Animal Drug Product Types: A Comparison

A high-level summary outlining the pivotal differences between Brand-name (Pioneer), Generic, and Compounded drug products available to support animal health in the US.

Aspect	Pioneer Animal Drug	Generic Animal Drug	Compounded Animal Drug
Manufacturing/ Quality Testing	Manufacturing and testing of drug products is done in accordance with strict requirements of the FDA per the CFR	Same as Pioneer	Manufacturing and quality testing, if any, of compounded drugs are largely unregulated and are not monitored
Facilities	FDA proactively and routinely inspects: manufacturing, laboratories, ingredient manufacturers, animal testing facilties, etc.	Same as Pioneer	Per existing requirements, FDA inspections are infrequent and reactive based on a severe adverse event (that becomes publicly known)
Quality Ingredients	All ingredients tested according to FDA approved criteria prior to use in final product	Same as Pioneer	No verification
Drug Efficacy	Extensive efficacy studies in labeled species	Bioequivalence studies (pioneer vs generic) are required to be performed using the same acceptance criteria as human generics	No verification or assurance of effectiveness
Drug Safety	Safety studies required in all labeled species	Bioequivalence studies (pioneer vs generic) are required to be performed using the same acceptance criteria as human generics	No verification or assurance of safety
Human Food Safety	Studies evaluating the duration of drug residue in edible tissues of food-producing animals are required to confirm withdrawal time	FDA determines compliance with pioneer withdrawl times: Sponsor may obtain a biowaiver or must perform new studies	No FDA oversight of drug residues if food animal drugs are compounded
Long-term Stability Studies	Stability studies, including assessment of extreme conditions and impurities, are required by FDA to justify the labeled shelf life	Same as Pioneer	No requirement
Label material /advertising	FDA reviewed/approved	Same as Pioneer	No FDA review
FDA approval	Must meet rigorous standards established by the FDA with respect to identity, strength, quality, purity, and potency	Same as Pioneer	None
Product Defects/ Safety issues	Mandatory reporting of all defects of which the manufacturer becomes aware	Same as Pioneer	Not required - At the discretion of prescribing veterinarian
Issue Enforcement	Subject to FDA recall or facility shut down	Same as Pioneer	None - Only if risk is reported
Consumer Cost	**High**	**Low-Moderate**	**Low-Moderate**
Range of drug type availability	**High**	**Low**	**High**
Avenues to Market in US	**Moderate** Standard approval: 1 to multiple species, 1 to many claims, Supplements allowed to add species or claims Conditional Approval: Minor use, minor species, new expanded avenues	**Low** Standard approval: full label claim of pioneer required at approval	**High** Minimal restrictions
Cost to Market	**High**	**Moderate-High**	**Very Low** due to lack of FDA regulatory requirements

FAST FACTS: Generic & Pioneer Medications

- All pioneer and generic medications go through FDA approval to show the medications are safe and effective before sale in the U.S.
- Not all pioneers have generic versions.
- Bioequivalence studies, required only for generics, are often difficult or impossible to achieve in all labelled species.
- Some generic products, by nature of their chemical properties may qualify for a waiver from the requirement to perform bioequivalence studies.
- A pioneer gets patent and exclusivity protection so generics can't compete right away.
- Generics must meet the same quality, strength, and purity standards as pioneer drugs, so they have the same benefits and effects.
- Generics must have the same strength, dose, route of administration, and active ingredient(s) as the pioneer.
- Pioneers and generic drugs may not look exactly alike (color, size, shape, packaging), but they work the same.
- Generics cost less than the pioneer.
- Veterinarians are often the pharmacists for animal medications prescribed to their patients.
- Many unapproved compounded drug products have ingredients that can negatively impact potency and efficacy.

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