

New Animal Drug Approval Fact Sheet

- Dating back to 1972, the FDA has approved fifty-three new animal drugs for sub-therapeutic use invoking NEPA categorical exclusions.
 - Fifty drugs were approved under the categorical exclusion for animal drugs marketed under the same conditions as previously approved animal drugs.
 - Three were approved under the CE for drugs for minor species when the drug has been previously approved for use in another or the same species where similar management practices are used.
- Sixty-four percent of the approved drugs (or combinations of drugs) contain antimicrobials.
 - Since the FDA began reporting in 2009 the amount of antimicrobials sold and distributed domestically for food producing animals, antimicrobial use has risen nearly 4%.
- Of the fifty-three approved new animal drugs, there are twenty-seven corresponding environmental assessments available on the FDA website.
- Of the published environmental assessments, many fail to address the environmental impacts of applying the drugs, but rather only address the environmental impacts of manufacturing the drug.
- Of the published environmental assessments, many rely on outdated information
 - Eleven of the new animal drug approvals rely on environmental assessments written more than ten years prior to the drugs approval.
 - Twenty of the new animal drugs were approved more than ten years ago.
 - The environmental assessment for lincomycin was written in 1984 and based its assessment on applying the drug to 2.6 million swine.
 - The 2006 environmental assessment for monensin sodium relies on twenty-one studies, twelve of which predate 1995 and the rest are from 2002. These cited drug studies rely on tests of the drug on cattle during the 1970s.
- Eighteen of the new animal drug approvals were for a combination of drugs and there does not appear to be an environmental analysis of the combination of drugs.
- Three of the approved new animal drugs were approved for use in a different species than the underlying environmental assessment.

Summary of NADA Approvals

New Animal Drug Approval	Year of approval for the categorically excluded drug	Year of EA as found on the FDA website
Progesterone & Estrodiol Benzoate	1998	1996
Chlortetracycline HCL Premix	1998	1994*
Bacitracin methylene disalicylate and chlortetracycline	1998	1994 (chlortetracycline)* 1989 (BMD) No EA for drug mix
Bambermycins	1998	2001
Tricaine Methanesulfonate	1997	None
dinoprost trompethamine injection	1999	None
Carbadox	1972	None
Sometribove Zinc suspension	2001	None
Lasalocid sodium-Ionophore	2003	1989
Chlortetracycline	2000	1994*
Chlortetracycline HCL & sulfamethazine	2003	1994* No EA for drug mix
Trenbolone acetate & estradiol, & tylosin tartrate	2004	No EA for drug mix
Oxytocin Injection	2004	None
Chlortetracycline, Sulfathiazole & penicillin	1997	1994* No EA for drug mix
Melengestrol acetate plus zilpaterol hydrochloride and monensin USP	2009	1997 (melengestrol acetate) 2006 (zilpaterol hydrochloride) 1990 (monensin USP) No EA for drug mix
Oxytetracycline hydrochloride	2007	1989
Oxytetracycline hydrochloride	2004 2005	1989

* There is an EA for chlortetracycline hydrochloride for the drug Chloratet-50 Type A medicated premix on the FDA website.

Bacitracin Zinc plus nicarbazin	2010	1980 No EA for nicarbazin No EA for drug mix
Melengestrol acetate, ractopamine hydrochloride and monensin USP	2010	1990 (monensin USP) 1997 (melengestrol acetate) 2003 (ractopamine) No EA for drug mix
Tylosin Phosphate	2006	None
Zeranol	2005	None
Sometribove Zinc suspension	2003	1993
Cloprostenol sodium	2004	None
Tiamulin hydrogen fumarate	2011	1994
Neomycin sulfate	2000	1987
Ractopamine hydrochloride	2009	2003
Chlortetracycline Premix	1998 [†]	1994*
Monensin sodium	1999	1989
Lincomycin hydrochloride monohydrate	1998	1984
Ractopamine hydrochloride	2006	1999
Trenolone Acetate & Estradiol Benzoate	1998	1996
Trenbolone Acetate & Estradiol	1994 2001, supplement	1994
Trenbolone Acetate & Estradiol	1999	1996
Melengestrol Acetate	2004	1994
Trenbolone Acetate & Estradiol	2005 2003 2003 2002 2002	1994
Trenbolone Acetate & Estradiol & Tylosin tartrate	2004 2003	1994 No EA for combination

[†] Variations in dosage and animal applications were approved.

	2000	
Trenbolone Acetate & Estradiol	2003	1988
Trenbolone Acetate & Estradiol	2007	1994