

## Section 4.0 EXCLUSIVITY PERIODS

Under the Federal Food, Drug and Cosmetic Act, the approval of a New Animal Drug Application (NADA), or of a supplemental NADA, may in some cases provide the sponsor of the application with a period of exclusivity, as defined in the Act. This exclusivity period allows the sponsor to market the approved product for either 3 or 5 years, during which time no generic copy may be approved (in the case of 3-year exclusivity), or no generic application may be submitted (in the case of 5-year exclusivity). The following exclusivity periods have been granted by the FDA and have not expired as of December 31, 2003. Some of the 3-year exclusivity periods are granted for the product, as approved in an original NADA. Others apply only to certain conditions of use of the approved product, as approved in a supplemental application. Persons considering submitting an ANADA to the FDA must determine which conditions of use for an approved product are protected by exclusivity. In order to assist in making this determination, the column entitled "Greenbook Supplement" is included in this table. This column refers to the date of the Monthly Update (Section VIII) of the "FDA Approved Animal Drug Products" listing, in which the original or supplemental NADA approval was described. Back issues can be viewed at the web site: <http://dil.vetmed.vt.edu/Exclusivity/Exclus.html>.

NADA No.	TRADE NAMES	PERIOD	EXPIRATION DATE	GREEN BOOK SUPPLEMENT
048-761	Aureomycin <sup>®</sup> 50 Granular	3 years	Jan 24, 2005	Jul 2002
048-761	Aureomycin <sup>®</sup> 90 Granular	3 years	Jan 24, 2005	Jul 2002
048-761	Aureomycin <sup>®</sup> 100 Granular	3 years	Jan 24, 2005	Jul 2002
094-170	Phenylbutazone Tablets, USP 200 mg	3 years	Jan 12, 2004	Apr 2001
096-298	Bovatec <sup>®</sup> 68 Type A Medicated Article	3 years	Apr 09, 2006	Jul 2003
097-505	Lincomix <sup>®</sup> 50 Feed Medications	3 years	Feb 28, 2005	Jun 2002
097-505	Lincomix <sup>®</sup> 20 Feed Medications	3 years	Feb 28, 2005	Jun 2002
131-675	Safe-Guard <sup>®</sup> Type A Medicated Article	3 years	Mar 14, 2006	Jul 2003
134-314	Eqvalan <sup>®</sup> Paste For Horses	3 years	Apr 02, 2006	Aug 2003
139-472	Denagard <sup>®</sup> 10 Medicated Premix	3 years	Nov 26, 2004	Mar 2002
139-472	Denagard <sup>®</sup> 5 Medicated Premix	3 years	Nov 26, 2004	Mar 2002
140-338	Naxcel <sup>®</sup> Sterile Powder	3 years	May 29, 2004	Jul 2001
140-863	Paylean <sup>®</sup>	5 years	Dec 22, 2004	Feb 2000
140-872	Posilac; Posilac 1 Step <sup>®</sup>	None	Not applicable	May 2002
140-890	Excenel <sup>®</sup> RTU	3 years	Feb 08, 2005	Aug 2002
140-951	Clinacox <sup>™</sup>	5 years	Apr 21, 2004	Aug 1999
140-951	Clinacox <sup>™</sup>	3 years	Sep 21, 2005	Jan 2002
140-992	Revalor <sup>®</sup> -200	3 years	Dec 06, 2004	Mar 2002
141-035	Program <sup>®</sup> Flavor Tabs <sup>®</sup>	3 years	Jun 11, 2006	Sep 2003
141-040	Celerin <sup>™</sup>	3 years	Jun 25, 2006	Sep 2003
141-041	Celerin <sup>™</sup> C	3 years	Jun 26, 2006	Sep 2003
141-043	Synovex <sup>®</sup> Choice	3 years	Oct 03, 2005	Jan 2003
141-053	Rimadyl <sup>®</sup> Caplets for Dogs	3 years	Jul 08, 2005	Nov 2002
141-053	Rimadyl <sup>®</sup> Caplets for Dogs	3 years	Sep 21, 2004	Jan 2002
141-084	Sentinel <sup>®</sup> Flavor Tabs <sup>®</sup>	3 years	Jun 12, 2006	Aug 2003
141-099	Cyductin <sup>®</sup> (moxidectin) 0.5% Pour-On for Beef and Dairy Cattle	3 years	Jun 18, 2004	Oct 2001
141-103	SevoFlo <sup>™</sup>	5 years	Nov 17, 2004	Jan 2000
141-123	GastroGard <sup>®</sup>	5 years	Mar 16, 2004	May 1999
141-143	Tetradure <sup>™</sup> 300 (Rx)	3 years	Jul 25, 2006	Oct 2003
141-143	Oxytetracycline Injection 300 mg/ml (OTC)	3 years	Jul 25, 2006	Oct 2003
141-151	Zeniquin <sup>®</sup>	5 years	Jun 26, 2004	Aug 1999
141-151	Zeniquin <sup>®</sup>	3 years	Aug 01, 2004	Oct 2001
141-152	Revolution <sup>™</sup>	5 years	May 26, 2004	Aug 1999
141-162	Hartz <sup>®</sup> Flea Control Capsules <sup>™</sup>	5 years	Jan 24, 2005	May 2000
141-162	Zodiac <sup>®</sup> Fleatrol Flea Caps <sup>™</sup>	5 years	Jan 24, 2005	May 2000
141-171	Purina Sugar Mag Block 1440 BVT Medicated Mineral Block	3 years	Aug 20, 2005	Jan 2003
141-175	Capstar <sup>®</sup> Tablets	5 years	Oct 20, 2005	Dec 2000
141-175	Capstar <sup>®</sup> Tablets	3 years	Jun 11, 2006	Sep 2003
141-177	Mometamax <sup>™</sup> Otic Suspension	3 years	Jan 09, 2005	Apr 2003
141-180	Torpex <sup>™</sup>	5 years	Nov 16, 2006	Mar 2002
141-188	Marquis <sup>™</sup>	5 years	Jul 19, 2006	Sep 2001
141-189	ProHeart <sup>®</sup> 6 Sustained Release Injectable for Dogs	3 years	Jun 13, 2005	Oct 2002
141-189	ProHeart <sup>®</sup> 6 Sustained Release Injectable for Dogs	3 years	Jun 06, 2004	Aug 2001

**Section 4.0**  
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NADA No.	TRADENAMES	PERIOD	EXPIRATION DATE	GREENBOOK SUPPLEMENT
141-192	Ralgro <sup>®</sup> L. A.	3 years	Nov 02, 2004	Mar 2002
141-193	Zubrin <sup>™</sup> Rapidly-Disintegrating Tablets	5 years	Mar 31, 2008	Jul 2003
141-199	Rimadyl <sup>®</sup> Injectable	3 years	Mar 03, 2006	Jun 2003
141-199	Rimadyl <sup>®</sup> Injectable	3 years	Apr 02, 2006	Aug 2003
141-199	Rimadyl <sup>®</sup> Injectable	3 years	Mar 25, 2006	Jul 2003
141-200	EAZI-Breed <sup>™</sup> CIDR <sup>®</sup> Cattle Insert	3 years	Jul 29, 2006	Nov 2003
141-200	EAZI-Breed <sup>™</sup> CIDR <sup>®</sup> Cattle Insert	3 years	May 02, 2005	Jul 2002
141-203	DERAMAXX <sup>™</sup> Chewable Tablets	5 years	Aug 21, 2007	Dec 2002
141-203	DERAMAXX <sup>™</sup> Chewable Tablets	3 years	Feb 11, 2006	May 2003
141-204	Sentinel <sup>®</sup> Flavor Tabs <sup>®</sup> and Capstar <sup>®</sup> Tablets Flea Management System <sup>™</sup>	3 years	Jun 11, 2006	Sep 2003
141-205	Program <sup>®</sup> Flavor Tabs <sup>®</sup> and Capstar <sup>®</sup> Tablets Flea Management System <sup>™</sup>	3 years	Jun 11, 2006	Sep 2003
141-206	Nuflor <sup>®</sup> Concentrate Solution	3 years	Sep 04, 2005	Jan 2003
141-207	A180 <sup>®</sup>	5 years	Sep 20, 2007	Jan 2003
141-208	Advantage <sup>®</sup> DUO	3 years	Sep 27, 2005	Jan 2003
141-209	Naxcel <sup>®</sup> XT Sterile Suspension	3 years	Sep 05, 2006	Nov 2003
141-210	Genesis <sup>™</sup> Topical Spray	3 years	Nov 04, 2005	Feb 2003
141-213	Metacam <sup>®</sup> Oral Suspension	5 years	Apr 15, 2008	Aug 2003
141-214	Zimecterin <sup>®</sup> Gold Paste	3 years	Apr 17, 2006	Jul 2003
141-215	Equimax <sup>™</sup> Paste	3 years	Jul 11, 2006	Oct 2003
141-216	Quest <sup>®</sup> Plus Gel	3 years	May 14, 2006	Sep 2003
141-217	Neutersol <sup>®</sup> Injectable Solution	5 years	Mar 18, 2008	Jun 2003
141-218	Atopica <sup>®</sup>	3 years	Aug 15, 2006	Oct 2003
141-221	Optaflexx <sup>™</sup> 45	3 years	Jun 13, 2006	Oct 2003
141-222	Matrix <sup>™</sup>	3 years	Sep 30, 2006	Nov 2003
200-346	Component <sup>®</sup> E-C with Tylan <sup>®</sup>	3 years	Apr 18, 2006	Aug 2003