About GADA

The Generic Animal Drug Alliance (GADA) is the only independent, professional trade association serving organizations with interests in generic animal drug products in the United States. GADA represents the majority of companies with generic investigational new animal drugs (JINADs) filed with the FDA's Center for Veterinary Medicine (CVM) and with approved and/or pending abbreviated new animal drug applications (ANADAs).

Issue Summary

Under current regulations, generic animal drug applications are at a significant disadvantage in the new animal drug approval process for two reasons:

1. Requirements to prove bioequivalency to pioneer drugs in all species on pioneer drugs' labels
2. Inability to obtain the same Type A Medicated Articles combinations as pioneer products

Bioequivalence Background

The Generic Animal Drug and Patent Term Restoration Act (GADPTRA) was passed in 1988 modifying the Federal Food Drug and Cosmetic Act (FFDCA) (21 U.S.C. 360b). The legislation was modeled after the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) and enacted to bring generic approvals to animal drugs with slight variations that take into account the differences between human and animal drugs.

One of the key differences is the fact that animal drugs are often used in more than one species. Unique language in GADPTRA addresses the specific bioequivalence requirements for multi-species drugs, and the topic was the subject of extensive discussion during the legislative process. The differences associated with multi-species animal drugs impacts a key provision of Hatch-Waxman that is mirrored in GADPTRA: when submitting an Abbreviated New Animal Drug Application (ANADA), generic animal drugs must include bioequivalence data on all species for which the reference listed drug (pioneer drug) is approved and labeled.

However, the current industry standard is to carve out generic drugs to treat one or a subset of species treated by a pioneer drug. Therefore, this provision creates a burden to generic drug companies. In other words, the 35-year-old provision requires animal drug makers submitting an ANADA to prove their drug is bioequivalent to the pioneer drug for every animal species on the pioneer's label, even though generic animal drugs are only developed for a particular species and generic animal drug makers have no intention to treat other species.

Subsequent regulations and guidance documents from CVM have outlined several exceptions to this identical labeling requirement, such as differences in the manufacturers and, as appropriate, patent exclusivity.

In fact, in the FDA's 2002 Bioequivalence Guidance the Agency laid out several factors to determine appropriate labeling for generic animal drugs when a pioneer is no longer marketed and/or multiple approved new animal drug applications exist for the same product. The Guidance instructs that "[b]ioequivalence testing should be conducted against the single approved product which bears the labeling that the generic sponsor intends to copy." By releasing these instructions, the FDA appears to envision situations in which bioequivalence is not necessary – and therefore nor is labeling – for every possible species on which a pioneer drug may be used.

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GENERIC ANIMAL DRUG ALLIANCE
2331 Rock Spring Road, Forest Hill, Maryland 21050
Phone: 443 640.1046 Email: info@gadaonline.org Web: www.gadaonline.org

In 2018, GADA sat down with CVM to relay the organization's concerns about the obstacles created by the labeling requirements. Following that meeting, and as a result of similar meetings with other stakeholders, CVM included this issue in their A19 priorities, proposing legislative action to allow the FDA to "clarify labeling requirements for generic animal drugs by explicitly including an exception from the requirement that a generic animal drug's labeling be the same as the labeling of a reference listed new animal drug (RLNAD) where the RLNAD is approved in more than one species."

Industry practice, regulatory guidance, and legal history support GADA's position to update the bioequivalency labeling burden.

Combination Background

The Animal Drug Availability Act of 1996 (ADAA) amended the FFDCA to expedite the approval process for the combination of Type A Medicated Articles under 512(d)(4). Type A Medicated Articles are products containing one or more new animal drugs intended for use in the manufacture of another medicated article or a medicated feed.

At the time of the ADAA's passage, the generic animal drug industry did not object to its updates because each generic Type A Medicated Article approved was believed to be entitled to obtain the same streamlined combinations as the pioneer animal drug product, meaning the industry believed that the principals adopted in ADAA would be extended to generics. However, this has not been the case.

Over the years, both pioneer and generic sponsors have asked CVM to permit ADAA combination requirements to applications seeking approval to combine both pioneer product + generic product, and generic product + generic product. In meetings with GADA members, CVM has responded that the provisions approved in the ADAA do not apply to generics; therefore, the antiquated requirements persist for such combinations. This puts generic animal drug makers at a disadvantage: pioneer companies no longer need to conduct any additional studies, and as a result, the animal drug industry's ability to innovate through generic and pioneer combinations has been impeded, as have the economical solutions provided by a robust generic market.

NOTE: *CVM has declined to give any scientific or safety explanation to prohibit the generic combinations that will further enhance innovation, only reiterating that the regulation does not allow for its inclusion.*

Solution

H.R. 1683, the Generic Animal Drug Advancement Act, would update FDA animal drug labeling requirements to allow generic animal drugs to gain approval for single species, rather than all species labeled on a pioneer drug, *as well as* expand pathways for use of generic drugs in combination approvals.