CURRENT REGULATORY STATUS OF EXCIPIENTS

The Regulation of Excipients

• No independent regulatory approval process exists for new excipients
• New excipients are only approved after a new drug application approval
• New excipients need supporting safety data, testing strategy developed on a case by case basis, large investment for safety studies
• Drug product manufacturers are reluctant to use new excipients, generally rely on excipients already used in approved drug products

What are New Excipients?

• According to the FDA and ICH guidance, an excipient is considered new if it is used for the first time in a human drug product
• Excipients not listed in the FDA Inactive Ingredient Database (IID) are new or novel in the US
• Additional example: Co-processed mixtures of established excipients
• New Chemical Entity

FDA Inactive Ingredient Database (IID)

• IID lists excipients used in approved drug products, their route of administration and the maximum dosage (maximum potency per dosage unit)
• IID is currently worked on by the FDA to improve the presentation of the data listed in the IID regarding labels for families of excipients for nomenclature, maximum potency amounts etc.

FDA Guidance on Safety Evaluation of Excipients (see box in panel 4)

• Describes testing strategies for pharmaceuticals proposed for short-term, intermediate, and long-term use
• Also describes recommended toxicity testing for other routes of administration (pulmonary, intraperitoneal, and topical product)

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