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Cipla receives final approval for generic version of Migranal

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This is Cipla's first ANDA approval for a nasal spray

Cipla has announced that it has received final approval for its Abbreviated New Drug Application ("ANDA") for Dihydroergotamine Mesylate Nasal Spray 4mg/mL from the United States Food and Drug Administration (U.S. FDA) with a Competitive Generic Therapy ("CGT") designation.

Cipla is the "first approved applicant" for such CGT and, is therefore, eligible for 180 days of CGT exclusivity which will begin to run from the commercial marketing of Cipla's product. This 180-day CGT exclusivity will not block the commercialization of the existing approvals of Dihydroergotamine Mesylate Nasal Spray, 4 mg/mL.

Cipla's Dihydroergotamine Mesylate Nasal Spray 4mg/mL is AB-rated generic therapeutic equivalent version of Bausch Health US LLC's Migranal®.

This is Cipla's first ANDA approval for a nasal spray. It is indicated for the acute treatment of migraine headaches with or without aura.

According to IQVIA (IMS Health), Migranal® and its authorized generic equivalents had U.S. sales of approximately $102M for the 12-month period ending March 2020.