Aetna Better Health® of New Jersey

FDA Approval Process: "Follow-on" Drugs

The FDA has three regulatory pathways:

- NDA-s for new drugs not yet approved
- ANDA's for generic products
- 505(b) [1] also known as "follow-on" or copy-cat for biosimilar drugs that is a hybrid between the NDA and ANDA and which results in an abbreviated approval[1]

The "follow-along" pathway is used for drugs that are not strictly generics but are often not entirely new molecular entities, either. This pathway can be an option for drugs with a new aspect (e.g. indication, dosage form or regimen, strength, combination with other products, or other unique traits). The manufacturer can submit their product for FDA review by including data and/or study results originally collected by another manufacturer and by building a connection between their version of the product and the reference product.

Admelog (insulin lispro injection) was the first short-acting insulin approved as a "follow-along" product[2]. The manufacturer demonstrated a connection to **Humalog** (insulin lispro injection) and provided Admelog-specific data including two phase 3 clinical trials which enrolled approximately 500 patients in each trial. Study results demonstrated non-inferiority between Admelog and Humalog in A1C change from baseline.

Ademlog and Humalog are highly similar in safety, effectiveness and dosing and are both indicated for type 1 and type 2 diabetics in patients three years of age or older.

1. https://www.pharmacytimes.com/contributor/ryan-chandanais-ms-cpht/2017/11/505-b2-regulatory-pathway-for-new-drug-approvals-
2. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm588466.htm