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FDA Reminds Stakeholders of Animal Drug 'Approved by FDA' Labeling Requirements

On April 1, 2024, the U.S. Food and Drug Administration (FDA) issued a statement reminding stakeholders, especially animal drug manufacturers and veterinarians, of certain labeling requirements for approved animal drugs, which had previously been subject to the agency's enforcement discretion.

Specifically, section 502(w)(3) of the Federal Food, Drug and Cosmetic Act (as amended by the Animal Drug User Fee Act and Animal Generic Drug User Fee Act of 2018) requires the statement "Approved by FDA" to appear on the labeling of approved animal drugs. This requirement applies to both brand name animal drugs and generic animal drugs, and requires use of specific language, as applicable:

- For brand name animal drugs: "Approved by FDA under NADA # XXX-XXX"
- For generic animal drugs: "Approved by FDA under ANADA # XXX-XXX"

While FDA considers any approved animal drug not bearing the applicable language to be misbranded, it had previously exercised enforcement discretion for this requirement until March 30, 2024, due to stakeholder feedback citing, among other concerns, supply chain issues impacting compliance with the Sept. 30, 2023, deadline.

FDA's recent statement also notes the parallel labeling requirement for Type A medicated articles (i.e., animal drugs that are used to manufacture medicated feeds), except for so-called Blue Bird labels under

21 C.F.R. § 514.1(b)(3)(v)(b) (i.e., representative labeling prepared as a guide for final medicated animal feed labels).

Along with FDA's recent statement, FDA also issued a "Dear Veterinarian" letter explaining these requirements in an effort to help veterinarians distinguish between approved and unapproved animal drugs.

Manufacturers of both brand name and generic animal drugs should immediately ensure compliance with this labeling requirement due to the risk of FDA enforcement action (e.g., warning letter), now that FDA no longer intends to exercise enforcement discretion regarding this requirement.

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