

**TABLE A4**  
**Summary of the Incidence of Nonneoplastic Lesions in Male Rats in the 2-Year Feed Study of Fumonisin B<sub>1</sub><sup>a</sup>**

|   | 0 ppm   | 5 ppm    | 15 ppm   | 50 ppm   | 150 ppm  |
|---|---------|----------|----------|----------|----------|
| <b>Disposition Summary</b>              |         |          |          |          |          |
| 6-Week evaluation                       | 4       | 4        | 4        | 4        | 4        |
| 10-Week evaluation                      | 4       | 4        | 4        | 4        | 4        |
| 14-Week evaluation                      | 4       | 4        | 4        | 4        | 4        |
| 26-Week evaluation                      | 4       | 4        | 4        | 4        | 4        |
| Animals initially in 2-year study       | 48      | 40       | 48       | 48       | 48       |
| Early deaths                            |         |          |          |          |          |
| Removed from study                      | 2       |          |          | 2        |          |
| Moribund                                | 24      | 19       | 19       | 19       | 21       |
| Natural deaths                          | 6       | 4        | 4        | 9        | 2        |
| Survivors                               |         |          |          |          |          |
| Terminal sacrifice                      | 16      | 17       | 25       | 18       | 25       |
| Animals examined microscopically        | 64      | 56       | 64       | 64       | 64       |
| <b>6-Week Evaluation</b>                |         |          |          |          |          |
| Kidney                                  | (4)     | (4)      | (4)      | (4)      | (4)      |
| Apoptosis, cortex, renal tubule         |         |          | 4 (100%) | 4 (100%) | 4 (100%) |
| Cyst, medulla                           | 1 (25%) |          |          |          |          |
| Cytoplasmic alter, cortex, renal tubule | 1 (25%) |          |          |          |          |
| Liver                                   | (4)     | (4)      | (4)      | (4)      | (4)      |
| Fatty change, centrilobular             |         | 1 (25%)  |          |          |          |
| Inflammation, chronic                   |         | 1 (25%)  |          |          |          |
| <b>10-Week Evaluation</b>               |         |          |          |          |          |
| Kidney                                  | (4)     | (4)      | (4)      | (4)      | (4)      |
| Apoptosis, cortex, renal tubule         |         |          | 4 (100%) | 4 (100%) | 4 (100%) |
| Cyst, medulla                           |         |          |          |          | 1 (25%)  |
| Inflammation, chronic, pelvis           | 1 (25%) | 2 (50%)  |          |          |          |
| Nephropathy                             | 1 (25%) | 1 (25%)  | 1 (25%)  | 1 (25%)  |          |
| Liver                                   | (4)     | (4)      | (4)      | (4)      | (4)      |
| Angiectasis, focal, sinusoid            |         |          |          |          | 1 (25%)  |
| Hyperplasia, bile duct                  |         |          |          |          | 1 (25%)  |
| Necrosis, focal                         |         | 1 (25%)  |          |          |          |
| Mesentery                               |         |          |          | (1)      |          |
| Necrosis, focal, fat                    |         |          |          | 1 (100%) |          |
| <b>14-Week Evaluation</b>               |         |          |          |          |          |
| Kidney                                  | (4)     | (4)      | (4)      | (4)      | (4)      |
| Apoptosis, cortex, renal tubule         |         |          | 4 (100%) | 4 (100%) | 4 (100%) |
| Cyst, medulla                           |         |          |          | 1 (25%)  |          |
| Cytoplasmic alter, cortex, renal tubule | 2 (50%) |          |          |          |          |
| Nephropathy                             |         | 3 (75%)  | 1 (25%)  | 1 (25%)  | 2 (50%)  |
| Liver                                   | (4)     | (4)      | (4)      | (4)      | (4)      |
| Hyperplasia, bile duct                  |         | 2 (50%)  | 1 (25%)  | 1 (25%)  |          |
| Inflammation, chronic                   |         |          | 1 (25%)  | 1 (25%)  |          |
| Necrosis, multifocal                    |         |          | 1 (25%)  |          |          |
| Testes                                  |         | (1)      |          |          |          |
| Hemorrhage                              |         | 1 (100%) |          |          |          |

<sup>a</sup> Number of animals examined microscopically at the site and the number of animals with lesion

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|---|----------|----------|---------|----------|----------|
| <b>26-Week Evaluation</b>                 |          |          |         |          |          |
| Intestine large                           |          |          |         |          | (1)      |
| Hemorrhage, focal, cecum, submucosa       |          |          |         |          | 1 (100%) |
| Kidney                                    | (4)      | (4)      | (4)     | (4)      | (4)      |
| Apoptosis, cortex, renal tubule           |          | 1 (25%)  |         | 4 (100%) | 4 (100%) |
| Mineralization                            | 2 (50%)  |          |         |          | 1 (25%)  |
| Nephropathy                               | 4 (100%) | 3 (75%)  | 1 (25%) | 3 (75%)  | 4 (100%) |
| Liver                                     | (4)      | (4)      | (4)     | (4)      | (4)      |
| Devel malfor                              |          |          | 1 (4%)  |          |          |
| Fatty change, centrilobular               | 4 (100%) | 4 (100%) |         | 4 (100%) | 4 (100%) |
| Hyperplasia, bile duct                    | 1 (25%)  | 2 (50%)  | 3 (75%) | 4 (100%) | 2 (50%)  |
| Inflammation, chronic                     | 4 (100%) | 3 (75%)  | 3 (75%) | 3 (75%)  | 2 (50%)  |
| Necrosis, focal                           | 1 (25%)  |          |         | 1 (25%)  |          |
| Necrosis, multifocal                      |          |          | 1 (25%) |          |          |
| Vacuoliz cyto, focal                      | 2 (50%)  |          | 1 (25%) | 1 (25%)  | 1 (25%)  |
| <b>2-Year Study</b>                       |          |          |         |          |          |
| Adrenal gland                             | (47)     | (22)     | (25)    | (31)     | (47)     |
| Angiectasis, bilateral, cortex            |          |          |         |          | 1 (2%)   |
| Angiectasis, cortex                       |          |          |         | 1 (3%)   |          |
| Hema cell prol, cortex                    |          |          |         | 1 (3%)   | 1 (2%)   |
| Hyperplasia, focal, bilateral, cortex     |          |          |         |          | 1 (2%)   |
| Hyperplasia, focal, bilateral, medulla    | 1 (2%)   | 1 (5%)   | 1 (4%)  | 2 (6%)   |          |
| Hyperplasia, focal, cortex                | 5 (11%)  | 1 (5%)   | 1 (4%)  | 1 (3%)   | 1 (2%)   |
| Hyperplasia, focal, medulla               | 7 (15%)  | 3 (14%)  | 2 (8%)  | 3 (10%)  | 5 (11%)  |
| Infiltrat cell, lymphocytic               | 1 (2%)   |          |         |          |          |
| Vacuoliz cyto, diffuse, bilateral, cortex | 1 (2%)   |          |         | 1 (3%)   |          |
| Vacuoliz cyto, diffuse, cortex            | 2 (4%)   |          | 1 (4%)  |          | 1 (2%)   |
| Vacuoliz cyto, focal, bilateral, cortex   | 1 (2%)   |          |         |          | 1 (2%)   |
| Vacuoliz cyto, focal, cortex              | 11 (23%) | 4 (18%)  |         | 5 (17%)  | 8 (17%)  |
| Blood vessel                              | (47)     | (23)     | (23)    | (30)     | (47)     |
| Inflammation, chronic, mesent artery      |          | 1 (4%)   |         |          |          |
| Bone                                      | (48)     | (23)     | (23)    | (30)     | (48)     |
| Degen, epiphysis                          |          |          |         |          | 1 (2%)   |
| Degen, joint, cartilage                   |          | 1 (4%)   |         |          |          |
| Hyperostosis, turbinate                   | 1 (2%)   |          |         |          |          |
| Inflammation, chronic, joint              |          |          |         | 1 (3%)   |          |
| Bone, femur                               | (48)     | (23)     | (23)    | (29)     | (48)     |
| Hyperplasia, cartilage, epiphysis         |          |          | 2 (9%)  |          |          |
| Bone marrow                               | (47)     | (23)     | (23)    | (30)     | (48)     |
| Angiectasis                               |          |          |         |          | 1 (2%)   |
| Atrophy                                   |          |          |         | 1 (3%)   |          |
| Depletion                                 | 1 (2%)   |          | 3 (13%) | 2 (7%)   | 3 (6%)   |
| Hyperplasia                               | 7 (15%)  | 3 (13%)  | 3 (13%) | 7 (23%)  | 12 (25%) |
| Myelofibrosis                             | 1 (2%)   |          |         |          |          |
| Brain                                     | (48)     | (24)     | (23)    | (31)     | (48)     |
| Compression, hypothalamus                 | 11 (23%) | 7 (29%)  | 6 (26%) | 8 (26%)  | 4 (8%)   |
| Hemorrhage, hypothalamus                  |          |          |         | 1 (3%)   |          |
| Hemorrhage, ventricle                     |          |          |         | 1 (3%)   |          |
| Necrosis, hippocampus, neuron             |          |          |         |          | 1 (2%)   |
| Brain, cerebrum                           | (48)     | (24)     | (23)    | (31)     | (48)     |
| Compression                               |          | 1 (4%)   |         |          |          |
| Hemorrhage                                |          |          |         | 1 (3%)   |          |

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|  | 0 ppm    | 5 ppm    | 15 ppm   | 50 ppm   | 150 ppm  |
|--|----------|----------|----------|----------|----------|
| <b>2-Year Study</b> (continued)        |          |          |          |          |          |
| Coagulating gland                      | (48)     | (22)     | (23)     | (29)     | (48)     |
| Atrophy                                | 9 (19%)  | 2 (9%)   | 2 (9%)   | 1 (3%)   | 3 (6%)   |
| Atrophy, bilateral                     | 14 (29%) | 4 (18%)  | 8 (35%)  | 6 (21%)  | 16 (33%) |
| Degen, bilateral                       |          |          | 1 (4%)   |          |          |
| Infiltrat cell, lymphocytic            |          |          |          |          | 1 (2%)   |
| Inflammation, acute                    |          |          |          | 1 (3%)   |          |
| Inflammation, chronic active           |          | 1 (5%)   |          |          |          |
| Epididymis                             | (48)     | (23)     | (22)     | (28)     | (47)     |
| Atrophy                                |          |          |          |          | 1 (2%)   |
| Atrophy, bilateral                     | 2 (4%)   |          | 3 (14%)  | 1 (4%)   |          |
| Degen, mucoid, bilateral, epithelium   | 2 (4%)   | 1 (4%)   | 1 (5%)   |          | 2 (4%)   |
| Degen, mucoid, epithelium              | 6 (13%)  |          | 1 (5%)   | 1 (4%)   | 6 (13%)  |
| Hyperplasia, epithelium                |          | 1 (4%)   |          |          |          |
| Inflammation, chronic                  | 1 (2%)   |          |          |          | 1 (2%)   |
| Esophagus                              | (48)     | (22)     | (23)     | (30)     | (48)     |
| Inflammation, chronic, muscularis      |          |          |          | 1 (3%)   |          |
| Eye                                    | (47)     | (24)     | (26)     | (35)     | (48)     |
| Atrophy, bilateral, retina             | 32 (68%) | 7 (29%)  | 14 (54%) | 20 (57%) | 27 (56%) |
| Atrophy, retina                        | 5 (11%)  | 5 (21%)  | 3 (12%)  | 3 (9%)   | 5 (10%)  |
| Cataract, bilateral, lens              | 21 (45%) | 4 (17%)  | 7 (27%)  | 13 (37%) | 15 (31%) |
| Cataract, lens                         | 4 (9%)   | 1 (4%)   | 2 (9%)   | 3 (9%)   | 3 (6%)   |
| Degen, optic nerve                     |          |          |          |          | 1 (2%)   |
| Inflammation, acute, cornea            |          |          | 1 (4%)   |          |          |
| Inflammation, acute, iris              |          | 1 (4%)   |          |          |          |
| Inflammation, chronic, cornea          | 1 (2%)   |          |          |          |          |
| Necrosis, optic nerve                  | 1 (2%)   |          |          |          |          |
| Harderian gland                        | (48)     | (23)     | (23)     | (30)     | (48)     |
| Atrophy, focal                         | 2 (4%)   |          |          |          |          |
| Hyperplasia, focal                     |          |          |          | 1 (3%)   |          |
| Infiltrat cell, lymphocytic            | 15 (31%) | 4 (17%)  | 5 (22%)  | 11 (37%) | 18 (38%) |
| Infiltrat cell, lymphocytic, bilateral | 9 (19%)  | 3 (13%)  | 1 (4%)   | 2 (7%)   | 5 (10%)  |
| Inflammation, chronic                  |          |          |          | 2 (7%)   | 1 (2%)   |
| Heart                                  | (48)     | (23)     | (24)     | (30)     | (48)     |
| Cardiomyopathy                         | 42 (89%) | 15 (65%) | 14 (58%) | 23 (77%) | 37 (77%) |
| Inflammation, chronic, coron artery    |          | 1 (4%)   |          |          |          |
| Inflammation, chronic, epicardium      |          | 1 (4%)   |          |          |          |
| Inflammation, chronic, pericardium     |          | 1 (4%)   |          |          |          |
| Inflammation, chronic, valve           |          | 1 (4%)   |          |          | 3 (6%)   |
| Thrombus, atrium                       | 1 (2%)   | 2 (9%)   | 1 (4%)   |          | 1 (2%)   |
| Intestine large, cecum                 | (45)     | (23)     | (23)     | (25)     | (47)     |
| Parasite meta                          |          |          |          |          | 1 (2%)   |
| Intestine large, colon                 | (47)     | (23)     | (23)     | (28)     | (47)     |
| Hyperplasia, lymphoid                  |          |          | 1 (4%)   |          |          |
| Parasite meta                          |          |          |          |          | 1 (2%)   |
| Ulcer                                  |          | 1 (4%)   |          |          |          |
| Intestine large, rectum                | (48)     | (23)     | (23)     | (30)     | (47)     |
| Hemorrhage                             |          |          |          | 1 (3%)   |          |
| Hyperplasia, focal, epithelium         |          |          |          | 1 (3%)   |          |
| Parasite meta                          |          |          |          |          | 1 (2%)   |
| Intestine small, ileum                 | (45)     | (23)     | (22)     | (26)     | (47)     |
| Hyperplasia, lymphoid                  |          |          | 1 (5%)   |          |          |

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|--|----------|----------|----------|----------|----------|
| <b>2-Year Study</b> (continued)          |          |          |          |          |          |
| Kidney                                   | (48)     | (40)     | (48)     | (48)     | (48)     |
| Acc hyaline d, bilateral, renal tubule   | 1 (2%)   |          |          | 1 (2%)   | 1 (2%)   |
| Cyst                                     | 2 (4%)   | 1 (3%)   |          | 3 (6%)   | 7 (15%)  |
| Cyst, bilateral                          |          |          |          |          | 1 (2%)   |
| Cytoplas alter, bilateral, renal tubule  |          |          |          |          | 1 (2%)   |
| Hydronephrosis                           | 1 (2%)   |          |          |          |          |
| Hyperplasia, focal, renal tubule         | 2 (4%)   | 1 (3%)   | 4 (8%)   | 14 (29%) | 8 (17%)  |
| Inflammation, acute, bilateral, pelvis   |          |          |          | 1 (2%)   |          |
| Inflammation, chronic, artery            |          |          | 1 (2%)   | 1 (2%)   |          |
| Inflammation, chronic, artery, pelvis    |          | 1 (3%)   |          |          |          |
| Inflammation, chronic, bilateral, artery | 1 (2%)   | 1 (3%)   | 1 (2%)   |          |          |
| Mineralization                           | 1 (2%)   |          | 1 (2%)   | 1 (2%)   | 1 (2%)   |
| Mineralization, bilateral                |          | 1 (3%)   |          |          |          |
| Nephropathy                              |          |          | 1 (2%)   | 4 (8%)   | 3 (6%)   |
| Nephropathy, bilateral                   | 44 (92%) | 38 (95%) | 43 (90%) | 34 (71%) | 39 (81%) |
| Pigment, bilateral, renal tubule         | 13 (27%) | 8 (20%)  | 8 (17%)  | 2 (4%)   | 6 (13%)  |
| Pigment, renal tubule                    |          | 1 (3%)   |          | 1 (2%)   | 1 (2%)   |
| Lacrimal gland                           | (47)     | (23)     | (22)     | (30)     | (48)     |
| Atrophy, diffuse                         |          | 1 (4%)   |          |          |          |
| Atrophy, focal                           |          | 2 (9%)   | 1 (5%)   | 4 (13%)  | 1 (2%)   |
| Cyst                                     |          |          |          |          | 1 (2%)   |
| Hyperplasia, duct                        |          |          |          |          | 1 (2%)   |
| Infiltrat cell, lymphocytic              | 11 (23%) | 11 (48%) | 5 (23%)  | 9 (30%)  | 20 (42%) |
| Larynx                                   | (46)     | (21)     | (22)     | (29)     | (46)     |
| Cyst                                     | 2 (4%)   | 2 (10%)  | 2 (9%)   |          | 2 (4%)   |
| Inflammation, chronic                    | 1 (2%)   | 2 (10%)  |          | 1 (3%)   | 3 (7%)   |
| Inflammation, chronic active             | 2 (4%)   | 1 (5%)   |          |          |          |
| Liver                                    | (48)     | (40)     | (48)     | (48)     | (48)     |
| Angiectasis, focal                       | 1 (2%)   | 1 (3%)   |          | 1 (2%)   |          |
| Basoph focus                             | 3 (6%)   | 11 (28%) | 7 (15%)  | 9 (19%)  | 23 (48%) |
| Clear cl focus                           | 5 (10%)  | 10 (25%) | 14 (29%) | 6 (13%)  | 10 (21%) |
| Congestion                               |          | 1 (3%)   | 1 (2%)   | 1 (2%)   |          |
| Degen, cystic, focal                     | 6 (13%)  | 4 (10%)  | 5 (10%)  | 3 (6%)   | 2 (4%)   |
| Degen, cystic, focal, hepatocyte         |          |          | 1 (2%)   |          |          |
| Eosin focus                              | 5 (10%)  | 6 (15%)  | 10 (21%) | 5 (10%)  | 10 (21%) |
| Hdn                                      | 3 (6%)   | 3 (8%)   | 2 (4%)   | 3 (6%)   | 5 (10%)  |
| Hema cell prol                           |          |          | 1 (2%)   | 1 (2%)   |          |
| Hemorrhage                               | 1 (2%)   |          |          |          |          |
| Hyperplasia, bile duct                   | 38 (79%) | 35 (88%) | 45 (94%) | 42 (88%) | 43 (90%) |
| Inflammation, chronic                    | 2 (4%)   | 4 (10%)  | 2 (4%)   | 1 (2%)   | 4 (8%)   |
| Mixed cl focus                           | 5 (10%)  | 6 (15%)  | 5 (10%)  | 4 (8%)   | 9 (19%)  |
| Necrosis                                 | 4 (8%)   |          | 1 (2%)   | 5 (10%)  | 1 (2%)   |
| Pigment                                  |          |          |          |          | 1 (2%)   |
| Tension lipoid                           | 3 (6%)   | 5 (13%)  | 7 (15%)  | 7 (15%)  | 7 (15%)  |
| Thrombus, vein                           |          |          | 1 (2%)   |          |          |
| Vacuoliz cyto, hepatocyte                | 13 (27%) | 8 (20%)  | 12 (25%) | 9 (19%)  | 13 (27%) |
| Lung                                     | (48)     | (24)     | (23)     | (32)     | (48)     |
| Congestion                               |          |          |          |          | 1 (2%)   |
| Foreign body                             |          |          | 1 (4%)   |          |          |
| Hyperplasia, focal, alveolar epith       |          | 1 (4%)   |          | 2 (6%)   | 1 (2%)   |
| Infiltrat cell, histiocytic              |          | 1 (4%)   | 1 (4%)   | 1 (3%)   | 1 (2%)   |
| Infiltrat cell, lymphocytic              |          |          |          |          | 1 (2%)   |
| Inflammation, chronic, interstitium      | 1 (2%)   |          | 1 (4%)   | 2 (6%)   | 1 (2%)   |
| Lung, bronchus                           | (48)     | (24)     | (23)     | (31)     | (48)     |
| Inflammation, chronic active             |          |          | 1 (4%)   |          |          |

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|--|----------|---------|----------|----------|----------|
| <b>2-Year Study</b> (continued)              |          |         |          |          |          |
| Lymph node                                   | (48)     | (24)    | (27)     | (33)     | (48)     |
| Degen, cystic, deep cervical                 |          |         | 1 (4%)   |          |          |
| Degen, cystic, mediastinal                   |          | 1 (4%)  |          |          |          |
| Degen, cystic, renal                         |          | 1 (4%)  |          |          |          |
| Lymph node, mandibular                       | (48)     | (23)    | (26)     | (32)     | (48)     |
| Degen, cystic                                | 6 (13%)  |         | 2 (8%)   | 3 (9%)   | 6 (13%)  |
| Hemorrhage                                   | 1 (2%)   |         |          | 3 (9%)   | 1 (2%)   |
| Hyperplasia, lymphoid                        | 5 (10%)  | 4 (17%) |          | 5 (16%)  | 10 (21%) |
| Infiltrat cell, histiocytic                  | 1 (2%)   | 1 (4%)  |          | 2 (6%)   |          |
| Lymph node, mesenteric                       | (47)     | (23)    | (23)     | (30)     | (48)     |
| Atrophy                                      | 1 (2%)   |         | 1 (4%)   | 1 (3%)   |          |
| Degen, cystic                                | 3 (6%)   | 1 (4%)  | 1 (4%)   | 1 (3%)   | 3 (6%)   |
| Hemorrhage                                   | 1 (2%)   | 1 (4%)  | 2 (9%)   | 3 (10%)  | 1 (2%)   |
| Hyperplasia, lymphoid                        |          | 1 (4%)  |          | 2 (7%)   |          |
| Infiltrat cell, histiocytic                  | 27 (57%) | 9 (39%) | 11 (48%) | 15 (50%) | 27 (56%) |
| Inflammation, chronic                        |          |         |          |          | 1 (2%)   |
| Mammary gland                                | (40)     | (20)    | (24)     | (24)     | (42)     |
| Cyst   | 11 (28%) | 3 (15%) | 3 (13%)  | 5 (21%)  | 4 (10%)  |
| Galactocele                                  | 5 (13%)  | 3 (15%) | 7 (29%)  |          | 8 (19%)  |
| Hyperplasia, epithelium                      |          |         | 1 (4%)   | 1 (4%)   |          |
| Hyperplasia, focal, epithelium               |          |         |          |          | 1 (2%)   |
| Mesentery                                    | (4)      | (3)     | (3)      | (4)      | (4)      |
| Accessory spln                               |          | 1 (33%) |          |          |          |
| Inflammation, chronic, artery                |          | 1 (33%) |          |          |          |
| Necrosis, fat                                | 3 (75%)  | 1 (33%) | 3 (100%) | 3 (75%)  | 3 (75%)  |
| Nose   | (48)     | (23)    | (23)     | (29)     | (48)     |
| Cytoplas alter, olfactory epi                | 20 (42%) | 7 (30%) | 10 (43%) | 6 (21%)  | 18 (38%) |
| Foreign body                                 | 2 (4%)   | 3 (13%) | 1 (4%)   | 1 (3%)   | 3 (6%)   |
| Inflammation, acute                          |          |         | 1 (4%)   | 1 (3%)   | 1 (2%)   |
| Inflammation, acute, nasolacrim dct          | 1 (2%)   | 1 (4%)  | 1 (4%)   | 2 (7%)   | 1 (2%)   |
| Inflammation, chronic                        | 1 (2%)   | 2 (9%)  | 1 (4%)   | 1 (3%)   |          |
| Inflammation, chronic active                 | 1 (2%)   | 2 (9%)  | 1 (4%)   | 2 (7%)   | 2 (4%)   |
| Inflammation, chronic active, nasolacrim dct | 5 (10%)  | 4 (17%) |          | 3 (10%)  | 10 (21%) |
| Inflammation, chronic, nasolacrim dct        | 7 (15%)  | 2 (9%)  | 4 (17%)  |          | 4 (8%)   |
| Pancreas                                     | (47)     | (24)    | (25)     | (30)     | (48)     |
| Atrophy, diffuse, acinar cell                | 2 (4%)   | 1 (4%)  | 2 (8%)   | 1 (3%)   | 1 (2%)   |
| Atrophy, focal, acinar cell                  | 20 (43%) | 8 (33%) | 9 (36%)  | 13 (43%) | 28 (58%) |
| Basoph focus, acinar cell                    |          |         | 1 (4%)   |          | 2 (4%)   |
| Hyperplasia, focal                           |          | 1 (4%)  | 1 (4%)   |          | 1 (2%)   |
| Hyperplasia, focal, acinar cell              | 1 (2%)   |         |          |          | 1 (2%)   |
| Hyperplasia, focal, duct                     | 1 (2%)   |         |          |          |          |
| Infiltrat cell, lymphocytic                  |          |         |          | 1 (3%)   | 2 (4%)   |
| Inflammation, chronic, artery                | 1 (2%)   | 1 (4%)  | 1 (4%)   |          | 2 (4%)   |
| Necrosis, focal                              |          | 1 (4%)  |          |          |          |
| Parathyroid gland                            | (46)     | (21)    | (22)     | (26)     | (47)     |
| Hyperplasia, focal                           |          |         |          |          | 1 (2%)   |
| Pigment                                      |          |         |          |          | 1 (2%)   |
| Pituitary gland                              | (43)     | (28)    | (33)     | (33)     | (45)     |
| Angiectasis, pars distalis                   |          |         |          | 1 (3%)   | 1 (2%)   |
| Atypical cells, pars nervosa                 |          |         |          |          | 1 (2%)   |
| Cyst, pars distalis                          |          |         |          |          | 2 (4%)   |
| Cyst, pars intermed                          | 1 (2%)   |         |          |          | 1 (2%)   |
| Cyst, pars nervosa                           |          |         |          |          | 1 (2%)   |
| Cyst, Rathke's cleft                         |          |         |          |          | 1 (2%)   |
| Hemorrhage                                   | 1 (2%)   |         |          | 1 (3%)   |          |
| Hemorrhage, pars distalis                    |          |         |          | 1 (3%)   |          |
| Hyperplasia, focal, pars distalis            | 3 (7%)   | 1 (4%)  | 2 (6%)   | 1 (3%)   | 7 (16%)  |
| Hypertrophy, focal, pars distalis            |          | 1 (4%)  | 2 (6%)   |          | 1 (2%)   |

**TABLE A4**  
**Summary of the Incidence of Nonneoplastic Lesions in Male Rats in the 2-Year Feed Study of Fumonisin B<sub>1</sub>**

|  | 0 ppm    | 5 ppm    | 15 ppm   | 50 ppm   | 150 ppm  |
|--|----------|----------|----------|----------|----------|
| <b>2-Year Study</b> (continued)          |          |          |          |          |          |
| Preputial gland                          | (43)     | (19)     | (20)     | (30)     | (44)     |
| Foreign body                             |          |          |          |          | 1 (2%)   |
| Hyperplasia, focal                       | 3 (7%)   |          |          |          |          |
| Inflammation, acute                      | 1 (2%)   |          |          |          |          |
| Inflammation, chronic                    | 18 (42%) | 6 (32%)  | 9 (45%)  | 15 (50%) | 13 (30%) |
| Inflammation, chronic active             |          |          | 1 (5%)   |          | 4 (9%)   |
| Inflammation, chronic active, bilateral  |          | 2 (11%)  |          | 2 (7%)   | 2 (5%)   |
| Inflammation, chronic, bilateral         | 7 (16%)  | 3 (16%)  | 6 (30%)  | 5 (17%)  | 9 (20%)  |
| Prostate                                 | (48)     | (22)     | (23)     | (30)     | (48)     |
| Atrophy                                  | 10 (21%) | 4 (18%)  | 5 (22%)  | 6 (20%)  | 12 (25%) |
| Cyst                                     |          | 1 (5%)   |          |          |          |
| Cytoplas alter, epithelium               |          |          |          |          | 1 (2%)   |
| Fibrosis                                 |          |          | 1 (4%)   |          |          |
| Hyperplasia, focal, epithelium           | 1 (2%)   |          |          | 3 (10%)  | 3 (6%)   |
| Inflammation, acute                      | 7 (15%)  | 3 (14%)  | 2 (9%)   | 7 (23%)  | 6 (13%)  |
| Inflammation, chronic                    | 3 (6%)   |          | 3 (13%)  | 2 (7%)   | 2 (4%)   |
| Inflammation, chronic active             | 11 (23%) | 8 (36%)  | 4 (17%)  | 3 (10%)  | 10 (21%) |
| Salivary glands                          | (48)     | (23)     | (23)     | (30)     | (48)     |
| Atrophy, diffuse, parotid gland          | 2 (4%)   | 1 (4%)   | 3 (13%)  | 1 (3%)   | 4 (8%)   |
| Cyst                                     |          | 1 (4%)   |          |          |          |
| Cytoplas alter, focal, submandibul gland | 1 (2%)   |          |          |          | 1 (2%)   |
| Infiltrat cell, lymphocytic              |          |          |          |          | 1 (2%)   |
| Inflammation, chronic, submandibul gland |          |          |          |          | 1 (2%)   |
| Seminal vesicle                          | (48)     | (23)     | (24)     | (30)     | (48)     |
| Atrophy                                  | 8 (17%)  | 1 (4%)   | 2 (8%)   | 1 (3%)   | 5 (10%)  |
| Atrophy, bilateral                       | 19 (40%) | 11 (48%) | 13 (54%) | 10 (33%) | 18 (38%) |
| Skeletal muscle, thigh                   | (48)     | (23)     | (24)     | (30)     | (48)     |
| Degen                                    |          | 1 (4%)   |          | 1 (3%)   | 1 (2%)   |
| Hemorrhage                               |          |          | 1 (4%)   |          |          |
| Skin                                     | (48)     | (27)     | (28)     | (32)     | (48)     |
| Atrophy, hair follicle                   |          |          |          |          | 1 (2%)   |
| Inflammation, chronic                    | 1 (2%)   |          |          | 1 (3%)   |          |
| Spinal cord, thoracic                    | (47)     | (23)     | (23)     | (30)     | (48)     |
| Hemorrhage                               | 1 (2%)   |          |          |          |          |
| Spleen                                   | (48)     | (29)     | (33)     | (41)     | (48)     |
| Atrophy, lymph follic                    | 1 (2%)   |          | 2 (6%)   | 1 (2%)   |          |
| Congestion                               | 2 (4%)   | 1 (3%)   | 1 (3%)   | 1 (2%)   | 3 (6%)   |
| Depletion, focal                         | 1 (2%)   |          |          | 2 (5%)   |          |
| Fibrosis, focal                          | 1 (2%)   | 2 (7%)   |          | 3 (7%)   | 2 (4%)   |
| Hema cell prol                           | 5 (10%)  | 4 (14%)  | 3 (9%)   | 5 (12%)  | 6 (13%)  |
| Infarct, focal                           |          |          | 1 (3%)   |          |          |
| Inflammation, chronic active             |          |          |          | 1 (2%)   |          |
| Inflammation, chronic, capsule           | 1 (2%)   |          | 1 (3%)   |          |          |
| Pigment                                  | 4 (8%)   |          | 4 (12%)  | 3 (7%)   | 2 (4%)   |
| Stomach, forestomach                     | (48)     | (23)     | (23)     | (30)     | (48)     |
| Edema                                    | 2 (4%)   |          |          | 1 (3%)   | 1 (2%)   |
| Erosion, focal                           | 1 (2%)   |          |          |          |          |
| Hyperplasia, epithelium                  | 8 (17%)  | 3 (13%)  | 4 (17%)  | 3 (10%)  | 4 (8%)   |
| Inflammation, acute                      |          |          |          | 1 (3%)   |          |
| Inflammation, chronic                    | 4 (8%)   | 2 (9%)   | 2 (9%)   | 5 (17%)  | 1 (2%)   |
| Inflammation, chronic active             | 1 (2%)   |          |          |          | 1 (2%)   |
| Ulcer                                    | 1 (2%)   |          |          | 2 (7%)   | 2 (4%)   |

**TABLE A4**  
**Summary of the Incidence of Nonneoplastic Lesions in Male Rats in the 2-Year Feed Study of Fumonisin B<sub>1</sub>**

|   | 0 ppm    | 5 ppm   | 15 ppm   | 50 ppm  | 150 ppm  |
|---|----------|---------|----------|---------|----------|
| <b>2-Year Study</b> (continued)               |          |         |          |         |          |
| Stomach, glandular                            | (48)     | (23)    | (23)     | (30)    | (48)     |
| Cyst  | 3 (6%)   | 2 (9%)  |          |         |          |
| Edema   |          | 1 (4%)  |          |         | 1 (2%)   |
| Erosion                                       |          |         | 1 (4%)   |         |          |
| Erosion, focal                                | 1 (2%)   |         | 2 (9%)   |         |          |
| Inflammation, acute                           | 1 (2%)   |         |          |         |          |
| Inflammation, chronic                         | 1 (2%)   | 1 (4%)  | 1 (4%)   | 1 (3%)  |          |
| Necrosis                                      | 1 (2%)   |         |          |         | 1 (2%)   |
| Testes  | (48)     | (39)    | (46)     | (46)    | (48)     |
| Atrophy, bilateral, germinal epith            | 3 (6%)   |         | 2 (4%)   |         |          |
| Atrophy, germinal epith                       | 6 (13%)  | 1 (3%)  | 10 (22%) | 6 (13%) | 9 (19%)  |
| Granuloma sperm                               | 1 (2%)   |         |          |         |          |
| Hyperplasia, focal, bilateral, interstit cell | 2 (4%)   | 2 (5%)  |          | 1 (2%)  |          |
| Hyperplasia, focal, interstit cell            | 4 (8%)   | 6 (15%) | 10 (22%) | 5 (11%) | 2 (4%)   |
| Inflammation, chronic, artery                 | 1 (2%)   |         |          |         |          |
| Mineralization                                |          | 1 (3%)  | 1 (2%)   |         | 1 (2%)   |
| Thymus  | (37)     | (19)    | (21)     | (24)    | (41)     |
| Atrophy                                       | 13 (35%) | 5 (26%) | 9 (43%)  | 8 (33%) | 19 (46%) |
| Cyst  | 1 (3%)   |         |          |         | 1 (2%)   |
| Hemorrhage                                    | 2 (5%)   |         |          | 3 (13%) | 4 (10%)  |
| Hyperplasia, lymphoid                         |          |         | 1 (5%)   |         |          |
| Thyroid gland                                 | (48)     | (24)    | (25)     | (31)    | (48)     |
| Cyst, follicle                                |          |         |          | 2 (6%)  |          |
| Hyperplasia, focal, c cell                    | 10 (21%) | 6 (25%) | 5 (20%)  | 3 (10%) | 9 (19%)  |
| Inflammation, chronic                         | 1 (2%)   |         |          |         |          |
| Umbilical cyst                                | 2 (4%)   | 1 (4%)  |          |         | 1 (2%)   |
| Tissue NOS                                    | (2)      |         | (2)      | (1)     | (1)      |
| Cyst  | 1 (50%)  |         |          |         |          |
| Inflammation, chronic                         |          |         | 1 (50%)  |         |          |
| Inflammation, chronic, mediastinum            |          |         |          |         | 1 (100%) |
| Tongue  | (48)     | (23)    | (23)     | (30)    | (48)     |
| Inflammation, chronic                         |          |         | 1 (4%)   |         | 1 (2%)   |
| Inflammation, chronic, artery                 |          | 1 (4%)  |          |         |          |
| Trachea                                       | (48)     | (23)    | (23)     | (30)    | (48)     |
| Inflammation, chronic                         |          | 1 (4%)  |          |         | 1 (2%)   |
| Urinary bladder                               | (47)     | (22)    | (23)     | (30)    | (48)     |
| Dilatation                                    |          |         |          | 1 (3%)  |          |
| Hyperplasia, transit epithel                  |          | 1 (5%)  |          |         |          |
| Infiltrate cell, lymphocytic                  | 2 (4%)   | 2 (9%)  |          |         | 1 (2%)   |
| Inflammation, acute                           |          |         |          | 2 (7%)  |          |
| Inflammation, chronic                         |          | 1 (5%)  |          |         |          |