

Glucagon-like Peptide-1 (GLP-1) Receptor Agonists: FDA Shortage Summary and Mitigation Efforts

Multistakeholder Workshop on Shortages of Glucagon-Like
Peptide-1 (GLP-1) Receptor Agonists

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Outline

- FDA's role in working with drug supply
- Drug shortage tools FDA utilizes
- US supply of GLP-1 receptor agonists
- FDA's supportive measures to assist with communication and supply



Drug Shortage Staff Role

DSS supports FDA's mission of ensuring that safe and effective drugs are available to patients

- Facilitate short-term and long-term strategies
- Coordinate a timely and comprehensive risk/benefit analysis
- Distribute information

FDA Toolbox

- Communicate possible shortage concerns to other suppliers
- Regulatory flexibility and discretion
- Expedite review of proposals and regulatory submissions
- Temporary importation of an unapproved product



GLP-1 Receptor Agonists - US Supply Update

- First posted in 2022
- Subsequent postings in 2022, 2023, and 2024
- Injectable versus oral formulations
- Supply improving



Supporting Measures to Assist with Communication and Supply

- Interact regularly with Sponsors
- Post supply updates on website
- Respond to public inquiries
- Expedite review of proposals and regulatory submissions
- Collaborate with international regulators

THANK YOU.

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