (T)	363 (T)
	CAFE P-Value	0.448N	0.500N	0.624	0.507	0.500N	0.517N
	Severity Profile	8 1 0 0	7 1 0 0	8 1 0 0	8 1 0 0	7 1 0 0	9 0 0 0
	JT/SW P-Value	0.384N	0.384N	0.519N	0.615N	0.501N	0.467N
	RTE P-Value	0.395N	0.384N	0.500	0.382	0.384N	0.351N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 8. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Prostate, Ventral Lobe * Inflammation,Suppurative	Simple Incidence	3/20 ( 15.0%)	2/20 ( 10.0%)	2/20 ( 10.0%)	6/18 ( 33.3%)	4/20 ( 20.0%)	2/22 ( 9.1%)
	Terminal Incidence	3/20 ( 15.0%)	2/20 ( 10.0%)	2/19 ( 10.5%)	6/18 ( 33.3%)	4/20 ( 20.0%)	2/22 ( 9.1%)
	Time-to-First	364 (T)	361 (T)	364 (T)	364 (T)	363 (T)	364 (T)
	CAFE P-Value	0.423	0.500N	0.500N	0.173	0.500	0.453N
	Severity Profile	2 1 0 0	2 0 0 0	2 0 0 0	6 0 0 0	4 0 0 0	2 0 0 0
	JT/SW P-Value	0.425	0.698	0.789	0.098	0.259	0.478
	RTE P-Value	0.385	0.310N	0.310N	0.082	0.359	0.278N
Testes * Degeneration,Seminiferous Tubule	Simple Incidence	6/20 ( 30.0%)	7/20 ( 35.0%)	9/20 ( 45.0%)	4/19 ( 21.1%)	9/20 ( 45.0%)	6/22 ( 27.3%)
	Terminal Incidence	6/20 ( 30.0%)	7/20 ( 35.0%)	9/19 ( 47.4%)	4/19 ( 21.1%)	9/20 ( 45.0%)	6/22 ( 27.3%)
	Time-to-First	360 (T)	361 (T)	363 (T)	363 (T)	362 (T)	363 (T)
	CAFE P-Value	0.477N	0.500	0.257	0.394N	0.257	0.557N
	Severity Profile	5 0 0 1	3 0 0 4	6 1 0 2	3 0 0 1	6 0 0 3	4 1 0 1
	JT/SW P-Value	0.437N	0.728N	0.872N	0.390N	0.764N	0.603N
	RTE P-Value	0.454N	0.263	0.149	0.308N	0.132	0.461N
<b>Hematopoietic System</b>							
Bone Marrow * Hyperplasia,Myeloid Cell	Simple Incidence	0/20 ( 0.0%)	0/20 ( 0.0%)	2/20 ( 10.0%)	0/19 ( 0.0%)	1/20 ( 5.0%)	0/22 ( 0.0%)
	Terminal Incidence	0/20 ( 0.0%)	0/20 ( 0.0%)	2/19 ( 10.5%)	0/19 ( 0.0%)	1/20 ( 5.0%)	0/22 ( 0.0%)
	Time-to-First	----	----	363 (T)	----	365 (T)	----
	CAFE P-Value	0.514		0.244		0.500	
	Severity Profile	---	---	0 0 1 1	---	0 0 1 0	---
	JT/SW P-Value	0.453	0.500	0.047 * 1	0.198	0.232	0.300
	RTE P-Value	0.433	0.500	0.020 *	0.500	0.165	0.500
Spleen * Hematopoietic Cell Proliferation	Simple Incidence	0/20 ( 0.0%)	1/20 ( 5.0%)	0/20 ( 0.0%)	0/19 ( 0.0%)	1/20 ( 5.0%)	2/22 ( 9.1%)
	Terminal Incidence	0/20 ( 0.0%)	1/20 ( 5.0%)	0/19 ( 0.0%)	0/19 ( 0.0%)	1/20 ( 5.0%)	2/22 ( 9.1%)
	Time-to-First	----	363 (T)	----	----	365 (T)	364 (T)
	CAFE P-Value	0.105	0.500			0.500	0.268
	Severity Profile	---	0 0 1 0	---	---	0 0 1 0	1 0 1 0
	JT/SW P-Value	0.079	0.159	0.323	0.406	0.173	0.067
	RTE P-Value	0.097	0.194	0.500	0.500	0.195	0.090



RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 8. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Stop Dose Arm</b>							
<b>System and Nonneoplasm</b>	<b>Treatment (ug/kg)</b>						
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>2.5</b>	<b>25</b>	<b>250</b>	<b>2500</b>	<b>25000</b>
Spleen * Pigmentation	Simple Incidence	12/20 ( 60.0%)	14/20 ( 70.0%)	13/20 ( 65.0%)	18/19 ( 94.7%)	15/20 ( 75.0%)	18/22 ( 81.8%)
	Terminal Incidence	12/20 ( 60.0%)	14/20 ( 70.0%)	13/19 ( 68.4%)	18/19 ( 94.7%)	15/20 ( 75.0%)	18/22 ( 81.8%)
	Time-to-First	363 (T)	361 (T)	363 (T)	363 (T)	362 (T)	363 (T)
	CAFE P-Value	0.035 *	0.371	0.500	0.012 *	0.250	0.111
	Severity Profile	4 6 2 0	5 9 0 0	7 5 1 0	11 7 0 0	5 10 0 0	6 11 0 1
	JT/SW P-Value	0.068	0.398	0.577	0.241	0.298	0.148
	RTE P-Value	0.084	0.386	0.358N	0.225	0.256	0.115
Thymus * Atrophy	Simple Incidence	18/20 ( 90.0%)	19/20 ( 95.0%)	17/20 ( 85.0%)	18/19 ( 94.7%)	18/20 ( 90.0%)	21/22 ( 95.5%)
	Terminal Incidence	18/20 ( 90.0%)	19/20 ( 95.0%)	17/19 ( 89.5%)	18/19 ( 94.7%)	18/20 ( 90.0%)	21/22 ( 95.5%)
	Time-to-First	360 (T)	361 (T)	363 (T)	363 (T)	362 (T)	362 (T)
	CAFE P-Value	0.363	0.500	0.500N	0.520	0.698N	0.463
	Severity Profile	0 0 6 12	0 2 5 12	1 3 3 10	0 4 3 11	0 0 3 15	0 5 2 14
	JT/SW P-Value	0.333	0.525	0.792	0.761	0.299	0.497
	RTE P-Value	0.324	0.490N	0.146N	0.368N	0.231	0.473N
<b>Integumentary System</b>							
Mammary Gland * Hyperplasia,Lobular	Simple Incidence	0/19 ( 0.0%)	1/20 ( 5.0%)	2/20 ( 10.0%)	2/19 ( 10.5%)	0/17 ( 0.0%)	1/22 ( 4.5%)
	Terminal Incidence	0/19 ( 0.0%)	1/20 ( 5.0%)	1/19 ( 5.3%)	2/19 ( 10.5%)	0/17 ( 0.0%)	1/22 ( 4.5%)
	Time-to-First	----	363 (T)	131	365 (T)	----	365 (T)
	CAFE P-Value	0.464	0.513	0.256	0.243		0.537
	Severity Profile	---	1 0 0 0	1 1 0 0	1 1 0 0	---	1 0 0 0
	JT/SW P-Value	0.406	0.165	0.092	0.117	0.223	0.239
	RTE P-Value	0.423	0.246	0.073	0.078	0.500	0.261
<b>Urinary System</b>							
Kidney * Cyst,Cortex	Simple Incidence	2/20 ( 10.0%)	4/20 ( 20.0%)	6/20 ( 30.0%)	6/19 ( 31.6%)	6/20 ( 30.0%)	4/22 ( 18.2%)
	Terminal Incidence	2/20 ( 10.0%)	4/20 ( 20.0%)	6/19 ( 31.6%)	6/19 ( 31.6%)	6/20 ( 30.0%)	4/22 ( 18.2%)
	Time-to-First	364 (T)	364 (T)	363 (T)	364 (T)	362 (T)	362 (T)
	CAFE P-Value	0.212	0.331	0.118	0.101	0.118	0.380
Kidney * Cyst,Renal Tubule	Simple Incidence	5/20 ( 25.0%)	4/20 ( 20.0%)	8/20 ( 40.0%)	6/19 ( 31.6%)	6/20 ( 30.0%)	8/22 ( 36.4%)
	Terminal Incidence	5/20 ( 25.0%)	4/20 ( 20.0%)	8/19 ( 42.1%)	6/19 ( 31.6%)	6/20 ( 30.0%)	8/22 ( 36.4%)
	Time-to-First	360 (T)	361 (T)	363 (T)	364 (T)	363 (T)	362 (T)
	CAFE P-Value	0.194	0.500N	0.250	0.460	0.500	0.323

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 8. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Kidney * Nephropathy	Simple Incidence	19/20 (95.0%)	20/20 (100.0%)	19/20 (95.0%)	17/19 (89.5%)	20/20 (100.0%)	21/22 (95.5%)
	Terminal Incidence	19/20 (95.0%)	20/20 (100.0%)	19/19 (100.0%)	17/19 (89.5%)	20/20 (100.0%)	21/22 (95.5%)
	Time-to-First	360 (T)	361 (T)	363 (T)	363 (T)	362 (T)	362 (T)
	CAFE P-Value	0.519N	0.500	0.756N	0.480N	0.500	0.732
	Severity Profile	5 11 3 0	6 11 3 0	7 5 4 3	10 4 2 1	6 10 3 1	10 3 4 4
	JT/SW P-Value	0.458N	0.536N	0.699N	0.091N	0.382N	0.499N
	RTE P-Value	0.441N	0.454	0.353	0.078N	0.370	0.477

P-values for dose trend are presented in the "Control" column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

<sup>1</sup> Nonsignificant SW test due to the assumption of monotonicity.

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 9 Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>		<i>Treatment (ug/kg)</i>					
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
<b>Alimentary System</b>							
Liver * Basophilic Focus	Simple Incidence	1/23 ( 4.3%)	0/22 ( 0.0%)	0/22 ( 0.0%)	5/24 ( 20.8%)	0/20 ( 0.0%)	1/24 ( 4.2%)
	Terminal Incidence	1/21 ( 4.8%)	0/22 ( 0.0%)	0/21 ( 0.0%)	5/22 ( 22.7%)	0/20 ( 0.0%)	1/24 ( 4.2%)
	Time-to-First	362 (T)	----	----	362 (T)	----	361 (T)
	CAFE P-Value	0.332	0.511N	0.511N	0.104	0.535N	0.745N
Liver * Fatty Change	Simple Incidence	2/23 ( 8.7%)	4/22 ( 18.2%)	2/22 ( 9.1%)	1/24 ( 4.2%)	0/20 ( 0.0%)	1/24 ( 4.2%)
	Terminal Incidence	2/21 ( 9.5%)	4/22 ( 18.2%)	2/21 ( 9.5%)	1/22 ( 4.5%)	0/20 ( 0.0%)	1/24 ( 4.2%)
	Time-to-First	362 (T)	361 (T)	360 (T)	361 (T)	----	361 (T)
	CAFE P-Value	0.052N	0.311	0.679	0.484N	0.280N	0.484N
	Severity Profile	0 1 1 0	1 2 1 0	1 1 0 0	0 1 0 0	---	0 0 1 0
	JT/SW P-Value	0.042N*	0.806N	0.566N	0.370N	0.188N	0.269N
	RTE P-Value	0.039N*	0.122	0.495N	0.268N	0.097N	0.278N
Liver * Hepatodiaphragmatic Nodule	Simple Incidence	2/23 ( 8.7%)	2/22 ( 9.1%)	1/22 ( 4.5%)	2/24 ( 8.3%)	1/20 ( 5.0%)	0/24 ( 0.0%)
	Terminal Incidence	2/21 ( 9.5%)	2/22 ( 9.1%)	1/21 ( 4.8%)	2/22 ( 9.1%)	1/20 ( 5.0%)	0/24 ( 0.0%)
	Time-to-First	359 (T)	361 (T)	363 (T)	361 (T)	362 (T)	----
	CAFE P-Value	0.124N	0.679	0.517N	0.679N	0.554N	0.234N
Liver * Hyperplasia,Bile Duct	Simple Incidence	3/23 ( 13.0%)	6/22 ( 27.3%)	5/22 ( 22.7%)	5/24 ( 20.8%)	3/20 ( 15.0%)	2/24 ( 8.3%)
	Terminal Incidence	3/21 ( 14.3%)	6/22 ( 27.3%)	5/21 ( 23.8%)	4/22 ( 18.2%)	3/20 ( 15.0%)	2/24 ( 8.3%)
	Time-to-First	362 (T)	360 (T)	362 (T)	322	362 (T)	361 (T)
	CAFE P-Value	0.196N	0.207	0.324	0.375	0.597	0.479N
	Severity Profile	3 0 0 0	4 2 0 0	3 2 0 0	4 1 0 0	3 0 0 0	1 1 0 0
	JT/SW P-Value	0.184N	0.898N	0.886N	0.863N	0.701N	0.493N
	RTE P-Value	0.185N	0.086	0.161	0.235	0.437	0.370N
Liver * Infiltration Cellular,Mononuclear Cell	Simple Incidence	4/23 ( 17.4%)	6/22 ( 27.3%)	4/22 ( 18.2%)	5/24 ( 20.8%)	5/20 ( 25.0%)	4/24 ( 16.7%)
	Terminal Incidence	4/21 ( 19.0%)	6/22 ( 27.3%)	4/21 ( 19.0%)	5/22 ( 22.7%)	5/20 ( 25.0%)	4/24 ( 16.7%)
	Time-to-First	362 (T)	361 (T)	362 (T)	361 (T)	363 (T)	362 (T)
	CAFE P-Value	0.471N	0.331	0.624	0.529	0.405	0.625N
	Severity Profile	4 0 0 0	5 1 0 0	4 0 0 0	5 0 0 0	5 0 0 0	4 0 0 0
	JT/SW P-Value	0.432N	0.802N	0.610N	0.694N	0.759N	0.621N
	RTE P-Value	0.442N	0.174	0.475	0.389	0.275	0.476N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 9 Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Continuous Dose Arm</b>							
<b>System and Nonneoplasm</b>	<b>Treatment (ug/kg)</b>						
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>2.5</b>	<b>25</b>	<b>250</b>	<b>2500</b>	<b>25000</b>
Liver * Mixed Cell Focus	Simple Incidence	0/23 ( 0.0%)	0/22 ( 0.0%)	0/22 ( 0.0%)	2/24 ( 8.3%)	0/20 ( 0.0%)	0/24 ( 0.0%)
	Terminal Incidence	0/21 ( 0.0%)	0/22 ( 0.0%)	0/21 ( 0.0%)	1/22 ( 4.5%)	0/20 ( 0.0%)	0/24 ( 0.0%)
	Time-to-First	----	----	----	256	----	----
	CAFE P-Value	0.417			0.255		
Liver * Tension Lipidosis	Simple Incidence	3/23 ( 13.0%)	3/22 ( 13.6%)	2/22 ( 9.1%)	2/24 ( 8.3%)	1/20 ( 5.0%)	1/24 ( 4.2%)
	Terminal Incidence	2/21 ( 9.5%)	3/22 ( 13.6%)	2/21 ( 9.5%)	2/22 ( 9.1%)	1/20 ( 5.0%)	1/24 ( 4.2%)
	Time-to-First	307	358 (T)	361 (T)	362 (T)	363 (T)	362 (T)
	CAFE P-Value	0.094N	0.646	0.522N	0.479N	0.359N	0.288N
	Severity Profile	0 2 1 0	0 1 1 1	0 1 0 1	0 1 1 0	0 0 1 0	1 0 0 0
	JT/SW P-Value	0.078N	0.554N	0.431N	0.399N	0.272N	0.188N
	RTE P-Value	0.077N	0.450	0.339N	0.295N	0.222N	0.146N
Liver * Vacuolization Cytoplasmic	Simple Incidence	2/23 ( 8.7%)	1/22 ( 4.5%)	1/22 ( 4.5%)	1/24 ( 4.2%)	1/20 ( 5.0%)	1/24 ( 4.2%)
	Terminal Incidence	2/21 ( 9.5%)	1/22 ( 4.5%)	1/21 ( 4.8%)	1/22 ( 4.5%)	1/20 ( 5.0%)	1/24 ( 4.2%)
	Time-to-First	360 (T)	361 (T)	362 (T)	363 (T)	363 (T)	361 (T)
	CAFE P-Value	0.328N	0.517N	0.517N	0.484N	0.554N	0.484N
	Severity Profile	2 0 0 0	1 0 0 0	1 0 0 0	1 0 0 0	0 1 0 0	1 0 0 0
	JT/SW P-Value	0.292N	0.291N	0.334N	0.319N	0.370N	0.331N
	RTE P-Value	0.301N	0.271N	0.271N	0.249N	0.312N	0.249N
Pancreas * Degeneration,Acinus	Simple Incidence	13/23 ( 56.5%)	13/22 ( 59.1%)	14/22 ( 63.6%)	19/24 ( 79.2%)	13/20 ( 65.0%)	18/24 ( 75.0%)
	Terminal Incidence	12/21 ( 57.1%)	13/22 ( 59.1%)	14/21 ( 66.7%)	17/22 ( 77.3%)	13/20 ( 65.0%)	18/24 ( 75.0%)
	Time-to-First	56	358 (T)	360 (T)	256	362 (T)	361 (T)
	CAFE P-Value	0.067	0.551	0.428	0.088	0.400	0.152
	Severity Profile	5 5 2 1	7 4 1 1	7 6 0 1	8 7 4 0	6 5 1 1	5 10 1 2
	JT/SW P-Value	0.044 *	0.567	0.554	0.119	0.276	0.110
	RTE P-Value	0.052	0.407N	0.496N	0.104	0.399	0.086
Pancreas * Infiltration Cellular,Lymphocyte	Simple Incidence	0/23 ( 0.0%)	2/22 ( 9.1%)	0/22 ( 0.0%)	0/24 ( 0.0%)	1/20 ( 5.0%)	0/24 ( 0.0%)
	Terminal Incidence	0/21 ( 0.0%)	2/22 ( 9.1%)	0/21 ( 0.0%)	0/22 ( 0.0%)	1/20 ( 5.0%)	0/24 ( 0.0%)
	Time-to-First	----	361 (T)	----	----	361 (T)	----
	CAFE P-Value	0.374N	0.233			0.465	
	Severity Profile	---	1 0 1 0	---	---	1 0 0 0	---
	JT/SW P-Value	0.303N	0.928N	0.583N	0.618N	0.760N	0.648N
	RTE P-Value	0.314N	0.007 **	0.500	0.500	0.138	0.500

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 9 Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>		<i>Treatment (ug/kg)</i>					
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
<b>Cardiovascular System</b>							
Heart * Cardiomyopathy	Simple Incidence	7/23 ( 30.4%)	10/22 ( 45.5%)	9/22 ( 40.9%)	8/24 ( 33.3%)	9/20 ( 45.0%)	7/24 ( 29.2%)
	Terminal Incidence	7/21 ( 33.3%)	10/22 ( 45.5%)	8/21 ( 38.1%)	7/22 ( 31.8%)	9/20 ( 45.0%)	7/24 ( 29.2%)
	Time-to-First	360 (T)	358 (T)	311	322	361 (T)	361 (T)
	CAFE P-Value	0.431N	0.233	0.337	0.540	0.252	0.588N
	Severity Profile	6 1 0 0	8 2 0 0	7 2 0 0	8 0 0 0	8 1 0 0	6 1 0 0
	JT/SW P-Value	0.378N	0.856N	0.857N	0.651N	0.814N	0.608N
	RTE P-Value	0.397N	0.140	0.215	0.469	0.177	0.465N
<b>Endocrine System</b>							
Adrenal Cortex * Degeneration,Cystic	Simple Incidence	2/23 ( 8.7%)	2/22 ( 9.1%)	3/22 ( 13.6%)	2/24 ( 8.3%)	2/20 ( 10.0%)	2/24 ( 8.3%)
	Terminal Incidence	2/21 ( 9.5%)	2/22 ( 9.1%)	3/21 ( 14.3%)	2/22 ( 9.1%)	2/20 ( 10.0%)	2/24 ( 8.3%)
	Time-to-First	362 (T)	360 (T)	361 (T)	362 (T)	363 (T)	362 (T)
	CAFE P-Value	0.497N	0.679	0.478	0.679N	0.641	0.679N
	Severity Profile	1 0 1 0	0 2 0 0	1 1 0 1	0 1 0 1	0 1 1 0	1 0 1 0
	JT/SW P-Value	0.471N	0.518N	0.706N	0.620N	0.672N	0.630N
	RTE P-Value	0.476N	0.483	0.288	0.498	0.432	0.484N
Adrenal Cortex * Vacuolization Cytoplasmic	Simple Incidence	2/23 ( 8.7%)	0/22 ( 0.0%)	1/22 ( 4.5%)	0/24 ( 0.0%)	0/20 ( 0.0%)	0/24 ( 0.0%)
	Terminal Incidence	1/21 ( 4.8%)	0/22 ( 0.0%)	1/21 ( 4.8%)	0/22 ( 0.0%)	0/20 ( 0.0%)	0/24 ( 0.0%)
	Time-to-First	56	----	363 (T)	----	----	----
	CAFE P-Value	0.045N*	0.256N	0.517N	0.234N	0.280N	0.234N
	Severity Profile	0 2 0 0	---	0 1 0 0	---	---	---
	JT/SW P-Value	0.031N*	0.081N	0.180N	0.059N	0.050N	0.027N*
	RTE P-Value	0.037N*	0.025N*	0.299N	0.031N*	0.017N*	0.031N*
Parathyroid Gland * Hyperplasia	Simple Incidence	2/23 ( 8.7%)	0/21 ( 0.0%)	3/20 ( 15.0%)	2/23 ( 8.7%)	1/20 ( 5.0%)	1/23 ( 4.3%)
	Terminal Incidence	1/21 ( 4.8%)	0/21 ( 0.0%)	3/20 ( 15.0%)	1/21 ( 4.8%)	1/20 ( 5.0%)	1/23 ( 4.3%)
	Time-to-First	56	----	362 (T)	322	363 (T)	361 (T)
	CAFE P-Value	0.422N	0.267N	0.431	0.696N	0.554N	0.500N
	Severity Profile	2 0 0 0	---	2 1 0 0	1 1 0 0	1 0 0 0	0 1 0 0
	JT/SW P-Value	0.394N	0.086N	0.522N	0.584N	0.430N	0.405N
	RTE P-Value	0.402N	0.141N	0.160	0.484	0.323N	0.301N
Pituitary Gland * Cyst,Pars Distalis	Simple Incidence	2/23 ( 8.7%)	0/22 ( 0.0%)	0/22 ( 0.0%)	2/24 ( 8.3%)	1/20 ( 5.0%)	2/24 ( 8.3%)
	Terminal Incidence	2/21 ( 9.5%)	0/22 ( 0.0%)	0/21 ( 0.0%)	2/22 ( 9.1%)	1/20 ( 5.0%)	2/24 ( 8.3%)
	Time-to-First	360 (T)	----	----	362 (T)	363 (T)	361 (T)
	CAFE P-Value	0.332	0.256N	0.256N	0.679N	0.554N	0.679N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 9 Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Continuous Dose Arm</b>							
<b>System and Nonneoplasm</b>	<b>Treatment (ug/kg)</b>						
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>2.5</b>	<b>25</b>	<b>250</b>	<b>2500</b>	<b>25000</b>
Pituitary Gland * Hyperplasia,Pars Distalis	Simple Incidence	18/23 ( 78.3%)	17/22 ( 77.3%)	18/22 ( 81.8%)	15/24 ( 62.5%)	16/20 ( 80.0%)	20/24 ( 83.3%)
	Terminal Incidence	17/21 ( 81.0%)	17/22 ( 77.3%)	17/21 ( 81.0%)	15/22 ( 68.2%)	16/20 ( 80.0%)	20/24 ( 83.3%)
	Time-to-First	307	356 (T)	311	360 (T)	361 (T)	361 (T)
	CAFE P-Value	0.448	0.609N	0.530	0.195N	0.595	0.471
	Severity Profile	8 6 3 1	7 6 3 1	7 4 5 2	8 4 2 1	8 6 1 1	7 8 4 1
	JT/SW P-Value	0.451	0.477	0.273	0.684	0.708	0.355
	RTE P-Value	0.474	0.478	0.232	0.118N	0.413N	0.263
Thyroid Gland * Hyperplasia,C-Cell	Simple Incidence	14/23 ( 60.9%)	11/22 ( 50.0%)	15/21 ( 71.4%)	12/24 ( 50.0%)	8/20 ( 40.0%)	16/24 ( 66.7%)
	Terminal Incidence	14/21 ( 66.7%)	11/22 ( 50.0%)	15/21 ( 71.4%)	11/22 ( 50.0%)	8/20 ( 40.0%)	16/24 ( 66.7%)
	Time-to-First	359 (T)	356 (T)	360 (T)	322	361 (T)	361 (T)
	CAFE P-Value	0.457N	0.333N	0.338	0.325N	0.145N	0.456
	Severity Profile	8 6 0 0	9 2 0 0	12 3 0 0	9 3 0 0	4 3 1 0	12 3 1 0
	JT/SW P-Value	0.423N	0.126N	0.343N	0.174N	0.145N	0.309N
	RTE P-Value	0.408N	0.126N	0.443	0.140N	0.114N	0.492
Thyroid Gland * Ultimobranchial Cyst	Simple Incidence	7/23 ( 30.4%)	7/22 ( 31.8%)	5/21 ( 23.8%)	8/24 ( 33.3%)	6/20 ( 30.0%)	11/24 ( 45.8%)
	Terminal Incidence	7/21 ( 33.3%)	7/22 ( 31.8%)	5/21 ( 23.8%)	8/22 ( 36.4%)	6/20 ( 30.0%)	11/24 ( 45.8%)
	Time-to-First	361 (T)	358 (T)	362 (T)	361 (T)	361 (T)	361 (T)
	CAFE P-Value	0.166	0.587	0.440N	0.540	0.619N	0.216
<b>Genital System</b>							
Ovary * Atrophy	Simple Incidence	10/23 ( 43.5%)	7/22 ( 31.8%)	9/22 ( 40.9%)	14/24 ( 58.3%)	11/20 ( 55.0%)	11/24 ( 45.8%)
	Terminal Incidence	10/21 ( 47.6%)	7/22 ( 31.8%)	8/21 ( 38.1%)	13/22 ( 59.1%)	11/20 ( 55.0%)	11/24 ( 45.8%)
	Time-to-First	361 (T)	356 (T)	311	322	361 (T)	361 (T)
	CAFE P-Value	0.153	0.309N	0.551N	0.234	0.327	0.552
	Severity Profile	1 4 0 5	0 3 0 4	0 2 0 7	6 4 0 4	2 1 0 8	0 2 0 9
	JT/SW P-Value	0.096	0.748	0.514	0.430	0.226	0.299
	RTE P-Value	0.091	0.267N	0.432	0.350	0.173	0.283
Ovary * Cyst	Simple Incidence	1/23 ( 4.3%)	0/22 ( 0.0%)	2/22 ( 9.1%)	0/24 ( 0.0%)	1/20 ( 5.0%)	0/24 ( 0.0%)
	Terminal Incidence	1/21 ( 4.8%)	0/22 ( 0.0%)	2/21 ( 9.5%)	0/22 ( 0.0%)	1/20 ( 5.0%)	0/24 ( 0.0%)
	Time-to-First	362 (T)	----	361 (T)	----	362 (T)	----
	CAFE P-Value	0.334N	0.511N	0.483	0.489N	0.720	0.489N
Ovary * Cyst,Bursa	Simple Incidence	0/23 ( 0.0%)	0/22 ( 0.0%)	3/22 ( 13.6%)	2/24 ( 8.3%)	1/20 ( 5.0%)	3/24 ( 12.5%)
	Terminal Incidence	0/21 ( 0.0%)	0/22 ( 0.0%)	3/21 ( 14.3%)	2/22 ( 9.1%)	1/20 ( 5.0%)	3/24 ( 12.5%)
	Time-to-First	----	----	361 (T)	362 (T)	361 (T)	362 (T)
	CAFE P-Value	0.056		0.109	0.255	0.465	0.125

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 9 Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>		<i>Treatment (ug/kg)</i>					
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Ovary * Cyst,Corpus Luteum	Simple Incidence	0/23 ( 0.0%)	0/22 ( 0.0%)	0/22 ( 0.0%)	0/24 ( 0.0%)	2/20 ( 10.0%)	1/24 ( 4.2%)
	Terminal Incidence	0/21 ( 0.0%)	0/22 ( 0.0%)	0/21 ( 0.0%)	0/22 ( 0.0%)	2/20 ( 10.0%)	1/24 ( 4.2%)
	Time-to-First	----	----	----	----	363 (T)	364 (T)
	CAFE P-Value	0.047 *				0.210	0.511
Ovary * Cyst,Follicle	Simple Incidence	8/23 ( 34.8%)	4/22 ( 18.2%)	10/22 ( 45.5%)	5/24 ( 20.8%)	10/20 ( 50.0%)	11/24 ( 45.8%)
	Terminal Incidence	8/21 ( 38.1%)	4/22 ( 18.2%)	9/21 ( 42.9%)	5/22 ( 22.7%)	10/20 ( 50.0%)	11/24 ( 45.8%)
	Time-to-First	361 (T)	356 (T)	311	361 (T)	361 (T)	361 (T)
	CAFE P-Value	0.083	0.179N	0.335	0.229N	0.242	0.318
Ovary * Depletion,Corpus Luteum	Simple Incidence	4/23 ( 17.4%)	4/22 ( 18.2%)	7/22 ( 31.8%)	4/24 ( 16.7%)	8/20 ( 40.0%)	9/24 ( 37.5%)
	Terminal Incidence	4/21 ( 19.0%)	4/22 ( 18.2%)	6/21 ( 28.6%)	4/22 ( 18.2%)	8/20 ( 40.0%)	9/24 ( 37.5%)
	Time-to-First	362 (T)	356 (T)	311	361 (T)	361 (T)	361 (T)
	CAFE P-Value	0.032 *	0.624	0.219	0.625N	0.095	0.112
Ovary * Diestrus	Simple Incidence	15/23 ( 65.2%)	12/22 ( 54.5%)	8/22 ( 36.4%)	12/24 ( 50.0%)	8/20 ( 40.0%)	9/24 ( 37.5%)
	Terminal Incidence	14/21 ( 66.7%)	12/22 ( 54.5%)	8/21 ( 38.1%)	10/22 ( 45.5%)	8/20 ( 40.0%)	9/24 ( 37.5%)
	Time-to-First	56	360 (T)	360 (T)	256	361 (T)	361 (T)
	CAFE P-Value	0.031N*	0.335N	0.050N	0.224N	0.089N	0.053N
Ovary * Hypertrophy,Interstitial Cell	Simple Incidence	4/23 ( 17.4%)	4/22 ( 18.2%)	6/22 ( 27.3%)	3/24 ( 12.5%)	8/20 ( 40.0%)	9/24 ( 37.5%)
	Terminal Incidence	4/21 ( 19.0%)	4/22 ( 18.2%)	5/21 ( 23.8%)	2/22 ( 9.1%)	8/20 ( 40.0%)	9/24 ( 37.5%)
	Time-to-First	362 (T)	356 (T)	311	322	361 (T)	361 (T)
	CAFE P-Value	0.030 *	0.624	0.331	0.475N	0.095	0.112
	Severity Profile	0 4 0 0	0 3 1 0	0 2 4 0	0 0 2 1	0 6 2 0	1 7 1 0
	JT/SW P-Value	0.038 *	0.446	0.174	0.428	0.049 * <sup>1</sup>	0.066
	RTE P-Value	0.031 *	0.445	0.154	0.462N	0.042 *	0.068
Ovary * Metestrus	Simple Incidence	3/23 ( 13.0%)	3/22 ( 13.6%)	4/22 ( 18.2%)	6/24 ( 25.0%)	1/20 ( 5.0%)	5/24 ( 20.8%)
	Terminal Incidence	2/21 ( 9.5%)	3/22 ( 13.6%)	4/21 ( 19.0%)	6/22 ( 27.3%)	1/20 ( 5.0%)	5/24 ( 20.8%)
	Time-to-First	307	361 (T)	360 (T)	360 (T)	362 (T)	361 (T)
	CAFE P-Value	0.373	0.646	0.474	0.253	0.359N	0.375
Ovary * Proestrus	Simple Incidence	1/23 ( 4.3%)	3/22 ( 13.6%)	3/22 ( 13.6%)	1/24 ( 4.2%)	3/20 ( 15.0%)	0/24 ( 0.0%)
	Terminal Incidence	1/21 ( 4.8%)	3/22 ( 13.6%)	3/21 ( 14.3%)	1/22 ( 4.5%)	3/20 ( 15.0%)	0/24 ( 0.0%)
	Time-to-First	364 (T)	360 (T)	362 (T)	362 (T)	361 (T)	----
	CAFE P-Value	0.292N	0.287	0.287	0.745N	0.252	0.489N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 9 Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Continuous Dose Arm</b>							
<b>System and Nonneoplasm</b>		<b>Treatment (ug/kg)</b>					
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>2.5</b>	<b>25</b>	<b>250</b>	<b>2500</b>	<b>25000</b>
Uterus * Apoptosis	Simple Incidence	2/23 ( 8.7%)	1/22 ( 4.5%)	4/21 ( 19.0%)	5/24 ( 20.8%)	5/20 ( 25.0%)	9/24 ( 37.5%)
	Terminal Incidence	2/21 ( 9.5%)	1/22 ( 4.5%)	4/21 ( 19.0%)	5/22 ( 22.7%)	5/20 ( 25.0%)	9/24 ( 37.5%)
	Time-to-First	362 (T)	361 (T)	361 (T)	361 (T)	362 (T)	361 (T)
	CAFE P-Value	0.001 **	0.517N	0.288	0.226	0.152	0.022 *
	Severity Profile	0 0 0 2	0 0 0 1	0 1 1 2	0 1 0 4	0 0 3 2	0 1 5 3
	JT/SW P-Value	0.003 **	0.709	0.181	0.147	0.112	0.013 *
	RTE P-Value	0.003 **	0.350N	0.219	0.142	0.103	0.010 **
Uterus * Cyst,Endometrium	Simple Incidence	0/23 ( 0.0%)	1/22 ( 4.5%)	1/21 ( 4.8%)	3/24 ( 12.5%)	0/20 ( 0.0%)	0/24 ( 0.0%)
	Terminal Incidence	0/21 ( 0.0%)	1/22 ( 4.5%)	1/21 ( 4.8%)	3/22 ( 13.6%)	0/20 ( 0.0%)	0/24 ( 0.0%)
	Time-to-First	----	356 (T)	363 (T)	360 (T)	----	----
	CAFE P-Value	0.496N	0.489	0.477	0.125		
Uterus * Diestrus	Simple Incidence	10/23 ( 43.5%)	12/22 ( 54.5%)	6/21 ( 28.6%)	11/24 ( 45.8%)	8/20 ( 40.0%)	5/24 ( 20.8%)
	Terminal Incidence	9/21 ( 42.9%)	12/22 ( 54.5%)	6/21 ( 28.6%)	9/22 ( 40.9%)	8/20 ( 40.0%)	5/24 ( 20.8%)
	Time-to-First	56	360 (T)	360 (T)	256	361 (T)	361 (T)
	CAFE P-Value	0.052N	0.329	0.239N	0.552	0.532N	0.088N
Uterus * Dilatation,Lumen	Simple Incidence	0/23 ( 0.0%)	1/22 ( 4.5%)	2/21 ( 9.5%)	2/24 ( 8.3%)	1/20 ( 5.0%)	2/24 ( 8.3%)
	Terminal Incidence	0/21 ( 0.0%)	1/22 ( 4.5%)	2/21 ( 9.5%)	2/22 ( 9.1%)	1/20 ( 5.0%)	2/24 ( 8.3%)
	Time-to-First	----	360 (T)	363 (T)	362 (T)	363 (T)	362 (T)
	CAFE P-Value	0.178	0.489	0.222	0.255	0.465	0.255
	Severity Profile	---	0 0 1 0	0 0 0 2	0 0 0 2	0 0 0 1	0 0 0 2
	JT/SW P-Value	0.142	0.153	0.075	0.114	0.175	0.151
	RTE P-Value	0.159	0.274	0.132	0.120	0.247	0.117
Uterus * Estrus	Simple Incidence	4/23 ( 17.4%)	2/22 ( 9.1%)	4/21 ( 19.0%)	5/24 ( 20.8%)	6/20 ( 30.0%)	9/24 ( 37.5%)
	Terminal Incidence	4/21 ( 19.0%)	2/22 ( 9.1%)	4/21 ( 19.0%)	5/22 ( 22.7%)	6/20 ( 30.0%)	9/24 ( 37.5%)
	Time-to-First	362 (T)	358 (T)	361 (T)	361 (T)	362 (T)	361 (T)
	CAFE P-Value	0.014 *	0.354N	0.596	0.529	0.269	0.112
Uterus * Hyperplasia,Cystic,Endometrium	Simple Incidence	5/23 ( 21.7%)	1/22 ( 4.5%)	4/21 ( 19.0%)	3/24 ( 12.5%)	7/20 ( 35.0%)	4/24 ( 16.7%)
	Terminal Incidence	5/21 ( 23.8%)	1/22 ( 4.5%)	4/21 ( 19.0%)	3/22 ( 13.6%)	7/20 ( 35.0%)	4/24 ( 16.7%)
	Time-to-First	362 (T)	361 (T)	361 (T)	361 (T)	362 (T)	361 (T)
	CAFE P-Value	0.246	0.103N	0.562N	0.325N	0.265	0.471N
	Severity Profile	1 2 1 1	1 0 0 0	1 2 1 0	1 1 1 0	0 6 1 0	0 3 0 1
	JT/SW P-Value	0.212	0.960	0.706	0.855	0.180	0.519
	RTE P-Value	0.178	0.051N	0.384N	0.175N	0.129	0.327N



RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 9 Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Uterus * Hyperplasia,Endometrium	Simple Incidence	2/23 ( 8.7%)	7/22 ( 31.8%)	5/21 ( 23.8%)	7/24 ( 29.2%)	5/20 ( 25.0%)	2/24 ( 8.3%)
	Terminal Incidence	2/21 ( 9.5%)	7/22 ( 31.8%)	5/21 ( 23.8%)	6/22 ( 27.3%)	5/20 ( 25.0%)	2/24 ( 8.3%)
	Time-to-First	362 (T)	360 (T)	360 (T)	256	361 (T)	361 (T)
	CAFE P-Value	0.417N	0.058	0.170	0.078	0.152	0.679N
	Severity Profile	0 2 0 0	3 3 1 0	0 4 1 0	2 4 1 0	1 2 2 0	0 2 0 0
	JT/SW P-Value	0.431N	0.967N	0.950N	0.977N	0.973N	0.635N
	RTE P-Value	0.437N	0.042 *	0.105	0.049 *	0.083	0.488N
Uterus * Metaplasia,Squamous	Simple Incidence	1/23 ( 4.3%)	1/22 ( 4.5%)	4/21 ( 19.0%)	3/24 ( 12.5%)	3/20 ( 15.0%)	5/24 ( 20.8%)
	Terminal Incidence	1/21 ( 4.8%)	1/22 ( 4.5%)	4/21 ( 19.0%)	3/22 ( 13.6%)	3/20 ( 15.0%)	5/24 ( 20.8%)
	Time-to-First	362 (T)	361 (T)	361 (T)	361 (T)	362 (T)	361 (T)
	CAFE P-Value	0.037 *	0.744	0.145	0.321	0.252	0.104
	Severity Profile	0 1 0 0	0 1 0 0	3 1 0 0	3 0 0 0	2 0 1 0	5 0 0 0
	JT/SW P-Value	0.041 *	0.487	0.063	0.144	0.178	0.073
	RTE P-Value	0.044 *	0.491	0.093	0.226	0.165	0.065
Uterus * Metestrus	Simple Incidence	7/23 ( 30.4%)	4/22 ( 18.2%)	7/21 ( 33.3%)	7/24 ( 29.2%)	2/20 ( 10.0%)	8/24 ( 33.3%)
	Terminal Incidence	6/21 ( 28.6%)	4/22 ( 18.2%)	7/21 ( 33.3%)	7/22 ( 31.8%)	2/20 ( 10.0%)	8/24 ( 33.3%)
	Time-to-First	307	356 (T)	360 (T)	360 (T)	362 (T)	361 (T)
	CAFE P-Value	0.488N	0.272N	0.546	0.588N	0.101N	0.540
Uterus * Proestrus	Simple Incidence	2/23 ( 8.7%)	4/22 ( 18.2%)	3/21 ( 14.3%)	1/24 ( 4.2%)	4/20 ( 20.0%)	2/24 ( 8.3%)
	Terminal Incidence	2/21 ( 9.5%)	4/22 ( 18.2%)	3/21 ( 14.3%)	1/22 ( 4.5%)	4/20 ( 20.0%)	2/24 ( 8.3%)
	Time-to-First	364 (T)	360 (T)	360 (T)	362 (T)	361 (T)	362 (T)
	CAFE P-Value	0.462N	0.311	0.455	0.484N	0.266	0.679N
Vagina * Diestrus	Simple Incidence	11/23 ( 47.8%)	11/22 ( 50.0%)	7/21 ( 33.3%)	10/24 ( 41.7%)	9/20 ( 45.0%)	7/24 ( 29.2%)
	Terminal Incidence	10/21 ( 47.6%)	11/22 ( 50.0%)	7/21 ( 33.3%)	9/22 ( 40.9%)	9/20 ( 45.0%)	7/24 ( 29.2%)
	Time-to-First	56	360 (T)	360 (T)	256	361 (T)	361 (T)
	CAFE P-Value	0.124N	0.560	0.252N	0.448N	0.548N	0.155N
Vagina * Estrus	Simple Incidence	3/23 ( 13.0%)	2/22 ( 9.1%)	3/21 ( 14.3%)	5/24 ( 20.8%)	7/20 ( 35.0%)	9/24 ( 37.5%)
	Terminal Incidence	3/21 ( 14.3%)	2/22 ( 9.1%)	3/21 ( 14.3%)	5/22 ( 22.7%)	7/20 ( 35.0%)	9/24 ( 37.5%)
	Time-to-First	362 (T)	358 (T)	363 (T)	361 (T)	361 (T)	361 (T)
	CAFE P-Value	0.003 **	0.522N	0.622	0.375	0.090	0.055

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 9 Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>		<i>Treatment (ug/kg)</i>					
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Vagina * Hyperplasia, Epithelium	Simple Incidence	3/23 ( 13.0%)	2/22 ( 9.1%)	2/21 ( 9.5%)	4/24 ( 16.7%)	6/20 ( 30.0%)	8/24 ( 33.3%)
	Terminal Incidence	3/21 ( 14.3%)	2/22 ( 9.1%)	2/21 ( 9.5%)	4/22 ( 18.2%)	6/20 ( 30.0%)	8/24 ( 33.3%)
	Time-to-First	362 (T)	358 (T)	363 (T)	361 (T)	362 (T)	361 (T)
	CAFE P-Value	0.008 **	0.522N	0.545N	0.525	0.162	0.097
	Severity Profile	0 1 2 0	0 1 1 0	0 1 1 0	0 0 4 0	0 1 5 0	0 1 7 0
	JT/SW P-Value	0.005 **	0.669	0.742	0.418	0.074	0.041 *
	RTE P-Value	0.005 **	0.360N	0.375N	0.343	0.067	0.030 *
Vagina * Metestrus	Simple Incidence	7/23 ( 30.4%)	5/22 ( 22.7%)	8/21 ( 38.1%)	8/24 ( 33.3%)	2/20 ( 10.0%)	8/24 ( 33.3%)
	Terminal Incidence	6/21 ( 28.6%)	5/22 ( 22.7%)	8/21 ( 38.1%)	7/22 ( 31.8%)	2/20 ( 10.0%)	8/24 ( 33.3%)
	Time-to-First	307	356 (T)	360 (T)	322	362 (T)	361 (T)
	CAFE P-Value	0.422N	0.403N	0.414	0.540	0.101N	0.540
Vagina * Mucification, Epithelium	Simple Incidence	10/23 ( 43.5%)	12/22 ( 54.5%)	7/21 ( 33.3%)	9/24 ( 37.5%)	7/20 ( 35.0%)	8/24 ( 33.3%)
	Terminal Incidence	10/21 ( 47.6%)	12/22 ( 54.5%)	7/21 ( 33.3%)	8/22 ( 36.4%)	7/20 ( 35.0%)	8/24 ( 33.3%)
	Time-to-First	360 (T)	358 (T)	360 (T)	256	361 (T)	361 (T)
	CAFE P-Value	0.123N	0.329	0.353N	0.452N	0.400N	0.339N
	Severity Profile	0 6 1 3	0 7 4 1	0 0 3 4	0 1 5 3	0 0 2 5	1 3 1 3
	JT/SW P-Value	0.272N	0.720N	0.552N	0.607N	0.638N	0.385N
	RTE P-Value	0.256N	0.317	0.447N	0.482N	0.471	0.288N
Vagina * Proestrus	Simple Incidence	2/23 ( 8.7%)	4/22 ( 18.2%)	2/21 ( 9.5%)	1/24 ( 4.2%)	2/20 ( 10.0%)	0/24 ( 0.0%)
	Terminal Incidence	2/21 ( 9.5%)	4/22 ( 18.2%)	2/21 ( 9.5%)	1/22 ( 4.5%)	2/20 ( 10.0%)	0/24 ( 0.0%)
	Time-to-First	364 (T)	360 (T)	362 (T)	362 (T)	361 (T)	----
	CAFE P-Value	0.072N	0.311	0.661	0.484N	0.641	0.234N
<b>Hematopoietic System</b>							
Spleen * Hematopoietic Cell Proliferation	Simple Incidence	3/23 ( 13.0%)	3/22 ( 13.6%)	2/22 ( 9.1%)	3/24 ( 12.5%)	1/20 ( 5.0%)	1/24 ( 4.2%)
	Terminal Incidence	2/21 ( 9.5%)	3/22 ( 13.6%)	1/21 ( 4.8%)	1/22 ( 4.5%)	1/20 ( 5.0%)	1/24 ( 4.2%)
	Time-to-First	56	356 (T)	311	256	361 (T)	361 (T)
	CAFE P-Value	0.118N	0.646	0.522N	0.646N	0.359N	0.288N
	Severity Profile	1 2 0 0	0 2 1 0	2 0 0 0	1 0 1 1	0 1 0 0	0 1 0 0
	JT/SW P-Value	0.107N	0.561N	0.381N	0.523N	0.276N	0.215N
	RTE P-Value	0.111N	0.447	0.314N	0.498	0.222N	0.191N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 9 Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Continuous Dose Arm</b>								
<b>System and Nonneoplasm</b>		<b>Treatment (ug/kg)</b>						
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>2.5</b>	<b>25</b>	<b>250</b>	<b>2500</b>	<b>25000</b>	
Spleen * Pigmentation	Simple Incidence	22/23 ( 95.7%)	21/22 ( 95.5%)	20/22 ( 90.9%)	24/24 (100.0%)	19/20 ( 95.0%)	23/24 ( 95.8%)	
	Terminal Incidence	21/21 (100.0%)	21/22 ( 95.5%)	19/21 ( 90.5%)	22/22 (100.0%)	19/20 ( 95.0%)	23/24 ( 95.8%)	
	Time-to-First	307	356 (T)	311	256	361 (T)	361 (T)	
	CAFE P-Value	0.451	0.744N	0.483N	0.489	0.720N	0.745	
	Severity Profile	0 8 10 4	4 6 8 3	2 4 9 5	1 7 11 5	0 6 8 5	1 5 12 5	
	JT/SW P-Value	0.123	0.851	0.601	0.430	0.439	0.421	
	RTE P-Value	0.115	0.166N	0.493	0.339	0.331	0.314	
Thymus * Atrophy	Simple Incidence	20/23 ( 87.0%)	20/22 ( 90.9%)	18/22 ( 81.8%)	21/24 ( 87.5%)	16/20 ( 80.0%)	22/24 ( 91.7%)	
	Terminal Incidence	19/21 ( 90.5%)	20/22 ( 90.9%)	18/21 ( 85.7%)	20/22 ( 90.9%)	16/20 ( 80.0%)	22/24 ( 91.7%)	
	Time-to-First	56	356 (T)	360 (T)	256	361 (T)	361 (T)	
	CAFE P-Value	0.525	0.522	0.474N	0.646	0.418N	0.479	
	Severity Profile	0 2 8 10	1 4 7 8	0 6 8 4	2 3 7 9	0 4 5 7	0 5 10 7	
	JT/SW P-Value	0.263N	0.282N	0.035N* <sup>1</sup>	0.131N	0.170N	0.187N	
	RTE P-Value	0.260N	0.287N	0.036N*	0.243N	0.156N	0.237N	
<b>Integumentary System</b>								
Mammary Gland * Atypical Focus	Simple Incidence	0/23 ( 0.0%)	3/22 ( 13.6%)	2/22 ( 9.1%)	2/24 ( 8.3%)	0/20 ( 0.0%)	0/24 ( 0.0%)	
	Terminal Incidence	0/21 ( 0.0%)	3/22 ( 13.6%)	2/21 ( 9.5%)	2/22 ( 9.1%)	0/20 ( 0.0%)	0/24 ( 0.0%)	
	Time-to-First	----	358 (T)	362 (T)	362 (T)	----	----	
	CAFE P-Value	0.186N	0.109	0.233	0.255			
	Severity Profile	---	1 2 0 0	0 2 0 0	2 0 0 0	---	---	
	JT/SW P-Value	0.149N	0.965N	0.934N	0.931N	0.636N	0.648N	
	RTE P-Value	0.133N	0.017 *	0.057	0.134	0.500	0.500	
Mammary Gland * Dilatation,Duct	Simple Incidence	2/23 ( 8.7%)	2/22 ( 9.1%)	7/22 ( 31.8%)	1/24 ( 4.2%)	2/20 ( 10.0%)	2/24 ( 8.3%)	
	Terminal Incidence	2/21 ( 9.5%)	2/22 ( 9.1%)	6/21 ( 28.6%)	1/22 ( 4.5%)	2/20 ( 10.0%)	2/24 ( 8.3%)	
	Time-to-First	362 (T)	358 (T)	311	362 (T)	362 (T)	361 (T)	
	CAFE P-Value	0.348N	0.679	0.058	0.484N	0.641	0.679N	
	Severity Profile	1 1 0 0	0 0 0 2	2 4 1 0	0 0 1 0	1 0 1 0	1 0 1 0	
	JT/SW P-Value	0.308N	0.555N	0.927N	0.447N	0.576N	0.604N	
	RTE P-Value	0.312N	0.428	0.010 **	0.338N	0.436	0.497N	

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 9 Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Continuous Dose Arm</b>							
<b>System and Nonneoplasm</b>		<b>Treatment (ug/kg)</b>					
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>2.5</b>	<b>25</b>	<b>250</b>	<b>2500</b>	<b>25000</b>
Mammary Gland * Hyperplasia,Lobular	Simple Incidence	10/23 ( 43.5%)	14/22 ( 63.6%)	13/22 ( 59.1%)	15/24 ( 62.5%)	13/20 ( 65.0%)	12/24 ( 50.0%)
	Terminal Incidence	10/21 ( 47.6%)	14/22 ( 63.6%)	12/21 ( 57.1%)	14/22 ( 63.6%)	13/20 ( 65.0%)	12/24 ( 50.0%)
	Time-to-First	361 (T)	356 (T)	311	256	361 (T)	361 (T)
	CAFE P-Value	0.355	0.145	0.227	0.155	0.135	0.438
	Severity Profile	5 5 0 0	7 7 0 0	7 6 0 0	11 3 1 0	10 2 0 1	9 1 1 1
	JT/SW P-Value	0.421N	0.894N	0.886N	0.889N	0.904N	0.700N
	RTE P-Value	0.444N	0.099	0.174	0.205	0.196	0.452
<b>Urinary System</b>							
Kidney * Casts Protein	Simple Incidence	2/23 ( 8.7%)	4/22 ( 18.2%)	2/22 ( 9.1%)	4/24 ( 16.7%)	3/20 ( 15.0%)	1/24 ( 4.2%)
	Terminal Incidence	1/21 ( 4.8%)	4/22 ( 18.2%)	2/21 ( 9.5%)	4/22 ( 18.2%)	3/20 ( 15.0%)	1/24 ( 4.2%)
	Time-to-First	307	361 (T)	360 (T)	361 (T)	361 (T)	362 (T)
	CAFE P-Value	0.348N	0.311	0.679	0.354	0.431	0.484N
	Severity Profile	2 0 0 0	4 0 0 0	2 0 0 0	4 0 0 0	3 0 0 0	0 1 0 0
	JT/SW P-Value	0.341N	0.823N	0.601N	0.790N	0.818N	0.452N
	RTE P-Value	0.351N	0.168	0.484	0.204	0.266	0.338N
Kidney * Cyst,Cortex	Simple Incidence	2/23 ( 8.7%)	2/22 ( 9.1%)	2/22 ( 9.1%)	4/24 ( 16.7%)	3/20 ( 15.0%)	2/24 ( 8.3%)
	Terminal Incidence	2/21 ( 9.5%)	2/22 ( 9.1%)	2/21 ( 9.5%)	3/22 ( 13.6%)	3/20 ( 15.0%)	2/24 ( 8.3%)
	Time-to-First	362 (T)	360 (T)	362 (T)	322	362 (T)	362 (T)
	CAFE P-Value	0.380	0.679	0.679	0.354	0.431	0.679N
Kidney * Cyst,Renal Tubule	Simple Incidence	0/23 ( 0.0%)	7/22 ( 31.8%)	3/22 ( 13.6%)	3/24 ( 12.5%)	3/20 ( 15.0%)	1/24 ( 4.2%)
	Terminal Incidence	0/21 ( 0.0%)	7/22 ( 31.8%)	3/21 ( 14.3%)	3/22 ( 13.6%)	3/20 ( 15.0%)	1/24 ( 4.2%)
	Time-to-First	----	356 (T)	361 (T)	361 (T)	361 (T)	362 (T)
	CAFE P-Value	0.324N	0.004 **	0.109	0.125	0.092	0.511
Kidney * Mineralization	Simple Incidence	11/23 ( 47.8%)	5/22 ( 22.7%)	11/22 ( 50.0%)	12/24 ( 50.0%)	11/20 ( 55.0%)	16/24 ( 66.7%)
	Terminal Incidence	10/21 ( 47.6%)	5/22 ( 22.7%)	10/21 ( 47.6%)	11/22 ( 50.0%)	11/20 ( 55.0%)	16/24 ( 66.7%)
	Time-to-First	307	360 (T)	311	256	361 (T)	361 (T)
	CAFE P-Value	0.017 *	0.073N	0.560	0.557	0.435	0.156
	Severity Profile	11 0 0 0	3 1 1 0	7 2 1 1	11 1 0 0	8 3 0 0	10 3 3 0
	JT/SW P-Value	0.006 **	0.923	0.319	0.416	0.274	0.035 *
	RTE P-Value	0.006 **	0.124N	0.232	0.401	0.204	0.025 *

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 9 Nonneoplasms by Body System for Interim Sacrifice Females Bisphenol-A Continuous Dose Arm</i>								
<i>System and Nonneoplasm</i>		<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>	
Kidney * Nephropathy	Simple Incidence	6/23 (26.1%)	7/22 (31.8%)	11/22 (50.0%)	8/24 (33.3%)	11/20 (55.0%)	7/24 (29.2%)	
	Terminal Incidence	5/21 (23.8%)	7/22 (31.8%)	10/21 (47.6%)	7/22 (31.8%)	11/20 (55.0%)	7/24 (29.2%)	
	Time-to-First	56	356 (T)	311	322	361 (T)	361 (T)	
	CAFE P-Value	0.258	0.462	0.089	0.412	0.052	0.536	
	Severity Profile	4 1 0 1	5 1 1 0	6 2 0 3	6 1 0 1	9 0 2 0	3 2 1 1	
	JT/SW P-Value	0.236	0.355	0.045 * <sup>1</sup>	0.171	0.057	0.196	
	RTE P-Value	0.213	0.372	0.036 *	0.334	0.048 *	0.356	

P-values for dose trend are presented in the "Control" column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

<sup>1</sup> Nonsignificant SW test due to the assumption of monotonicity.

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>		<i>Treatment (ug/kg)</i>					
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
<b>Alimentary System</b>							
Liver * Basophilic Focus	Simple Incidence	1/22 ( 4.5%)	0/22 ( 0.0%)	3/20 ( 15.0%)	0/24 ( 0.0%)	0/19 ( 0.0%)	0/22 ( 0.0%)
	Terminal Incidence	1/18 ( 5.6%)	0/22 ( 0.0%)	3/18 ( 16.7%)	0/24 ( 0.0%)	0/18 ( 0.0%)	0/21 ( 0.0%)
	Time-to-First	363 (T)	----	360 (T)	----	----	----
	CAFE P-Value	0.162N	0.500N	0.267	0.478N	0.537N	0.500N
Liver * Clear Cell Focus	Simple Incidence	3/22 ( 13.6%)	1/22 ( 4.5%)	0/20 ( 0.0%)	1/24 ( 4.2%)	0/19 ( 0.0%)	1/22 ( 4.5%)
	Terminal Incidence	3/18 ( 16.7%)	1/22 ( 4.5%)	0/18 ( 0.0%)	1/24 ( 4.2%)	0/18 ( 0.0%)	1/21 ( 4.8%)
	Time-to-First	361 (T)	362 (T)	----	361 (T)	----	362 (T)
	CAFE P-Value	0.097N	0.303N	0.134N	0.271N	0.144N	0.303N
Liver * Degeneration,Cystic	Simple Incidence	2/22 ( 9.1%)	0/22 ( 0.0%)	1/20 ( 5.0%)	0/24 ( 0.0%)	1/19 ( 5.3%)	0/22 ( 0.0%)
	Terminal Incidence	2/18 ( 11.1%)	0/22 ( 0.0%)	1/18 ( 5.6%)	0/24 ( 0.0%)	1/18 ( 5.6%)	0/21 ( 0.0%)
	Time-to-First	362 (T)	----	361 (T)	----	360 (T)	----
	CAFE P-Value	0.162N	0.244N	0.537N	0.223N	0.556N	0.244N
	Severity Profile	2 0 0	---	1 0 0	---	1 0 0	---
	JT/SW P-Value	0.122N	0.076N	0.184N	0.056N	0.169N	0.053N
	RTE P-Value	0.147N	0.037N*	0.224N	0.036N*	0.242N	0.037N*
Liver * Eosinophilic Focus	Simple Incidence	1/22 ( 4.5%)	0/22 ( 0.0%)	1/20 ( 5.0%)	1/24 ( 4.2%)	2/19 ( 10.5%)	1/22 ( 4.5%)
	Terminal Incidence	1/18 ( 5.6%)	0/22 ( 0.0%)	1/18 ( 5.6%)	1/24 ( 4.2%)	2/18 ( 11.1%)	1/21 ( 4.8%)
	Time-to-First	361 (T)	----	361 (T)	362 (T)	360 (T)	362 (T)
	CAFE P-Value	0.266	0.500N	0.732	0.733N	0.444	0.756
Liver * Fatty Change	Simple Incidence	0/22 ( 0.0%)	0/22 ( 0.0%)	2/20 ( 10.0%)	0/24 ( 0.0%)	0/19 ( 0.0%)	0/22 ( 0.0%)
	Terminal Incidence	0/18 ( 0.0%)	0/22 ( 0.0%)	2/18 ( 11.1%)	0/24 ( 0.0%)	0/18 ( 0.0%)	0/21 ( 0.0%)
	Time-to-First	----	----	359 (T)	----	----	----
	CAFE P-Value	0.423N		0.221			
	Severity Profile	---	---	0 2 0	---	---	---
	JT/SW P-Value	0.342N	0.500N	0.882N	0.618N	0.636N	0.648N
	RTE P-Value	0.324N	0.500	0.012 *	0.500	0.500	0.500
Liver * Hepatodiaphragmatic Nodule	Simple Incidence	0/22 ( 0.0%)	2/22 ( 9.1%)	2/20 ( 10.0%)	3/24 ( 12.5%)	4/19 ( 21.1%)	1/22 ( 4.5%)
	Terminal Incidence	0/18 ( 0.0%)	2/22 ( 9.1%)	1/18 ( 5.6%)	3/24 ( 12.5%)	3/18 ( 16.7%)	1/21 ( 4.8%)
	Time-to-First	----	362 (T)	319	360 (T)	244	362 (T)
	CAFE P-Value	0.158	0.244	0.221	0.133	0.038 *	0.500

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Liver * Hyperplasia,Bile Duct	Simple Incidence	3/22 ( 13.6%)	6/22 ( 27.3%)	2/20 ( 10.0%)	6/24 ( 25.0%)	5/19 ( 26.3%)	1/22 ( 4.5%)
	Terminal Incidence	2/18 ( 11.1%)	6/22 ( 27.3%)	2/18 ( 11.1%)	6/24 ( 25.0%)	5/18 ( 27.8%)	1/21 ( 4.8%)
	Time-to-First	258	360 (T)	361 (T)	359 (T)	360 (T)	362 (T)
	CAFE P-Value	0.318N	0.228	0.547N	0.277	0.265	0.303N
	Severity Profile	2 0 1 0	3 3 0 0	2 0 0 0	5 1 0 0	4 1 0 0	0 1 0 0
	JT/SW P-Value	0.286N	0.865N	0.421N	0.743N	0.819N	0.303N
	RTE P-Value	0.300N	0.101	0.354N	0.183	0.163	0.223N
Liver * Infiltration Cellular,Mononuclear Cell	Simple Incidence	5/22 ( 22.7%)	11/22 ( 50.0%)	9/20 ( 45.0%)	13/24 ( 54.2%)	11/19 ( 57.9%)	8/22 ( 36.4%)
	Terminal Incidence	5/18 ( 27.8%)	11/22 ( 50.0%)	9/18 ( 50.0%)	13/24 ( 54.2%)	11/18 ( 61.1%)	8/21 ( 38.1%)
	Time-to-First	361 (T)	360 (T)	359 (T)	359 (T)	360 (T)	359 (T)
	CAFE P-Value	0.149	0.058	0.115	0.029 *	0.023 *	0.255
	Severity Profile	5 0 0 0	11 0 0 0	9 0 0 0	12 1 0 0	11 0 0 0	8 0 0 0
	JT/SW P-Value	0.130	0.032 * <sup>1</sup>	0.059	0.015 *	0.016 *	0.046 *
	RTE P-Value	0.128	0.034 *	0.080	0.012 *	0.015 *	0.165
Liver * Tension Lipidosis	Simple Incidence	1/22 ( 4.5%)	0/22 ( 0.0%)	3/20 ( 15.0%)	3/24 ( 12.5%)	2/19 ( 10.5%)	1/22 ( 4.5%)
	Terminal Incidence	1/18 ( 5.6%)	0/22 ( 0.0%)	3/18 ( 16.7%)	3/24 ( 12.5%)	2/18 ( 11.1%)	1/21 ( 4.8%)
	Time-to-First	362 (T)	----	361 (T)	362 (T)	362 (T)	361 (T)
	CAFE P-Value	0.305	0.500N	0.267	0.338	0.444	0.756
	Severity Profile	0 1 0 0	---	0 2 0 1	0 1 2 0	1 1 0 0	0 0 1 0
	JT/SW P-Value	0.270	0.841	0.094	0.156	0.228	0.302
	RTE P-Value	0.274	0.292N	0.083	0.139	0.254	0.486
Liver * Vacuolization Cytoplasmic	Simple Incidence	8/22 ( 36.4%)	1/22 ( 4.5%)	6/20 ( 30.0%)	11/24 ( 45.8%)	8/19 ( 42.1%)	8/22 ( 36.4%)
	Terminal Incidence	8/18 ( 44.4%)	1/22 ( 4.5%)	6/18 ( 33.3%)	11/24 ( 45.8%)	8/18 ( 44.4%)	8/21 ( 38.1%)
	Time-to-First	359 (T)	362 (T)	361 (T)	360 (T)	360 (T)	361 (T)
	CAFE P-Value	0.073	0.011N*	0.457N	0.363	0.478	0.623N
	Severity Profile	6 2 0 0	1 0 0 0	4 2 0 0	6 5 0 0	6 2 0 0	4 4 0 0
	JT/SW P-Value	0.050	0.995	0.755	0.245	0.352	0.419
	RTE P-Value	0.046 *	0.014N*	0.356N	0.191	0.353	0.417
Pancreas * Basophilic Focus	Simple Incidence	0/22 ( 0.0%)	0/22 ( 0.0%)	0/20 ( 0.0%)	2/24 ( 8.3%)	0/19 ( 0.0%)	0/22 ( 0.0%)
	Terminal Incidence	0/18 ( 0.0%)	0/22 ( 0.0%)	0/18 ( 0.0%)	2/24 ( 8.3%)	0/18 ( 0.0%)	0/21 ( 0.0%)
	Time-to-First	----	----	----	362 (T)	----	----
	CAFE P-Value	0.410			0.267		

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Pancreas * Degeneration, Acinus	Simple Incidence	19/22 ( 86.4%)	21/22 ( 95.5%)	17/20 ( 85.0%)	23/24 ( 95.8%)	16/19 ( 84.2%)	19/22 ( 86.4%)
	Terminal Incidence	17/18 ( 94.4%)	21/22 ( 95.5%)	16/18 ( 88.9%)	23/24 ( 95.8%)	15/18 ( 83.3%)	19/21 ( 90.5%)
	Time-to-First	173	356 (T)	127	359 (T)	244	359 (T)
	CAFE P-Value	0.386N	0.303	0.620N	0.271	0.594N	0.668N
	Severity Profile	4 4 5 6	3 9 7 2	8 6 3 0	6 10 5 2	1 8 6 1	5 3 8 3
	JT/SW P-Value	0.358N	0.386N	0.010N* <sup>1</sup>	0.067N	0.133N	0.184N
	RTE P-Value	0.362N	0.452N	0.007N**	0.190N	0.267N	0.329N
Pancreas * Pigmentation	Simple Incidence	8/22 ( 36.4%)	7/22 ( 31.8%)	10/20 ( 50.0%)	13/24 ( 54.2%)	7/19 ( 36.8%)	11/22 ( 50.0%)
	Terminal Incidence	7/18 ( 38.9%)	7/22 ( 31.8%)	10/18 ( 55.6%)	13/24 ( 54.2%)	7/18 ( 38.9%)	11/21 ( 52.4%)
	Time-to-First	258	356 (T)	359 (T)	359 (T)	360 (T)	361 (T)
	CAFE P-Value	0.161	0.500N	0.281	0.180	0.614	0.272
	Severity Profile	6 2 0 0	5 2 0 0	9 1 0 0	13 0 0 0	6 1 0 0	8 3 0 0
	JT/SW P-Value	0.164	0.611	0.286	0.250	0.400	0.229
	RTE P-Value	0.176	0.393N	0.246	0.203	0.470N	0.178
<b>Cardiovascular System</b>							
Heart * Cardiomyopathy	Simple Incidence	16/22 ( 72.7%)	16/22 ( 72.7%)	16/20 ( 80.0%)	18/24 ( 75.0%)	15/20 ( 75.0%)	20/22 ( 90.9%)
	Terminal Incidence	14/18 ( 77.8%)	16/22 ( 72.7%)	15/18 ( 83.3%)	18/24 ( 75.0%)	14/18 ( 77.8%)	20/21 ( 95.2%)
	Time-to-First	258	356 (T)	319	360 (T)	300	359 (T)
	CAFE P-Value	0.116	0.632N	0.426	0.563	0.574	0.120
	Severity Profile	11 4 1 0	11 3 2 0	11 5 0 0	11 4 2 1	14 1 0 0	15 4 0 1
	JT/SW P-Value	0.326	0.475	0.422	0.383	0.596	0.240
	RTE P-Value	0.352	0.477	0.346	0.297	0.231N	0.178
<b>Endocrine System</b>							
Adrenal Cortex * Vacuolization Cytoplasmic	Simple Incidence	0/22 ( 0.0%)	3/22 ( 13.6%)	1/20 ( 5.0%)	2/24 ( 8.3%)	0/20 ( 0.0%)	2/22 ( 9.1%)
	Terminal Incidence	0/18 ( 0.0%)	3/22 ( 13.6%)	1/18 ( 5.6%)	2/24 ( 8.3%)	0/18 ( 0.0%)	2/21 ( 9.5%)
	Time-to-First	----	361 (T)	362 (T)	362 (T)	----	362 (T)
	CAFE P-Value	0.453	0.116	0.476	0.267	----	0.244
	Severity Profile	---	0 3 0 0	0 1 0 0	1 1 0 0	---	1 0 1 0
	JT/SW P-Value	0.416	0.038 * <sup>1</sup>	0.122	0.142	0.216	0.139
	RTE P-Value	0.431	0.031 *	0.250	0.141	0.500	0.109



RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

**Table 10. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Continuous Dose Arm**

<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Parathyroid Gland * Hyperplasia	Simple Incidence	7/22 ( 31.8%)	5/21 ( 23.8%)	7/19 ( 36.8%)	5/24 ( 20.8%)	2/19 ( 10.5%)	2/21 ( 9.5%)
	Terminal Incidence	7/18 ( 38.9%)	5/21 ( 23.8%)	7/17 ( 41.2%)	5/24 ( 20.8%)	2/17 ( 11.8%)	2/21 ( 9.5%)
	Time-to-First	361 (T)	356 (T)	360 (T)	359 (T)	361 (T)	361 (T)
	CAFE P-Value	0.018N*	0.404N	0.496	0.305N	0.102N	0.076N
	Severity Profile	3 4 0 0	2 3 0 0	3 3 1 0	1 4 0 0	0 2 0 0	1 1 0 0
	JT/SW P-Value	0.019N*	0.289N	0.547N	0.309N	0.097N	0.055N
	RTE P-Value	0.019N*	0.273N	0.333	0.216N	0.064N	0.045N*
Pituitary Gland * Cyst,Pars Distalis	Simple Incidence	1/22 ( 4.5%)	0/22 ( 0.0%)	0/20 ( 0.0%)	3/24 ( 12.5%)	1/20 ( 5.0%)	2/22 ( 9.1%)
	Terminal Incidence	1/18 ( 5.6%)	0/22 ( 0.0%)	0/18 ( 0.0%)	3/24 ( 12.5%)	1/18 ( 5.6%)	2/21 ( 9.5%)
	Time-to-First	361 (T)	----	----	362 (T)	362 (T)	359 (T)
	CAFE P-Value	0.129	0.500N	0.524N	0.338	0.732	0.500
Pituitary Gland * Hyperplasia,Pars Distalis	Simple Incidence	4/22 ( 18.2%)	6/22 ( 27.3%)	2/20 ( 10.0%)	4/24 ( 16.7%)	2/20 ( 10.0%)	4/22 ( 18.2%)
	Terminal Incidence	4/18 ( 22.2%)	6/22 ( 27.3%)	2/18 ( 11.1%)	4/24 ( 16.7%)	2/18 ( 11.1%)	4/21 ( 19.0%)
	Time-to-First	359 (T)	361 (T)	362 (T)	359 (T)	362 (T)	361 (T)
	CAFE P-Value	0.279N	0.360	0.380N	0.598N	0.380N	0.651
	Severity Profile	3 1 0 0	6 0 0 0	1 1 0 0	2 2 0 0	2 0 0 0	2 2 0 0
	JT/SW P-Value	0.288N	0.730N	0.311N	0.464N	0.303N	0.493N
	RTE P-Value	0.287N	0.246	0.256N	0.472N	0.234N	0.473
Thyroid Gland * Hyperplasia,C-Cell	Simple Incidence	10/22 ( 45.5%)	13/22 ( 59.1%)	9/20 ( 45.0%)	12/24 ( 50.0%)	7/18 ( 38.9%)	10/21 ( 47.6%)
	Terminal Incidence	8/18 ( 44.4%)	13/22 ( 59.1%)	9/18 ( 50.0%)	12/24 ( 50.0%)	7/18 ( 38.9%)	10/21 ( 47.6%)
	Time-to-First	173	356 (T)	360 (T)	362 (T)	361 (T)	360 (T)
	CAFE P-Value	0.344N	0.273	0.610N	0.495	0.462N	0.565
	Severity Profile	3 4 3 0	7 4 2 0	6 2 1 0	5 4 3 0	2 4 0 1	6 3 1 0
	JT/SW P-Value	0.263N	0.652N	0.343N	0.529N	0.422N	0.457N
	RTE P-Value	0.263N	0.327	0.294N	0.448	0.321N	0.368N
Thyroid Gland * Hyperplasia,Follicular Cell	Simple Incidence	1/22 ( 4.5%)	1/22 ( 4.5%)	2/20 ( 10.0%)	2/24 ( 8.3%)	2/18 ( 11.1%)	1/21 ( 4.8%)
	Terminal Incidence	1/18 ( 5.6%)	1/22 ( 4.5%)	2/18 ( 11.1%)	2/24 ( 8.3%)	2/18 ( 11.1%)	1/21 ( 4.8%)
	Time-to-First	359 (T)	360 (T)	361 (T)	362 (T)	361 (T)	362 (T)
	CAFE P-Value	0.385	0.756	0.463	0.533	0.423	0.744
	Severity Profile	0 1 0 0	0 0 1 0	1 0 1 0	0 1 1 0	0 0 2 0	0 0 1 0
	JT/SW P-Value	0.324	0.487	0.281	0.343	0.267	0.407
	RTE P-Value	0.329	0.486	0.251	0.307	0.174	0.475

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Thyroid Gland * Ultimobranchial Cyst	Simple Incidence	5/22 ( 22.7%)	4/22 ( 18.2%)	6/20 ( 30.0%)	5/24 ( 20.8%)	5/18 ( 27.8%)	7/21 ( 33.3%)
	Terminal Incidence	5/18 ( 27.8%)	4/22 ( 18.2%)	6/18 ( 33.3%)	5/24 ( 20.8%)	5/18 ( 27.8%)	7/21 ( 33.3%)
	Time-to-First	353 (T)	361 (T)	359 (T)	359 (T)	360 (T)	361 (T)
	CAFE P-Value	0.198	0.500N	0.426	0.578N	0.497	0.332
<b>Genital System</b>							
Epididymis * Exfoliated Germ Cell	Simple Incidence	1/22 ( 4.5%)	1/22 ( 4.5%)	1/20 ( 5.0%)	1/24 ( 4.2%)	0/20 ( 0.0%)	6/22 ( 27.3%)
	Terminal Incidence	1/18 ( 5.6%)	1/22 ( 4.5%)	1/18 ( 5.6%)	1/24 ( 4.2%)	0/18 ( 0.0%)	6/21 ( 28.6%)
	Time-to-First	362 (T)	362 (T)	362 (T)	362 (T)	----	360 (T)
	CAFE P-Value	0.021 *	0.756	0.732	0.733N	0.524N	0.047 *
	Severity Profile	1 0 0 0	1 0 0 0	0 1 0 0	1 0 0 0	---	6 0 0 0
	JT/SW P-Value	0.018 *	0.500	0.538	0.610	0.709	0.003 **
	RTE P-Value	0.019 *	0.500	0.458	0.480N	0.286N	0.002 **
Epididymis * Hypospermia	Simple Incidence	2/22 ( 9.1%)	4/22 ( 18.2%)	1/20 ( 5.0%)	2/24 ( 8.3%)	0/20 ( 0.0%)	2/22 ( 9.1%)
	Terminal Incidence	1/18 ( 5.6%)	4/22 ( 18.2%)	1/18 ( 5.6%)	2/24 ( 8.3%)	0/18 ( 0.0%)	2/21 ( 9.5%)
	Time-to-First	258	361 (T)	362 (T)	362 (T)	----	361 (T)
	CAFE P-Value	0.186N	0.332	0.537N	0.662N	0.268N	0.697N
	Severity Profile	0 0 1 1	0 0 0 4	0 0 0 1	0 0 0 2	---	0 0 0 2
	JT/SW P-Value	0.170N	0.828N	0.420N	0.526N	0.201N	0.429N
	RTE P-Value	0.168N	0.088	0.333N	0.482N	0.151N	0.482
Epididymis * Infiltration Cellular,Lymphocyte	Simple Incidence	0/22 ( 0.0%)	1/22 ( 4.5%)	3/20 ( 15.0%)	2/24 ( 8.3%)	0/20 ( 0.0%)	5/22 ( 22.7%)
	Terminal Incidence	0/18 ( 0.0%)	1/22 ( 4.5%)	3/18 ( 16.7%)	2/24 ( 8.3%)	0/18 ( 0.0%)	5/21 ( 23.8%)
	Time-to-First	----	362 (T)	360 (T)	362 (T)	----	361 (T)
	CAFE P-Value	0.032 *	0.500	0.099	0.267	----	0.024 *
	Severity Profile	---	0 1 0 0	3 0 0 0	2 0 0 0	---	5 0 0 0
	JT/SW P-Value	0.030 *	0.159	0.029 * <sup>1</sup>	0.083	0.182	0.004 **
	RTE P-Value	0.034 *	0.276	0.050	0.120	0.500	0.006 **
Prostate, Dorsal/Lateral Lobe * Infiltration Cellular,Lymphocyte	Simple Incidence	4/22 ( 18.2%)	10/22 ( 45.5%)	5/20 ( 25.0%)	6/24 ( 25.0%)	5/20 ( 25.0%)	7/22 ( 31.8%)
	Terminal Incidence	4/18 ( 22.2%)	10/22 ( 45.5%)	5/18 ( 27.8%)	6/24 ( 25.0%)	5/18 ( 27.8%)	7/21 ( 33.3%)
	Time-to-First	361 (T)	356 (T)	362 (T)	360 (T)	361 (T)	361 (T)
	CAFE P-Value	0.487	0.052	0.435	0.422	0.435	0.244
	Severity Profile	4 0 0 0	9 1 0 0	5 0 0 0	5 1 0 0	5 0 0 0	5 2 0 0
	JT/SW P-Value	0.413	0.025 * <sup>1</sup>	0.123	0.185	0.246	0.167
	RTE P-Value	0.419	0.025 *	0.320	0.282	0.320	0.126

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 10. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Continuous Dose Arm</b>							
<b>System and Nonneoplasm</b>	<b>Treatment (ug/kg)</b>						
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>2.5</b>	<b>25</b>	<b>250</b>	<b>2500</b>	<b>25000</b>
Prostate, Dorsal/Lateral Lobe * Inflammation,Suppurative	Simple Incidence	18/22 ( 81.8%)	20/22 ( 90.9%)	18/20 ( 90.0%)	22/24 ( 91.7%)	18/20 ( 90.0%)	19/22 ( 86.4%)
	Terminal Incidence	17/18 ( 94.4%)	20/22 ( 90.9%)	16/18 ( 88.9%)	22/24 ( 91.7%)	17/18 ( 94.4%)	19/21 ( 90.5%)
	Time-to-First	258	356 (T)	127	359 (T)	300	359 (T)
	CAFE P-Value	0.383	0.332	0.380	0.291	0.380	0.500
	Severity Profile	11 7 0 0	6 14 0 0	9 9 0 0	9 12 1 0	6 10 2 0	7 11 1 0
	JT/SW P-Value	0.076	0.022 * <sup>1</sup>	0.077	0.053	0.025 *	0.048 *
	RTE P-Value	0.074	0.025 *	0.175	0.048 *	0.022 *	0.063
Prostate, Ventral Lobe * Infiltration Cellular,Lymphocyte	Simple Incidence	8/22 ( 36.4%)	10/22 ( 45.5%)	10/20 ( 50.0%)	8/24 ( 33.3%)	9/20 ( 45.0%)	8/22 ( 36.4%)
	Terminal Incidence	7/18 ( 38.9%)	10/22 ( 45.5%)	9/18 ( 50.0%)	8/24 ( 33.3%)	8/18 ( 44.4%)	8/21 ( 38.1%)
	Time-to-First	173	360 (T)	127	360 (T)	244	360 (T)
	CAFE P-Value	0.434N	0.380	0.281	0.537N	0.399	0.623N
	Severity Profile	8 0 0 0	8 2 0 0	9 1 0 0	7 1 0 0	8 1 0 0	7 1 0 0
	JT/SW P-Value	0.437N	0.793N	0.883N	0.582N	0.745N	0.701N
	RTE P-Value	0.442N	0.209	0.162	0.468N	0.256	0.452
Prostate, Ventral Lobe * Inflammation,Suppurative	Simple Incidence	10/22 ( 45.5%)	3/22 ( 13.6%)	4/20 ( 20.0%)	5/24 ( 20.8%)	3/20 ( 15.0%)	1/22 ( 4.5%)
	Terminal Incidence	10/18 ( 55.6%)	3/22 ( 13.6%)	4/18 ( 22.2%)	5/24 ( 20.8%)	3/18 ( 16.7%)	1/21 ( 4.8%)
	Time-to-First	353 (T)	361 (T)	361 (T)	362 (T)	360 (T)	363 (T)
	CAFE P-Value	0.003N**	0.023N*	0.077N	0.071N	0.035N*	0.002N**
	Severity Profile	9 1 0 0	3 0 0 0	2 2 0 0	4 1 0 0	3 0 0 0	1 0 0 0
	JT/SW P-Value	0.003N**	0.010N*	0.027N*	0.026N*	0.012N*	<.001N***
	RTE P-Value	0.003N**	0.005N**	0.027N*	0.021N*	0.009N**	<.001N***
Testes * Degeneration,Seminiferous Tubule	Simple Incidence	6/22 ( 27.3%)	7/22 ( 31.8%)	9/20 ( 45.0%)	10/24 ( 41.7%)	5/20 ( 25.0%)	9/22 ( 40.9%)
	Terminal Incidence	4/18 ( 22.2%)	7/22 ( 31.8%)	9/18 ( 50.0%)	10/24 ( 41.7%)	5/18 ( 27.8%)	9/21 ( 42.9%)
	Time-to-First	258	361 (T)	360 (T)	359 (T)	360 (T)	360 (T)
	CAFE P-Value	0.303	0.500	0.191	0.238	0.574N	0.263
	Severity Profile	3 1 0 2	3 0 0 4	7 1 0 1	8 0 0 2	5 0 0 0	3 4 0 2
	JT/SW P-Value	0.326	0.336	0.216	0.252	0.428	0.198
	RTE P-Value	0.347	0.335	0.184	0.227	0.328N	0.152

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>		<i>Treatment (ug/kg)</i>					
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
<b>Hematopoietic System</b>							
Spleen * Hematopoietic Cell Proliferation	Simple Incidence	0/22 ( 0.0%)	0/22 ( 0.0%)	0/20 ( 0.0%)	0/24 ( 0.0%)	0/18 ( 0.0%)	2/22 ( 9.1%)
	Terminal Incidence	0/18 ( 0.0%)	0/22 ( 0.0%)	0/18 ( 0.0%)	0/24 ( 0.0%)	0/18 ( 0.0%)	1/21 ( 4.8%)
	Time-to-First	----	----	----	----	----	28
	CAFE P-Value	0.028 *					0.244
	Severity Profile	---	---	---	---	---	0 2 0 0
	JT/SW P-Value	0.019 *	0.500	0.583	0.618	0.636	0.009 **
	RTE P-Value	0.013 *	0.500	0.500	0.500	0.500	0.013 *
Spleen * Pigmentation	Simple Incidence	15/22 ( 68.2%)	16/22 ( 72.7%)	15/20 ( 75.0%)	16/24 ( 66.7%)	15/18 ( 83.3%)	13/22 ( 59.1%)
	Terminal Incidence	14/18 ( 77.8%)	16/22 ( 72.7%)	14/18 ( 77.8%)	16/24 ( 66.7%)	15/18 ( 83.3%)	13/21 ( 61.9%)
	Time-to-First	173	356 (T)	319	360 (T)	360 (T)	359 (T)
	CAFE P-Value	0.382N	0.500	0.443	0.582N	0.233	0.377N
	Severity Profile	6 7 1 1	7 9 0 0	2 10 3 0	7 9 0 0	2 13 0 0	6 6 1 0
	JT/SW P-Value	0.397N	0.475N	0.786N	0.414N	0.775N	0.288N
	RTE P-Value	0.433N	0.451N	0.094	0.320N	0.082	0.211N
Thymus * Atrophy	Simple Incidence	18/22 ( 81.8%)	21/22 ( 95.5%)	17/20 ( 85.0%)	22/24 ( 91.7%)	17/19 ( 89.5%)	20/21 ( 95.2%)
	Terminal Incidence	18/18 (100.0%)	21/22 ( 95.5%)	16/18 ( 88.9%)	22/24 ( 91.7%)	17/18 ( 94.4%)	20/20 (100.0%)
	Time-to-First	353 (T)	356 (T)	319	359 (T)	360 (T)	359 (T)
	CAFE P-Value	0.176	0.172	0.556	0.291	0.406	0.187
	Severity Profile	2 1 1 14	0 2 5 14	1 0 2 14	1 4 6 11	0 1 6 10	0 1 5 14
	JT/SW P-Value	0.454	0.288	0.351	0.546	0.595	0.288
	RTE P-Value	0.458	0.282	0.278	0.241N	0.456N	0.215
<b>Integumentary System</b>							
Mammary Gland * Hyperplasia,Lobular	Simple Incidence	2/22 ( 9.1%)	1/21 ( 4.8%)	0/20 ( 0.0%)	3/24 ( 12.5%)	1/19 ( 5.3%)	0/22 ( 0.0%)
	Terminal Incidence	2/18 ( 11.1%)	1/21 ( 4.8%)	0/18 ( 0.0%)	3/24 ( 12.5%)	1/17 ( 5.9%)	0/21 ( 0.0%)
	Time-to-First	361 (T)	361 (T)	----	362 (T)	362 (T)	----
	CAFE P-Value	0.257N	0.518N	0.268N	0.543	0.556N	0.244N
	Severity Profile	0 2 0 0	1 0 0 0	---	1 1 1 0	0 1 0 0	---
	JT/SW P-Value	0.224N	0.273N	0.097N	0.433N	0.410N	0.121N
	RTE P-Value	0.226N	0.256N	0.076N	0.307	0.295N	0.083N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Interim Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>		<i>Treatment (ug/kg)</i>					
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
<b>Urinary System</b>							
Kidney * Accumulation, Hyaline Droplet	Simple Incidence	2/22 ( 9.1%)	0/22 ( 0.0%)	0/20 ( 0.0%)	0/24 ( 0.0%)	0/19 ( 0.0%)	0/22 ( 0.0%)
	Terminal Incidence	0/18 ( 0.0%)	0/22 ( 0.0%)	0/18 ( 0.0%)	0/24 ( 0.0%)	0/18 ( 0.0%)	0/21 ( 0.0%)
	Time-to-First	282	----	----	----	----	----
	CAFE P-Value	0.028N*	0.244N	0.268N	0.223N	0.282N	0.244N
	Severity Profile	0 0 2	---	---	---	---	---
	JT/SW P-Value	0.019N*	0.076N	0.054N	0.024N*	0.020N*	0.009N**
	RTE P-Value	0.013N*	0.013N*	0.013N*	0.013N*	0.013N*	0.013N*
Kidney * Casts Protein	Simple Incidence	2/22 ( 9.1%)	1/22 ( 4.5%)	0/20 ( 0.0%)	1/24 ( 4.2%)	0/19 ( 0.0%)	0/22 ( 0.0%)
	Terminal Incidence	1/18 ( 5.6%)	1/22 ( 4.5%)	0/18 ( 0.0%)	1/24 ( 4.2%)	0/18 ( 0.0%)	0/21 ( 0.0%)
	Time-to-First	258	361 (T)	----	363 (T)	----	----
	CAFE P-Value	0.055N	0.500N	0.268N	0.467N	0.282N	0.244N
	Severity Profile	1 1 0 0	1 0 0 0	---	1 0 0 0	---	---
	JT/SW P-Value	0.039N*	0.268N	0.097N	0.166N	0.079N	0.051N
	RTE P-Value	0.035N*	0.130N	0.043N*	0.102N	0.046N*	0.047N*
Kidney * Cyst,Cortex	Simple Incidence	4/22 ( 18.2%)	7/22 ( 31.8%)	6/20 ( 30.0%)	2/24 ( 8.3%)	4/19 ( 21.1%)	5/22 ( 22.7%)
	Terminal Incidence	4/18 ( 22.2%)	7/22 ( 31.8%)	5/18 ( 27.8%)	2/24 ( 8.3%)	4/18 ( 22.2%)	5/21 ( 23.8%)
	Time-to-First	361 (T)	360 (T)	319	359 (T)	361 (T)	360 (T)
	CAFE P-Value	0.357N	0.244	0.296	0.291N	0.562	0.500
	Severity Profile	1 1 0 0	1 1 0 0	1 1 0 0	1 0 0 0	1 1 0 0	1 1 0 0
Kidney * Cyst,Renal Tubule	Simple Incidence	4/22 ( 18.2%)	6/22 ( 27.3%)	9/20 ( 45.0%)	7/24 ( 29.2%)	4/19 ( 21.1%)	7/22 ( 31.8%)
	Terminal Incidence	4/18 ( 22.2%)	6/22 ( 27.3%)	8/18 ( 44.4%)	7/24 ( 29.2%)	4/18 ( 22.2%)	7/21 ( 33.3%)
	Time-to-First	362 (T)	360 (T)	127	359 (T)	361 (T)	360 (T)
	CAFE P-Value	0.337	0.360	0.061	0.301	0.562	0.244
	Severity Profile	1 1 0 0	1 1 0 0	1 1 0 0	1 0 0 0	1 1 0 0	1 1 0 0
Kidney * Nephropathy	Simple Incidence	16/22 ( 72.7%)	20/22 ( 90.9%)	18/20 ( 90.0%)	19/24 ( 79.2%)	16/19 ( 84.2%)	17/22 ( 77.3%)
	Terminal Incidence	15/18 ( 83.3%)	20/22 ( 90.9%)	17/18 ( 94.4%)	19/24 ( 79.2%)	16/18 ( 88.9%)	17/21 ( 81.0%)
	Time-to-First	173	356 (T)	127	359 (T)	360 (T)	359 (T)
	CAFE P-Value	0.476N	0.120	0.152	0.434	0.308	0.500
	Severity Profile	9 5 2 0	12 7 1 0	10 6 2 0	10 7 2 0	8 7 0 1	11 6 0 0
	JT/SW P-Value	0.392N	0.801N	0.893N	0.812N	0.863N	0.544N
	RTE P-Value	0.396N	0.205	0.148	0.306	0.204	0.411N

P-values for dose trend are presented in the "Control" column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

<sup>1</sup> Nonsignificant SW test due to the assumption of monotonicity.

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 11. Nonneoplasms by Body System for Interim Sacrifice Females EE2 Continuous Dose Arm</b>				
<b>System and Nonneoplasm</b>	<b>Treatment (ug/kg)</b>			
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>0.05</b>	<b>0.50</b>
<b>Alimentary System</b>				
Liver * Basophilic Focus	Simple Incidence	1/23 ( 4.3%)	3/26 ( 11.5%)	3/26 ( 11.5%)
	Terminal Incidence	1/21 ( 4.8%)	3/24 ( 12.5%)	3/26 ( 11.5%)
	Time-to-First	362 (T)	361 (T)	360 (T)
	CAFE P-Value	0.279	0.353	0.353
Liver * Hyperplasia,Bile Duct	Simple Incidence	3/23 ( 13.0%)	8/26 ( 30.8%)	4/26 ( 15.4%)
	Terminal Incidence	3/21 ( 14.3%)	8/24 ( 33.3%)	4/26 ( 15.4%)
	Time-to-First	362 (T)	360 (T)	361 (T)
	CAFE P-Value	0.515	0.127	0.571
	Severity Profile	3 0 0	6 2 0	2 2 0
	JT/SW P-Value	0.401	0.061	0.204
	RTE P-Value	0.373	0.057	0.373
Liver * Infiltration Cellular,Mononuclear Cell	Simple Incidence	4/23 ( 17.4%)	7/26 ( 26.9%)	2/26 ( 7.7%)
	Terminal Incidence	4/21 ( 19.0%)	7/24 ( 29.2%)	2/26 ( 7.7%)
	Time-to-First	362 (T)	361 (T)	362 (T)
	CAFE P-Value	0.225N	0.326	0.276N
	Severity Profile	4 0 0	7 0 0	2 0 0
	JT/SW P-Value	0.165N	0.785N	0.224N
	RTE P-Value	0.220N	0.217	0.220N
Liver * Tension Lipidosis	Simple Incidence	3/23 ( 13.0%)	3/26 ( 11.5%)	0/26 ( 0.0%)
	Terminal Incidence	2/21 ( 9.5%)	3/24 ( 12.5%)	0/26 ( 0.0%)
	Time-to-First	307	362 (T)	----
	CAFE P-Value	0.076N	0.605N	0.096N
	Severity Profile	0 2 1 0	1 1 0 1	---
	JT/SW P-Value	0.043N*	0.430N	0.055N
	RTE P-Value	0.059N	0.418N	0.059N
Liver * Vacuolization Cytoplasmic	Simple Incidence	2/23 ( 8.7%)	2/26 ( 7.7%)	1/26 ( 3.8%)
	Terminal Incidence	2/21 ( 9.5%)	2/24 ( 8.3%)	1/26 ( 3.8%)
	Time-to-First	360 (T)	362 (T)	362 (T)
	CAFE P-Value	0.347N	0.647N	0.453N
	Severity Profile	2 0 0 0	2 0 0 0	1 0 0 0
	JT/SW P-Value	0.246N	0.450N	0.299N
	RTE P-Value	0.253N	0.445N	0.253N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 11. Nonneoplasms by Body System for Interim Sacrifice Females EE2 Continuous Dose Arm</b>				
<b>System and Nonneoplasm</b>	<b>Treatment (ug/kg)</b>			
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>0.05</b>	<b>0.50</b>
Pancreas * Basophilic Focus	Simple Incidence	0/23 ( 0.0%)	2/26 ( 7.7%)	0/26 ( 0.0%)
	Terminal Incidence	0/21 ( 0.0%)	1/24 ( 4.2%)	0/26 ( 0.0%)
	Time-to-First	----	257	----
	CAFE P-Value	0.639N	0.276	
Pancreas * Degeneration,Acinus	Simple Incidence	13/23 ( 56.5%)	20/26 ( 76.9%)	18/26 ( 69.2%)
	Terminal Incidence	12/21 ( 57.1%)	18/24 ( 75.0%)	18/26 ( 69.2%)
	Time-to-First	56	257	360 (T)
	CAFE P-Value	0.227	0.112	0.266
	Severity Profile	5 5 2 1	9 10 1 0	10 5 1 2
	JT/SW P-Value	0.390	0.204	0.320
	RTE P-Value	0.364	0.194	0.364
<b>Cardiovascular System</b>				
Heart * Cardiomyopathy	Simple Incidence	7/23 ( 30.4%)	8/26 ( 30.8%)	17/26 ( 65.4%)
	Terminal Incidence	7/21 ( 33.3%)	8/24 ( 33.3%)	17/26 ( 65.4%)
	Time-to-First	360 (T)	360 (T)	360 (T)
	CAFE P-Value	0.009 **	0.613	0.015 *
	Severity Profile	6 1 0 0	8 0 0 0	13 4 0 0
	JT/SW P-Value	0.004 **	0.530	0.006 **
	RTE P-Value	0.004 **	0.456N	0.004 **
<b>Endocrine System</b>				
Adrenal Cortex * Degeneration,Cystic	Simple Incidence	2/23 ( 8.7%)	0/26 ( 0.0%)	6/26 ( 23.1%)
	Terminal Incidence	2/21 ( 9.5%)	0/24 ( 0.0%)	6/26 ( 23.1%)
	Time-to-First	362 (T)	----	360 (T)
	CAFE P-Value	0.071	0.215N	0.166
	Severity Profile	1 0 1 0	---	1 4 1 0
	JT/SW P-Value	0.042 *	0.936	0.062
	RTE P-Value	0.056	0.173N	0.056
Parathyroid Gland * Hyperplasia	Simple Incidence	2/23 ( 8.7%)	2/26 ( 7.7%)	1/25 ( 4.0%)
	Terminal Incidence	1/21 ( 4.8%)	2/24 ( 8.3%)	1/25 ( 4.0%)
	Time-to-First	56	361 (T)	363 (T)
	CAFE P-Value	0.360N	0.647N	0.468N
	Severity Profile	2 0 0 0	0 2 0 0	1 0 0 0
	JT/SW P-Value	0.265N	0.483N	0.318N
	RTE P-Value	0.269N	0.475N	0.269N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 11. Nonneoplasms by Body System for Interim Sacrifice Females EE2 Continuous Dose Arm</b>				
<b>System and Nonneoplasm</b>	<b>Treatment (ug/kg)</b>			
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>0.05</b>	<b>0.50</b>
Pituitary Gland * Angiectasis	Simple Incidence	1/23 ( 4.3%)	2/25 ( 8.0%)	6/26 ( 23.1%)
	Terminal Incidence	1/21 ( 4.8%)	2/23 ( 8.7%)	6/26 ( 23.1%)
	Time-to-First	362 (T)	361 (T)	361 (T)
	CAFE P-Value	0.034 *	0.532	0.069
	Severity Profile	0 1 0 0	0 1 0 1	0 4 1 1
	JT/SW P-Value	0.022 *	0.294	0.026 *
	RTE P-Value	0.025 *	0.333	0.025 *
Pituitary Gland * Cyst,Pars Distalis	Simple Incidence	2/23 ( 8.7%)	0/25 ( 0.0%)	4/26 ( 15.4%)
	Terminal Incidence	2/21 ( 9.5%)	0/23 ( 0.0%)	4/26 ( 15.4%)
	Time-to-First	360 (T)	----	361 (T)
	CAFE P-Value	0.261	0.224N	0.395
Pituitary Gland * Hyperplasia,Pars Distalis	Simple Incidence	18/23 ( 78.3%)	20/25 ( 80.0%)	25/26 ( 96.2%)
	Terminal Incidence	17/21 ( 81.0%)	20/23 ( 87.0%)	25/26 ( 96.2%)
	Time-to-First	307	361 (T)	360 (T)
	CAFE P-Value	0.057	0.581	0.070
	Severity Profile	8 6 3 1	10 7 3 0	4 11 6 4
	JT/SW P-Value	0.002 **	0.598	0.003 **
	RTE P-Value	0.003 **	0.370N	0.003 **
Thyroid Gland * Hyperplasia,C-Cell	Simple Incidence	14/23 ( 60.9%)	11/26 ( 42.3%)	13/26 ( 50.0%)
	Terminal Incidence	14/21 ( 66.7%)	11/24 ( 45.8%)	13/26 ( 50.0%)
	Time-to-First	359 (T)	361 (T)	361 (T)
	CAFE P-Value	0.283N	0.156N	0.318N
	Severity Profile	8 6 0 0	7 4 0 0	11 11 1 0
	JT/SW P-Value	0.139N	0.094N	0.122N
	RTE P-Value	0.126N	0.087N	0.126N
Thyroid Gland * Ultimobranchial Cyst	Simple Incidence	7/23 ( 30.4%)	7/26 ( 26.9%)	11/26 ( 42.3%)
	Terminal Incidence	7/21 ( 33.3%)	7/24 ( 29.2%)	11/26 ( 42.3%)
	Time-to-First	361 (T)	361 (T)	360 (T)
	CAFE P-Value	0.226	0.517N	0.287



RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 11. Nonneoplasms by Body System for Interim Sacrifice Females EE2 Continuous Dose Arm</i>				
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>			
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>0.05</i>	<i>0.50</i>
<b>Genital System</b>				
Ovary * Atrophy	Simple Incidence	10/23 ( 43.5%)	9/25 ( 36.0%)	26/26 (100.0%)
	Terminal Incidence	10/21 ( 47.6%)	9/24 ( 37.5%)	26/26 (100.0%)
	Time-to-First	361 (T)	361 (T)	360 (T)
	CAFE P-Value	<.001 ***	0.407N	<.001 ***
	Severity Profile	1 4 0 5	0 3 0 6	0 0 0 26
	JT/SW P-Value	<.001 ***	0.616	<.001 ***
	RTE P-Value	<.001 ***	0.426N	<.001 ***
Ovary * Cyst	Simple Incidence	1/23 ( 4.3%)	1/25 ( 4.0%)	2/26 ( 7.7%)
	Terminal Incidence	1/21 ( 4.8%)	1/24 ( 4.2%)	2/26 ( 7.7%)
	Time-to-First	362 (T)	361 (T)	361 (T)
	CAFE P-Value	0.421	0.734N	0.547
Ovary * Cyst,Bursa	Simple Incidence	0/23 ( 0.0%)	1/25 ( 4.0%)	4/26 ( 15.4%)
	Terminal Incidence	0/21 ( 0.0%)	1/24 ( 4.2%)	4/26 ( 15.4%)
	Time-to-First	----	363 (T)	360 (T)
	CAFE P-Value	0.027 *	0.521	0.071
Ovary * Cyst,Follicle	Simple Incidence	8/23 ( 34.8%)	9/25 ( 36.0%)	26/26 (100.0%)
	Terminal Incidence	8/21 ( 38.1%)	9/24 ( 37.5%)	26/26 (100.0%)
	Time-to-First	361 (T)	361 (T)	360 (T)
	CAFE P-Value	<.001 ***	0.585	<.001 ***
Ovary * Depletion,Corpus Luteum	Simple Incidence	4/23 ( 17.4%)	6/25 ( 24.0%)	26/26 (100.0%)
	Terminal Incidence	4/21 ( 19.0%)	6/24 ( 25.0%)	26/26 (100.0%)
	Time-to-First	362 (T)	361 (T)	360 (T)
	CAFE P-Value	<.001 ***	0.419	<.001 ***
Ovary * Diestrus	Simple Incidence	15/23 ( 65.2%)	12/25 ( 48.0%)	0/26 ( 0.0%)
	Terminal Incidence	14/21 ( 66.7%)	11/24 ( 45.8%)	0/26 ( 0.0%)
	Time-to-First	56	257	----
	CAFE P-Value	<.001N***	0.182N	<.001N***

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 11. Nonneoplasms by Body System for Interim Sacrifice Females EE2 Continuous Dose Arm</b>				
<b>System and Nonneoplasm</b>	<b>Treatment (ug/kg)</b>			
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>0.05</b>	<b>0.50</b>
Ovary * Hypertrophy,Interstitial Cell	Simple Incidence	4/23 ( 17.4%)	5/25 ( 20.0%)	26/26 (100.0%)
	Terminal Incidence	4/21 ( 19.0%)	5/24 ( 20.8%)	26/26 (100.0%)
	Time-to-First	362 (T)	361 (T)	360 (T)
	CAFE P-Value	<.001 ***	0.556	<.001 ***
	Severity Profile	0 4 0 0	0 4 1 0	1 13 10 2
	JT/SW P-Value	<.001 ***	0.386	<.001 ***
	RTE P-Value	<.001 ***	0.339	<.001 ***
Ovary * Metestrus	Simple Incidence	3/23 ( 13.0%)	6/25 ( 24.0%)	0/26 ( 0.0%)
	Terminal Incidence	2/21 ( 9.5%)	6/24 ( 25.0%)	0/26 ( 0.0%)
	Time-to-First	307	361 (T)	----
	CAFE P-Value	0.107N	0.276	0.096N
Uterus * Apoptosis	Simple Incidence	2/23 ( 8.7%)	6/25 ( 24.0%)	18/26 ( 69.2%)
	Terminal Incidence	2/21 ( 9.5%)	6/24 ( 25.0%)	18/26 ( 69.2%)
	Time-to-First	362 (T)	361 (T)	360 (T)
	CAFE P-Value	<.001 ***	0.151	<.001 ***
	Severity Profile	0 0 0 2	0 1 2 3	0 2 6 10
	JT/SW P-Value	<.001 ***	0.096	<.001 ***
	RTE P-Value	<.001 ***	0.141	<.001 ***
Uterus * Cyst,Endometrium	Simple Incidence	0/23 ( 0.0%)	2/25 ( 8.0%)	2/26 ( 7.7%)
	Terminal Incidence	0/21 ( 0.0%)	2/24 ( 8.3%)	2/26 ( 7.7%)
	Time-to-First	----	362 (T)	362 (T)
	CAFE P-Value	0.206	0.266	0.276
Uterus * Diestrus	Simple Incidence	10/23 ( 43.5%)	8/25 ( 32.0%)	0/26 ( 0.0%)
	Terminal Incidence	9/21 ( 42.9%)	8/24 ( 33.3%)	0/26 ( 0.0%)
	Time-to-First	56	360 (T)	----
	CAFE P-Value	<.001N***	0.301N	<.001N***
Uterus * Estrus	Simple Incidence	4/23 ( 17.4%)	6/25 ( 24.0%)	21/26 ( 80.8%)
	Terminal Incidence	4/21 ( 19.0%)	6/24 ( 25.0%)	21/26 ( 80.8%)
	Time-to-First	362 (T)	361 (T)	360 (T)
	CAFE P-Value	<.001 ***	0.419	<.001 ***

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 11. Nonneoplasms by Body System for Interim Sacrifice Females EE2 Continuous Dose Arm</b>				
<b>System and Nonneoplasm</b>	<b>Treatment (ug/kg)</b>			
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>0.05</b>	<b>0.50</b>
Uterus * Hyperplasia,Cystic,Endometrium	Simple Incidence	5/23 ( 21.7%)	6/25 ( 24.0%)	14/26 ( 53.8%)
	Terminal Incidence	5/21 ( 23.8%)	6/24 ( 25.0%)	14/26 ( 53.8%)
	Time-to-First	362 (T)	361 (T)	360 (T)
	CAFE P-Value	0.012 *	0.563	0.021 *
	Severity Profile	1 2 1 1	3 3 0 0	4 6 2 2
	JT/SW P-Value	0.008 **	0.511	0.013 *
	RTE P-Value	0.012 *	0.452N	0.012 *
Uterus * Hyperplasia,Endometrial Glands	Simple Incidence	0/23 ( 0.0%)	1/25 ( 4.0%)	2/26 ( 7.7%)
	Terminal Incidence	0/21 ( 0.0%)	1/24 ( 4.2%)	2/26 ( 7.7%)
	Time-to-First	----	363 (T)	361 (T)
	CAFE P-Value	0.165	0.521	0.276
	Severity Profile	---	0 1 0 0	1 1 0 0
	JT/SW P-Value	0.091	0.169	0.106
	RTE P-Value	0.125	0.241	0.125
Uterus * Hyperplasia,Endometrium	Simple Incidence	2/23 ( 8.7%)	4/25 ( 16.0%)	0/26 ( 0.0%)
	Terminal Incidence	2/21 ( 9.5%)	4/24 ( 16.7%)	0/26 ( 0.0%)
	Time-to-First	362 (T)	361 (T)	----
	CAFE P-Value	0.185N	0.375	0.215N
	Severity Profile	0 2 0 0	0 4 0 0	---
	JT/SW P-Value	0.116N	0.775N	0.160N
	RTE P-Value	0.174N	0.232	0.174N
Uterus * Metaplasia,Squamous	Simple Incidence	1/23 ( 4.3%)	2/25 ( 8.0%)	14/26 ( 53.8%)
	Terminal Incidence	1/21 ( 4.8%)	2/24 ( 8.3%)	14/26 ( 53.8%)
	Time-to-First	362 (T)	361 (T)	361 (T)
	CAFE P-Value	<.001 ***	0.532	<.001 ***
	Severity Profile	0 1 0 0	1 0 1 0	8 4 2 0
	JT/SW P-Value	<.001 ***	0.303	<.001 ***
	RTE P-Value	<.001 ***	0.367	<.001 ***
Uterus * Metestrus	Simple Incidence	7/23 ( 30.4%)	9/25 ( 36.0%)	5/26 ( 19.2%)
	Terminal Incidence	6/21 ( 28.6%)	8/24 ( 33.3%)	5/26 ( 19.2%)
	Time-to-First	307	257	362 (T)
	CAFE P-Value	0.230N	0.460	0.282N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 11. Nonneoplasms by Body System for Interim Sacrifice Females EE2 Continuous Dose Arm</b>				
<b>System and Nonneoplasm</b>	<b>Treatment (ug/kg)</b>			
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>0.05</b>	<b>0.50</b>
Uterus * Proestrus	Simple Incidence	2/23 ( 8.7%)	2/25 ( 8.0%)	0/26 ( 0.0%)
	Terminal Incidence	2/21 ( 9.5%)	2/24 ( 8.3%)	0/26 ( 0.0%)
	Time-to-First	364 (T)	362 (T)	----
	CAFE P-Value	0.152N	0.663N	0.215N
Vagina * Diestrus	Simple Incidence	11/23 ( 47.8%)	10/25 ( 40.0%)	0/26 ( 0.0%)
	Terminal Incidence	10/21 ( 47.6%)	10/24 ( 41.7%)	0/26 ( 0.0%)
	Time-to-First	56	360 (T)	----
	CAFE P-Value	<.001N***	0.399N	<.001N***
Vagina * Estrus	Simple Incidence	3/23 ( 13.0%)	6/25 ( 24.0%)	20/26 ( 76.9%)
	Terminal Incidence	3/21 ( 14.3%)	6/24 ( 25.0%)	20/26 ( 76.9%)
	Time-to-First	362 (T)	361 (T)	360 (T)
	CAFE P-Value	<.001 ***	0.276	<.001 ***
Vagina * Hyperplasia,Epithelium	Simple Incidence	3/23 ( 13.0%)	7/25 ( 28.0%)	20/26 ( 76.9%)
	Terminal Incidence	3/21 ( 14.3%)	7/24 ( 29.2%)	20/26 ( 76.9%)
	Time-to-First	362 (T)	361 (T)	361 (T)
	CAFE P-Value	<.001 ***	0.180	<.001 ***
	Severity Profile	0 1 2 0	0 4 3 0	0 9 11 0
	JT/SW P-Value	<.001 ***	0.119	<.001 ***
	RTE P-Value	<.001 ***	0.150	<.001 ***
Vagina * Metestrus	Simple Incidence	7/23 ( 30.4%)	8/25 ( 32.0%)	6/26 ( 23.1%)
	Terminal Incidence	6/21 ( 28.6%)	7/24 ( 29.2%)	6/26 ( 23.1%)
	Time-to-First	307	257	361 (T)
	CAFE P-Value	0.335N	0.578	0.397N
Vagina * Mucification,Epithelium	Simple Incidence	10/23 ( 43.5%)	15/25 ( 60.0%)	18/26 ( 69.2%)
	Terminal Incidence	10/21 ( 47.6%)	15/24 ( 62.5%)	18/26 ( 69.2%)
	Time-to-First	360 (T)	360 (T)	360 (T)
	CAFE P-Value	0.048 *	0.196	0.063
	Severity Profile	0 6 1 3	0 5 1 9	1 4 6 7
	JT/SW P-Value	0.030 *	0.059	0.028 *
	RTE P-Value	0.027 *	0.052	0.027 *

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 11. Nonneoplasms by Body System for Interim Sacrifice Females EE2 Continuous Dose Arm</b>				
<b>System and Nonneoplasm</b>	<b>Treatment (ug/kg)</b>			
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>0.05</b>	<b>0.50</b>
<b>Hematopoietic System</b>				
Spleen * Pigmentation	Simple Incidence	22/23 (95.7%)	26/26 (100.0%)	26/26 (100.0%)
	Terminal Incidence	21/21 (100.0%)	24/24 (100.0%)	26/26 (100.0%)
	Time-to-First	307	257	360 (T)
	CAFE P-Value	0.307	0.469	0.469
	Severity Profile	0 8 10 4	0 10 11 5	0 2 10 14
	JT/SW P-Value	<.001 ***	0.415	<.001 ***
	RTE P-Value	0.001 **	0.418	0.001 **
Thymus * Atrophy	Simple Incidence	20/23 (87.0%)	20/25 (80.0%)	24/26 (92.3%)
	Terminal Incidence	19/21 (90.5%)	20/23 (87.0%)	24/26 (92.3%)
	Time-to-First	56	360 (T)	360 (T)
	CAFE P-Value	0.354	0.400N	0.440
	Severity Profile	0 2 8 10	0 5 6 9	0 6 2 16
	JT/SW P-Value	0.232	0.830	0.297
	RTE P-Value	0.249	0.180N	0.249
<b>Integumentary System</b>				
Mammary Gland * Dilatation,Duct	Simple Incidence	2/23 ( 8.7%)	3/26 ( 11.5%)	22/26 ( 84.6%)
	Terminal Incidence	2/21 ( 9.5%)	3/24 ( 12.5%)	22/26 ( 84.6%)
	Time-to-First	362 (T)	361 (T)	360 (T)
	CAFE P-Value	<.001 ***	0.560	<.001 ***
	Severity Profile	1 1 0 0	1 2 0 0	6 12 2 2
	JT/SW P-Value	<.001 ***	0.366	<.001 ***
	RTE P-Value	<.001 ***	0.373	<.001 ***
Mammary Gland * Galactocele	Simple Incidence	0/23 ( 0.0%)	0/26 ( 0.0%)	4/26 ( 15.4%)
	Terminal Incidence	0/21 ( 0.0%)	0/24 ( 0.0%)	4/26 ( 15.4%)
	Time-to-First	----	----	361 (T)
	CAFE P-Value	0.012 *		0.071
Mammary Gland * Hyperplasia,Lobular	Simple Incidence	10/23 ( 43.5%)	13/26 ( 50.0%)	23/26 ( 88.5%)
	Terminal Incidence	10/21 ( 47.6%)	13/24 ( 54.2%)	23/26 ( 88.5%)
	Time-to-First	361 (T)	360 (T)	360 (T)
	CAFE P-Value	<.001 ***	0.433	<.001 ***
	Severity Profile	5 5 0 0	6 6 1 0	11 11 1 0
	JT/SW P-Value	0.001 **	0.295	0.002 **
	RTE P-Value	0.002 **	0.279	0.002 **

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<b>Table 11. Nonneoplasms by Body System for Interim Sacrifice Females EE2 Continuous Dose Arm</b>				
<b>System and Nonneoplasm</b>	<b>Treatment (ug/kg)</b>			
<b>Lesion</b>	<b>Statistic</b>	<b>Control</b>	<b>0.05</b>	<b>0.50</b>
<b>Urinary System</b>				
Kidney * Casts Protein	Simple Incidence	2/23 ( 8.7%)	2/26 ( 7.7%)	4/26 ( 15.4%)
	Terminal Incidence	1/21 ( 4.8%)	1/24 ( 4.2%)	4/26 ( 15.4%)
	Time-to-First	307	315	361 (T)
	CAFE P-Value	0.297	0.647N	0.395
	Severity Profile	2 0 0	1 1 0	4 0 0
	JT/SW P-Value	0.222	0.534	0.274
	RTE P-Value	0.232	0.474N	0.232
Kidney * Cyst,Cortex	Simple Incidence	2/23 ( 8.7%)	4/26 ( 15.4%)	0/26 ( 0.0%)
	Terminal Incidence	2/21 ( 9.5%)	4/24 ( 16.7%)	0/26 ( 0.0%)
	Time-to-First	362 (T)	361 (T)	----
	CAFE P-Value	0.183N	0.395	0.215N
Kidney * Cyst,Renal Tubule	Simple Incidence	0/23 ( 0.0%)	5/26 ( 19.2%)	4/26 ( 15.4%)
	Terminal Incidence	0/21 ( 0.0%)	3/24 ( 12.5%)	4/26 ( 15.4%)
	Time-to-First	----	257	361 (T)
	CAFE P-Value	0.084	0.034 *	0.071
Kidney * Mineralization	Simple Incidence	11/23 ( 47.8%)	17/26 ( 65.4%)	14/26 ( 53.8%)
	Terminal Incidence	10/21 ( 47.6%)	16/24 ( 66.7%)	14/26 ( 53.8%)
	Time-to-First	307	257	360 (T)
	CAFE P-Value	0.407	0.171	0.447
	Severity Profile	11 0 0	10 6 1	7 5 1
	JT/SW P-Value	0.098	0.023 * <sup>1</sup>	0.064
	RTE P-Value	0.097	0.030 *	0.097
Kidney * Nephropathy	Simple Incidence	6/23 ( 26.1%)	13/26 ( 50.0%)	15/26 ( 57.7%)
	Terminal Incidence	5/21 ( 23.8%)	13/24 ( 54.2%)	15/26 ( 57.7%)
	Time-to-First	56	360 (T)	360 (T)
	CAFE P-Value	0.020 *	0.077	0.025 *
	Severity Profile	4 1 0	8 5 0	10 4 1
	JT/SW P-Value	0.021 *	0.051	0.022 *
	RTE P-Value	0.020 *	0.053	0.020 *

P-values for dose trend are presented in the “Control” column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

<sup>1</sup> Nonsignificant SW test due to the assumption of monotonicity.

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 12. Nonneoplasms by Body System for Interim Sacrifice Males EE2 Continuous Dose Arm</i>				
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>			
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>0.05</i>	<i>0.50</i>
<b>Alimentary System</b>				
Liver * Clear Cell Focus	Simple Incidence	3/22 ( 13.6%)	0/26 ( 0.0%)	2/26 ( 7.7%)
	Terminal Incidence	3/18 ( 16.7%)	0/22 ( 0.0%)	2/23 ( 8.7%)
	Time-to-First	361 (T)	----	362 (T)
	CAFE P-Value	0.331N	0.089N	0.419N
Liver * Fatty Change	Simple Incidence	0/22 ( 0.0%)	1/26 ( 3.8%)	4/26 ( 15.4%)
	Terminal Incidence	0/18 ( 0.0%)	1/22 ( 4.5%)	4/23 ( 17.4%)
	Time-to-First	----	361 (T)	361 (T)
	CAFE P-Value	0.028 *	0.542	0.077
	Severity Profile	---	0 0 1 0	0 1 3 0
	JT/SW P-Value	0.016 *	0.179	0.021 *
	RTE P-Value	0.019 *	0.294	0.019 *
Liver * Hepatodiaphragmatic Nodule	Simple Incidence	0/22 ( 0.0%)	4/26 ( 15.4%)	4/26 ( 15.4%)
	Terminal Incidence	0/18 ( 0.0%)	3/22 ( 13.6%)	4/23 ( 17.4%)
	Time-to-First	----	348	362 (T)
	CAFE P-Value	0.077	0.077	0.077
Liver * Hyperplasia,Bile Duct	Simple Incidence	3/22 ( 13.6%)	3/26 ( 11.5%)	4/26 ( 15.4%)
	Terminal Incidence	2/18 ( 11.1%)	3/22 ( 13.6%)	4/23 ( 17.4%)
	Time-to-First	258	362 (T)	360 (T)
	CAFE P-Value	0.508	0.582N	0.597
	Severity Profile	2 0 1 0	2 1 0 0	4 0 0 0
	JT/SW P-Value	0.450	0.593	0.539
	RTE P-Value	0.460	0.412N	0.460
Liver * Infiltration Cellular,Mononuclear Cell	Simple Incidence	5/22 ( 22.7%)	13/26 ( 50.0%)	5/26 ( 19.2%)
	Terminal Incidence	5/18 ( 27.8%)	13/22 ( 59.1%)	5/23 ( 21.7%)
	Time-to-First	361 (T)	359 (T)	360 (T)
	CAFE P-Value	0.408N	0.049 *	0.521N
	Severity Profile	5 0 0 0	13 0 0 0	5 0 0 0
	JT/SW P-Value	0.328N	0.973N	0.470N
	RTE P-Value	0.395N	0.024 *	0.395N

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 12. Nonneoplasms by Body System for Interim Sacrifice Males EE2 Continuous Dose Arm</i>				
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>			
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>0.05</i>	<i>0.50</i>
Liver * Tension Lipidosis	Simple Incidence	1/22 ( 4.5%)	1/26 ( 3.8%)	2/26 ( 7.7%)
	Terminal Incidence	1/18 ( 5.6%)	1/22 ( 4.5%)	2/23 ( 8.7%)
	Time-to-First	362 (T)	362 (T)	360 (T)
	CAFE P-Value	0.434	0.712N	0.564
	Severity Profile	0 1 0 0	0 0 1 0	0 1 1 0
	JT/SW P-Value	0.302	0.536	0.370
	RTE P-Value	0.313	0.472N	0.313
Liver * Vacuolization Cytoplasmic	Simple Incidence	8/22 ( 36.4%)	2/26 ( 7.7%)	4/26 ( 15.4%)
	Terminal Incidence	8/18 ( 44.4%)	2/22 ( 9.1%)	3/23 ( 13.0%)
	Time-to-First	359 (T)	362 (T)	315
	CAFE P-Value	0.059N	0.018N*	0.090N
	Severity Profile	6 2 0 0	1 1 0 0	3 1 0 0
	JT/SW P-Value	0.047N*	0.010N**	0.019N*
	RTE P-Value	0.032N*	0.007N**	0.032N*
Pancreas * Degeneration,Acinus	Simple Incidence	19/22 ( 86.4%)	18/26 ( 69.2%)	21/25 ( 84.0%)
	Terminal Incidence	17/18 ( 94.4%)	16/22 ( 72.7%)	20/23 ( 87.0%)
	Time-to-First	173	323	346
	CAFE P-Value	0.517N	0.144N	0.574N
	Severity Profile	4 4 5 6	4 6 5 3	7 7 4 3
	JT/SW P-Value	0.119N	0.055N	0.086N
	RTE P-Value	0.101N	0.050N*	0.101N
Pancreas * Pigmentation	Simple Incidence	8/22 ( 36.4%)	10/26 ( 38.5%)	8/25 ( 32.0%)
	Terminal Incidence	7/18 ( 38.9%)	9/22 ( 40.9%)	7/23 ( 30.4%)
	Time-to-First	258	348	346
	CAFE P-Value	0.431N	0.560	0.497N
	Severity Profile	6 2 0 0	6 4 0 0	6 2 0 0
	JT/SW P-Value	0.373N	0.614N	0.454N
	RTE P-Value	0.385N	0.388	0.385N



RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 12. Nonneoplasms by Body System for Interim Sacrifice Males EE2 Continuous Dose Arm</i>				
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>			
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>0.05</i>	<i>0.50</i>
<b>Cardiovascular System</b>				
Heart * Cardiomyopathy	Simple Incidence	16/22 ( 72.7%)	24/26 ( 92.3%)	23/26 ( 88.5%)
	Terminal Incidence	14/18 ( 77.8%)	21/22 ( 95.5%)	21/23 ( 91.3%)
	Time-to-First	258	323	315
	CAFE P-Value	0.106	0.077	0.154
	Severity Profile	11 4 1 0	15 7 2 0	14 5 4 0
	JT/SW P-Value	0.072	0.059	0.075
	RTE P-Value	0.066	0.062	0.066
<b>Endocrine System</b>				
Adrenal Cortex * Hyperplasia	Simple Incidence	0/22 ( 0.0%)	2/26 ( 7.7%)	0/26 ( 0.0%)
	Terminal Incidence	0/18 ( 0.0%)	2/22 ( 9.1%)	0/23 ( 0.0%)
	Time-to-First	----	361 (T)	----
	CAFE P-Value	0.629N	0.288	
	Severity Profile	---	0 1 1 0	---
	JT/SW P-Value	0.444N	0.906N	0.583N
	RTE P-Value	0.500N	0.059	0.500
Adrenal Cortex * Vacuolization Cytoplasmic	Simple Incidence	0/22 ( 0.0%)	3/26 ( 11.5%)	3/26 ( 11.5%)
	Terminal Incidence	0/18 ( 0.0%)	2/22 ( 9.1%)	3/23 ( 13.0%)
	Time-to-First	----	323	363 (T)
	CAFE P-Value	0.127	0.150	0.150
	Severity Profile	---	0 3 0 0	1 2 0 0
	JT/SW P-Value	0.088	0.052	0.087
	RTE P-Value	0.074	0.053	0.074
Parathyroid Gland * Hyperplasia	Simple Incidence	7/22 ( 31.8%)	6/26 ( 23.1%)	4/26 ( 15.4%)
	Terminal Incidence	7/18 ( 38.9%)	5/22 ( 22.7%)	4/23 ( 17.4%)
	Time-to-First	361 (T)	348	361 (T)
	CAFE P-Value	0.122N	0.361N	0.158N
	Severity Profile	3 4 0 0	0 6 0 0	1 2 1 0
	JT/SW P-Value	0.126N	0.335N	0.147N
	RTE P-Value	0.126N	0.311N	0.126N
Pituitary Gland * Cyst,Pars Distalis	Simple Incidence	1/22 ( 4.5%)	3/26 ( 11.5%)	3/26 ( 11.5%)
	Terminal Incidence	1/18 ( 5.6%)	3/22 ( 13.6%)	3/23 ( 13.0%)
	Time-to-First	361 (T)	361 (T)	362 (T)
	CAFE P-Value	0.295	0.371	0.371

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 12. Nonneoplasms by Body System for Interim Sacrifice Males EE2 Continuous Dose Arm</i>				
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>			
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>0.05</i>	<i>0.50</i>
Pituitary Gland * Hyperplasia,Pars Distalis	Simple Incidence	4/22 ( 18.2%)	7/26 ( 26.9%)	2/26 ( 7.7%)
	Terminal Incidence	4/18 ( 22.2%)	6/22 ( 27.3%)	2/23 ( 8.7%)
	Time-to-First	359 (T)	118	362 (T)
	CAFE P-Value	0.203N	0.357	0.256N
	Severity Profile	3 1 0 0	4 2 1 0	1 1 0 0
	JT/SW P-Value	0.161N	0.785N	0.224N
	RTE P-Value	0.192N	0.190	0.192N
Thyroid Gland * Hyperplasia,C-Cell	Simple Incidence	10/22 ( 45.5%)	7/25 ( 28.0%)	9/24 ( 37.5%)
	Terminal Incidence	8/18 ( 44.4%)	7/22 ( 31.8%)	9/23 ( 39.1%)
	Time-to-First	173	361 (T)	360 (T)
	CAFE P-Value	0.354N	0.174N	0.402N
	Severity Profile	3 4 3 0	4 2 1 0	4 5 0 0
	JT/SW P-Value	0.217N	0.073N	0.142N
	RTE P-Value	0.199N	0.065N	0.199N
Thyroid Gland * Hyperplasia,Follicular Cell	Simple Incidence	1/22 ( 4.5%)	4/25 ( 16.0%)	2/24 ( 8.3%)
	Terminal Incidence	1/18 ( 5.6%)	4/22 ( 18.2%)	2/23 ( 8.7%)
	Time-to-First	359 (T)	362 (T)	361 (T)
	CAFE P-Value	0.443	0.216	0.533
	Severity Profile	0 1 0 0	0 0 4 0	0 0 2 0
	JT/SW P-Value	0.330	0.091	0.210
	RTE P-Value	0.315	0.072	0.315
Thyroid Gland * Ultimobranchial Cyst	Simple Incidence	5/22 ( 22.7%)	3/25 ( 12.0%)	8/24 ( 33.3%)
	Terminal Incidence	5/18 ( 27.8%)	3/22 ( 13.6%)	8/23 ( 34.8%)
	Time-to-First	353 (T)	361 (T)	360 (T)
	CAFE P-Value	0.237	0.278N	0.320
<b>Genital System</b>				
Epididymis * Exfoliated Germ Cell	Simple Incidence	1/22 ( 4.5%)	4/26 ( 15.4%)	2/26 ( 7.7%)
	Terminal Incidence	1/18 ( 5.6%)	3/22 ( 13.6%)	2/23 ( 8.7%)
	Time-to-First	362 (T)	348	362 (T)
	CAFE P-Value	0.479	0.230	0.564
	Severity Profile	1 0 0 0	3 1 0 0	2 0 0 0
	JT/SW P-Value	0.396	0.109	0.243
	RTE P-Value	0.359	0.104	0.359

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 12. Nonneoplasms by Body System for Interim Sacrifice Males EE2 Continuous Dose Arm</i>				
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>			
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>0.05</i>	<i>0.50</i>
Epididymis * Hypospermia	Simple Incidence	2/22 ( 9.1%)	3/26 ( 11.5%)	1/26 ( 3.8%)
	Terminal Incidence	1/18 ( 5.6%)	2/22 ( 9.1%)	1/23 ( 4.3%)
	Time-to-First	258	323	363 (T)
	CAFE P-Value	0.333N	0.581	0.436N
	Severity Profile	0 0 1 1	0 0 0 3	0 0 0 1
	JT/SW P-Value	0.251N	0.630N	0.319N
	RTE P-Value	0.270N	0.362	0.270N
Epididymis * Infiltration Cellular,Lymphocyte	Simple Incidence	0/22 ( 0.0%)	1/26 ( 3.8%)	3/26 ( 11.5%)
	Terminal Incidence	0/18 ( 0.0%)	1/22 ( 4.5%)	3/23 ( 13.0%)
	Time-to-First	----	364 (T)	361 (T)
	CAFE P-Value	0.072	0.542	0.150
	Severity Profile	---	1 0 0 0	3 0 0 0
	JT/SW P-Value	0.038 *	0.179	0.046 *
	RTE P-Value	0.044 *	0.279	0.044 *
Prostate, Dorsal/Lateral Lobe * Infiltration Cellular,Lymphocyte	Simple Incidence	4/22 ( 18.2%)	9/26 ( 34.6%)	4/26 ( 15.4%)
	Terminal Incidence	4/18 ( 22.2%)	9/22 ( 40.9%)	4/23 ( 17.4%)
	Time-to-First	361 (T)	359 (T)	361 (T)
	CAFE P-Value	0.442N	0.171	0.548N
	Severity Profile	4 0 0 0	9 0 0 0	4 0 0 0
	JT/SW P-Value	0.361N	0.897N	0.484N
	RTE P-Value	0.409N	0.101	0.409N
Prostate, Dorsal/Lateral Lobe * Inflammation,Suppurative	Simple Incidence	18/22 ( 81.8%)	25/26 ( 96.2%)	25/26 ( 96.2%)
	Terminal Incidence	17/18 ( 94.4%)	22/22 (100.0%)	22/23 ( 95.7%)
	Time-to-First	258	323	237
	CAFE P-Value	0.069	0.126	0.126
	Severity Profile	11 7 0 0	13 11 0 1	12 13 0 0
	JT/SW P-Value	0.059	0.069	0.061
	RTE P-Value	0.051	0.070	0.051
Prostate, Ventral Lobe * Infiltration Cellular,Lymphocyte	Simple Incidence	8/22 ( 36.4%)	13/26 ( 50.0%)	13/26 ( 50.0%)
	Terminal Incidence	7/18 ( 38.9%)	12/22 ( 54.5%)	13/23 ( 56.5%)
	Time-to-First	173	118	361 (T)
	CAFE P-Value	0.222	0.256	0.256
	Severity Profile	8 0 0 0	11 2 0 0	12 1 0 0
	JT/SW P-Value	0.172	0.132	0.171
	RTE P-Value	0.156	0.132	0.156

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 12. Nonneoplasms by Body System for Interim Sacrifice Males EE2 Continuous Dose Arm</i>				
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>			
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>0.05</i>	<i>0.50</i>
Prostate, Ventral Lobe * Inflammation, Suppurative	Simple Incidence	10/22 ( 45.5%)	4/26 ( 15.4%)	5/26 ( 19.2%)
	Terminal Incidence	10/18 ( 55.6%)	4/22 ( 18.2%)	5/23 ( 21.7%)
	Time-to-First	353 (T)	361 (T)	361 (T)
	CAFE P-Value	0.034N*	0.024N*	0.050N
	Severity Profile	9 1 0 0	3 1 0 0	5 0 0 0
	JT/SW P-Value	0.025N*	0.015N*	0.016N*
	RTE P-Value	0.017N*	0.010N*	0.017N*
Testes * Degeneration, Seminiferous Tubule	Simple Incidence	6/22 ( 27.3%)	12/26 ( 46.2%)	6/25 ( 24.0%)
	Terminal Incidence	4/18 ( 22.2%)	10/22 ( 45.5%)	6/22 ( 27.3%)
	Time-to-First	258	323	361 (T)
	CAFE P-Value	0.440N	0.148	0.530N
	Severity Profile	3 1 0 2	8 1 0 3	6 0 0 0
	JT/SW P-Value	0.256N	0.878N	0.358N
	RTE P-Value	0.298N	0.101	0.298N
<b>Hematopoietic System</b>				
Spleen * Hematopoietic Cell Proliferation	Simple Incidence	0/22 ( 0.0%)	2/25 ( 8.0%)	0/25 ( 0.0%)
	Terminal Incidence	0/18 ( 0.0%)	0/22 ( 0.0%)	0/23 ( 0.0%)
	Time-to-First	----	323	----
	CAFE P-Value	0.638N	0.278	
	Severity Profile	---	0 2 0 0	---
	JT/SW P-Value	0.457N	0.910N	0.583N
	RTE P-Value	0.500	0.058	0.500
Spleen * Pigmentation	Simple Incidence	15/22 ( 68.2%)	18/25 ( 72.0%)	18/25 ( 72.0%)
	Terminal Incidence	14/18 ( 77.8%)	17/22 ( 77.3%)	16/23 ( 69.6%)
	Time-to-First	173	348	315
	CAFE P-Value	0.452	0.512	0.512
	Severity Profile	6 7 1 1	6 11 1 0	7 9 1 1
	JT/SW P-Value	0.416	0.398	0.478
	RTE P-Value	0.413	0.399	0.413

RR-9: CLARITY-BPA Core Study  
Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 12. Nonneoplasms by Body System for Interim Sacrifice Males EE2 Continuous Dose Arm</i>				
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>			
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>0.05</i>	<i>0.50</i>
Thymus * Atrophy	Simple Incidence	18/22 ( 81.8%)	24/26 ( 92.3%)	21/24 ( 87.5%)
	Terminal Incidence	18/18 (100.0%)	22/22 (100.0%)	20/22 ( 90.9%)
	Time-to-First	353 (T)	323	346
	CAFE P-Value	0.370	0.256	0.449
	Severity Profile	2 1 1 14	0 3 5 16	1 2 9 9
	JT/SW P-Value	0.145N	0.640N	0.195N
	RTE P-Value	0.160N	0.341	0.160N
<b>Integumentary System</b>				
Mammary Gland * Hyperplasia,Lobular	Simple Incidence	2/22 ( 9.1%)	3/26 ( 11.5%)	2/25 ( 8.0%)
	Terminal Incidence	2/18 ( 11.1%)	2/22 ( 9.1%)	2/22 ( 9.1%)
	Time-to-First	361 (T)	118	361 (T)
	CAFE P-Value	0.539N	0.581	0.645N
	Severity Profile	0 2 0 0	2 1 0 0	2 0 0 0
	JT/SW P-Value	0.402N	0.577N	0.487N
	RTE P-Value	0.414N	0.416	0.414N
<b>Nervous System</b>				
Brain, Cerebrum * Dilatation,Ventricle	Simple Incidence	0/22 ( 0.0%)	0/26 ( 0.0%)	2/26 ( 7.7%)
	Terminal Incidence	0/18 ( 0.0%)	0/22 ( 0.0%)	2/23 ( 8.7%)
	Time-to-First	----	----	363 (T)
	CAFE P-Value	0.120		0.288
	Severity Profile	---	---	1 1 0 0
	JT/SW P-Value	0.045 *	0.500	0.061
	RTE P-Value	0.061	0.500	0.061
<b>Urinary System</b>				
Kidney * Cyst,Cortex	Simple Incidence	4/22 ( 18.2%)	3/26 ( 11.5%)	6/25 ( 24.0%)
	Terminal Incidence	4/18 ( 22.2%)	3/22 ( 13.6%)	6/23 ( 26.1%)
	Time-to-First	361 (T)	361 (T)	361 (T)
	CAFE P-Value	0.359	0.403N	0.451
Kidney * Cyst,Renal Tubule	Simple Incidence	4/22 ( 18.2%)	10/26 ( 38.5%)	4/25 ( 16.0%)
	Terminal Incidence	4/18 ( 22.2%)	10/22 ( 45.5%)	4/23 ( 17.4%)
	Time-to-First	362 (T)	361 (T)	361 (T)
	CAFE P-Value	0.467N	0.110	0.573N

RR-9: CLARITY-BPA Core Study  
 Data from 33-Appendix XXXIII Interim Sacrifice Lesion Incidence Statistical Report-Non-Neoplastic

<i>Table 12. Nonneoplasms by Body System for Interim Sacrifice Males EE2 Continuous Dose Arm</i>				
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>			
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>0.05</i>	<i>0.50</i>
Kidney * Nephropathy	Simple Incidence	16/22 ( 72.7%)	23/26 ( 88.5%)	23/25 ( 92.0%)
	Terminal Incidence	15/18 ( 83.3%)	21/22 ( 95.5%)	22/23 ( 95.7%)
	Time-to-First	173	346	346
	CAFE P-Value	0.054	0.154	0.086
	Severity Profile	9 5 2 0	12 7 3 1	13 7 2 1
	JT/SW P-Value	0.122	0.108	0.128
	RTE P-Value	0.112	0.106	0.112

P-values for dose trend are presented in the “Control” column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

<sup>1</sup> Nonsignificant SW test due to the assumption of monotonicity.