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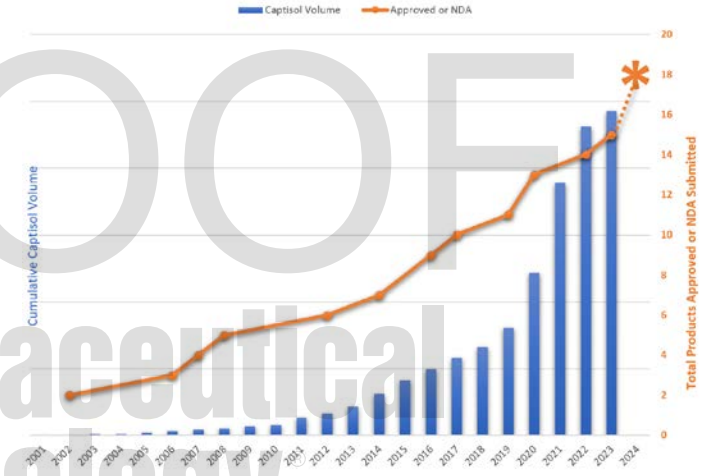
LIGAND PHARMACEUTICALS: SOLUBILITY-ENHANCING EXCIPIENT OPENS NEW ROUTES OF ADMINISTRATION

At Ligand Pharmaceuticals, we have seen a steady stream of inquiries for how Captisol® (sulfobutyl ether beta cyclodextrin) can help with solubility/bioavailability and stability of active pharmaceutical ingredients. There are currently at least 60 products in development pipelines around the world using Captisol for formulation enhancement.

"Another indication that APIs continue to need assistance in solubility improvement is the increased demand for Captisol and the number of product approvals containing Captisol expected in 2023-2024," says Vince Antle, PhD, Sr VP Technical Operations & QA (See **Figure 1**). "The most recent product approval is an oral admix used to chronically treat pediatric patients and upcoming product approvals open the door to the use of Captisol in new routes of administration, namely ocular, and subcutaneous."



"As most formulators know, best practices for dosage form development of poorly water-soluble compounds depend largely on the physical/chemical characteristics of the API, route of administration, indication, and whether the drug will be given on an acute or chronic regimen," says J.D. Pipkin, PhD, VP New Product Development. Lian Rajewski, PhD, Sr. Research Investigator, mentions, "Keeping the formulation as simple as possible is usually the best strategy from both a product and regulatory standpoint. Typically, the fastest way to move through the development process is to use safe, well-established, globally accepted excipients." For solubility and stability enhancement, Captisol has a 20-year proven record. The team look forward to what the next 20 years will bring.

ABOUT THE AUTHORS

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