FDA updates draft guidance to help increase supply of children's ibuprofen

FDA has revised the immediately-in-effect guidance on compounding certain ibuprofen products. FDA published this update to address increased demand for fever-reducing medications among state licensed pharmacies, in addition to hospitals and health-systems. The revision addresses the provision of such products to state licensed pharmacies (including those within hospitals and health systems), and to applicable federal facilities, for dispensing to patients following receipt of a patient-specific prescription.

On January 20th, FDA issued the initial immediately-in-effect guidance in an effort to improve the supply of pediatric ibuprofen amid record high demand. The U.S. is currently experiencing a significant number of infections from three viruses: COVID-19, respiratory syncytial virus (RSV) and influenza, any of which can cause fevers in young children.

Generally, outsourcing facilities cannot compound a copy of an FDA-approved medicine unless it appears on the FDA shortage webpage, but this guidance explains FDA's regulatory and enforcement priorities regarding the compounding of certain ibuprofen oral suspension products in outsourcing facilities for administration in hospitals, health systems, state licensed pharmacies and federal facilities.

FDA is continuously assessing the demand for and supply of ibuprofen oral suspension products and if the situation changes, the agency may update, modify or withdraw this policy as appropriate.