Association for Accessible Medicines
GRx+Biosims 2021

OFFICE OF GENERIC DRUGS
KEYNOTE

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Center for Drug Evaluation and Research
U.S. Food and Drug Administration

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Generic Drug Access

COVID-19
Complex Generics
GDUFA II Successes
FDA Partnerships
Addressing COVID-19*

Approvals that improved access to critical COVID-19 treatments:

• 69 COVID-related original ANDAs
• 1000+ COVID-related supplements

Guidance

• Development of ANDAs During the COVID-19 Pandemic – Questions and Answers
• Protecting Participants in Bioequivalence Studies for ANDAs During the COVID-19 Public Health Emergency
• Review Timelines for Applicant Responses to Complete Response Letters When a Facility Assessment Is Needed During the COVID-19 Public Health Emergency

Public Presentations

• COVID-19 Impact on Generic Drug Regulation and Evaluation
• Addressing Common Challenges in Bioequivalence Studies Due to COVID-19

* 2020-10/15/2021
GDUFA II Commitments

- ANDA original applications
- ANDA prior approval supplements
- Controlled Correspondence
- Product-Specific Guidance
Increasing Generic Drug Access

- 670+ full approvals
- 90+ first generics
- Milestone 100+ cumulative Competitive Generic Therapy (CGT) approvals

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<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Indication</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucagon for Injection packaged in an emergency kit</td>
<td>Glucagon for Injection packaged in an emergency kit</td>
<td>Severe hypoglycemia</td>
<td>12/28/2020</td>
</tr>
<tr>
<td>Linaclotide Capsules</td>
<td>Linzess Capsules</td>
<td>Irritable bowel syndrome with constipation and chronic idiopathic constipation</td>
<td>2/9/2021</td>
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<tr>
<td>Apremilast Tablets</td>
<td>Otezla Tablets</td>
<td>Moderate to severe plaque psoriasis</td>
<td>2/18/2021</td>
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<tr>
<td>Hydrocodone Bitartrate Extended-Release Tablets</td>
<td>Hysingla ER Tablets</td>
<td>Severe pain</td>
<td>3/1/2021</td>
</tr>
<tr>
<td>Ibrutinib Capsules</td>
<td>Imbruvica Capsules</td>
<td>Mantle cell lymphoma (MCL)</td>
<td>3/31/2021</td>
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<tr>
<td>Enzalutamide Capsules</td>
<td>Xtandi Capsules</td>
<td>Prostate cancer</td>
<td>5/14/2021</td>
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<tr>
<td>Lenalidomide Capsules</td>
<td>Revlimid Capsules</td>
<td>Multiple myeloma, anemia, and certain lymphomas</td>
<td>5/21/2021</td>
</tr>
<tr>
<td>Tofacitinib Tablets</td>
<td>Xeljanz Tablets</td>
<td>Certain types of arthritis and ulcerative colitis</td>
<td>6/1/2021</td>
</tr>
<tr>
<td>Varenicline Tablets</td>
<td>Chantix Tablets</td>
<td>Smoking cessation</td>
<td>8/11/2021</td>
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<tr>
<td>Linagliptin Tablets</td>
<td>Tradjenta Tablets</td>
<td>Type 2 Diabetes Mellitus</td>
<td>8/31/2021</td>
</tr>
</tbody>
</table>

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Product-Specific Guidances (PSGs)

- Scientific advice to assist generic drug product development
  - Revisions driven by science and research
- 135 PSGs in FY21
  - 53 (39%) PSGs for complex products
  - 20 PSGs provided a more efficient BE approach
- New PSG snapshot infographic

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FDA’s Pre-ANDA Program

- Reduce time from development to market
- Address complex scientific issues
- Communicate with prospective applicants
- Help applicants develop more complete submissions
- Clarify regulatory expectations

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The Center for Research on Complex Generics

- research and training
- webinars
- workshops
- laboratory projects
- Scholars program

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Recent Workshops

April 2021
• Generic Drug Forum 2021: Lifecycle of a Generic Drug

June 2021
Generic Drug Regulatory Science Initiatives Public Workshop

Aug. 2021
IVRT and IVPT Methods: Best Practices and Scientific Considerations for ANDA Submission

Sept. 2021
• Advancing Generic Drug Development: Translating Science to Approval
• Regulatory Utility of Mechanistic Modeling to Support Alternative BE Approaches

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Global Engagement

- Parallel Scientific Advice with European Medicines Agency
- ICH Generic Drug Discussion Group and ICH M13 Expert Working Group
- Generic Drug Global Cluster
- International Pharmaceutical Regulators Programme Working Groups

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Upcoming Events

GDUFA III Public Meeting

Generic Drug User Fee Amendments

On August 18, 2017, the President signed into law the Food and Drug Administration Reauthorization Act (FDARA), which includes the reauthorization of the Generic Drug User Fee Amendments (GDUFA) through September 2022. Congress first enacted GDUFA in 2012, following negotiations between the FDA and industry and with input from public stakeholders. Congress enacted GDUFA to ensure patients have access to safe, high-quality, and affordable generic drugs. GDUFA enables FDA to assess industry user fees to bring greater predictability and timeliness to the review of generic drug applications.

This page features news and information for industry and stakeholders about GDUFA, its...
Stay Informed

FDA’s GDUFA and Generic Drugs Updates listservs:
https://public.govdelivery.com/accounts/USFDA/subscriber/new

Webinars
- FDA Product-Specific Guidances: Lighting the Development Pathway for Generic Drugs
- Common Labeling Deficiencies and Tips for Generic Drug Applications

GDUFA Science and Research

Activities Metrics, such as:
- First Generic Drug Approvals
- Report of the Generic Drugs Program (Monthly Performance)