# Your organization navigates a range of pharmacy considerations every day

amneal Biosciences

## Injectable medicines that offer hope to patients living with cancer and other systemic diseases often have special handling requirements

### Special storage requirements[1,2]

Many infused or injectable drugs, as well as some oral medications, may need to be **refrigerated, frozen, or protected from light**.

Temperature-specific storage requirements can bring **logistical challenges**.

### Need for preparation[3-6]

Many injectable medicines **require reconstitution and/or dilution** prior to administration.

Having multiple drug-preparation steps is a contributing factor in medication errors, **which necessitates additional time for pharmacy checks**.

The need to calculate doses using BSA and/or weight **may increase pharmacy preparation time as well as patient wait time**.

### Drug supply[1,7]

Provider-administered medicines must be **maintained in an organization's inventory** to ensure timely delivery of care.

**Drug shortages are an ongoing problem** that can affect sterile injectable products.

**Amneal Biosciences is developing evolved formulations of injectable medicines designed to simplify storage and preparation.[8,9]**

BSA, body surface area.

# Amneal Biosciences is bringing innovative formulations of approved medicines to market[8]

## Of the FDA approval pathways, only 505(b)(2) allows for modifications to previously approved drugs[10]

| New Drug Application (NDA) | | Abbreviated NDA (ANDA) |
|---|---|---|
| 505(b)(1)[10] | 505(b)(2)[10-13] | 505(j)[10] |
| **ORIGINATOR PRODUCTS** | **EVOLVED PRODUCTS** | **GENERIC PRODUCTS** |
| • Contains **full safety and effectiveness reports** that were conducted by or for the applicant or for which the applicant has a right of reference or use | • Contains **full safety and effectiveness reports**, based at least in part on the originator product's data<br>• **Allows for modifications in product characteristics that may support operational efficiency**, such as ready-to-use formulations or other differences in dosage form, strength, or route of administration | • **Typically duplicates originator**<br>– based at least in part on the originator product's data<br>• Relies on safety and effectiveness data of the originator product<br>• Bioequivalent to the originator product |

## Fast facts about 505(b)(2)-approved products

The streamlined review path enables **quicker approval of affordable medication** options.[12,14]

As with all FDA-approved medicines, products approved under the 505(b)(2) pathway undergo rigorous evaluation, so you can **be assured of their efficacy, safety, and quality**.[11,15]

Most 505(b)(2)-approved products have their own **unique J-code for billing**, which allows for product-specific reimbursement and greater cost transparency.[16,17]

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