

# FDA: withdrawal of 16 antimicrobials for use in food animals

The FDA has announced the voluntary withdrawal of 16 antimicrobials for use in food-producing animals.



The US Food and Drug Administration (FDA) announced that five drug sponsors holding animal drug applications affected by [Guidance For Industry \(GFI\) #213](#) have requested that FDA withdraw approval of a collective 19 animal drug applications because the products are no longer manufactured or marketed.

Of these 19 applications, 16 are antimicrobials affected by GFI #213. The guidance outlines FDA's plan to help curb antimicrobial resistance by, among other things, [phasing out the use of medically important antimicrobials](#) in food-producing animals for production purposes.

<sup>1</sup> Denotes applications that were identified by FDA as being affected by Guidance For Industry (GFI) #213, "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209", December 2013.

FDA will update its chart of "[Applications Affected by GFI #213](#)" to reflect these withdrawals.

The following companies have requested that FDA withdraw approval for their listed products:

Provimi North America, Inc.:	
NADA	Product Name
103-089 <sup>1</sup>	TYLAN 5, 10, 20, or 40 (tylosin phosphate)
118-614	WORM-BAN 5 or 10 (pyrantel tartrate)
127-508 <sup>1</sup>	HYGROMIX 0.6 (hygromycin B)
131-413	FLAVOROMYCIN 0.4 or 2 (tiambermycins)
133-333 <sup>1</sup>	STAFAC 10 (virginiamycin)
Virbac AH, Inc.:	
NADA	Product Name
013-214 <sup>1</sup>	PURINA HYGROMIX (hygromycin B) for Swine
042-660 <sup>1</sup>	PURINA Pork-Plus (tylosin phosphate and sulfamethazine)
043-387 <sup>1</sup>	PURINA Hog Plus II (tylosin phosphate)
099-767 <sup>1</sup>	PURINA TYLAN 40 (tylosin) Plus Sulfamethazine
132-574 <sup>1</sup>	PURINA Check-R-Ton LI (lincomycin hydrochloride)
ADM Alliance Nutrition, Inc.:	
NADA	Product Name
091-582 <sup>1</sup>	Gilt Edge TYLAN (tylosin phosphate) Mix
108-484 <sup>1</sup>	HFA Tylosin-10 Plus Sulfa (tylosin phosphate and sulfamethazine)
110-045 <sup>1</sup>	Good Life TYLAN 10 (tylosin phosphate) Premix
110-439 <sup>1</sup>	HFA HYGROMIX 0.48 (hygromycin B) Medicated Premix
128-411 <sup>1</sup>	TYLAN 5 Sulfa (tylosin phosphate and sulfamethazine) Premix
Micro Beef Technologies LTD:	
NADA	Product Name
138-187 <sup>1</sup>	TYLAN 40 or 100 (tylosin phosphate)
Ridley Feed Ingredients:	
NADA	Product Name
099-468 <sup>1</sup>	Waynetra for Swine (tylosin phosphate)
131-958 <sup>1</sup>	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine)
132-136	Ban-A-Worm II (pyrantel tartrate)

by AllAboutFeed 11 Apr 2014