

The U.S. FDA's Generic Drug Program

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Outline



The Office of Generic Drugs (OGD)

- Mission and vision
- Organizational structure and leadership



OGD's impact on public health

- Recent approvals
- 2019 data
- COVID-19 pandemic



Enhancing access to generic drugs

- Drug Competition Action Plan (DCAP)
- Generic Drug User Fee Amendments (GDUFA)
 - GDUFA Regulatory Science
- Major web page enhancements



Opportunities for collaboration



Thank you!

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Division of Filing Review

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Generic Drugs Benefit the Public Health



When FDA announced approval of the first generic Advair Diskus (a complex generic drug-device combination product) in January 2019, OGD heard heartfelt remarks from people who were now able to afford their asthma medication. One such comment relayed:

"Thank you so very, very much for this – you have no idea how this generic brand will change the lives of untold numbers of people who were struggling to pay for their asthma medicine...

I paid \$398.96 for my inhaler back in January, and today, when the cashier at the pharmacy told me that my total was only \$188.65, I almost broke down in tears! ...

Again, thank you from the bottom of my heart!"

– anonymous patient

Public Health Impact – Recent Approvals

First generic albuterol sulfate inhalation aerosol (referencing ProAir HFA) – [2/24/2020](#)

- For the treatment or prevention of bronchospasm in patients four years of age and older with reversible obstructive airway disease and the prevention of exercise-induced bronchospasm in patients four years of age and older.
- **Albuterol is one of the most common metered dose inhaler products in the United States**
- **Complex generic combination product**

FDA supports development and approval of complex generic medicines

- Under the [Generic Drug User Fee Amendments](#) (GDUFA II), companies can meet with the FDA as part of its pre-Abbreviated New Drug Application (pre-ANDA) program.
- In 2013, FDA [published](#) a draft product-specific guidance* for proposed generic albuterol sulfate metered dose inhalers.

* PSG for albuterol sulfate metered aerosol initially published 2013, revised 12/2016, and 3/2020

Public Health Impact – Recent Approvals



First generic pyrimethamine Tablets (referencing Daraprim)– [2/28/2020](#)

- for the treatment of toxoplasmosis with used with a sulfonamide
- especially important for populations that are more susceptible to toxoplasmosis infections, such as pregnant women and individuals with HIV or AIDS

FDA has a longstanding commitment to increasing competition in markets with limited or no generic alternatives

- FDA prioritizes the review of submissions for generic drugs for which there are fewer than three approved generics for the reference listed drug (RLD) and for which there are no blocking patents or exclusivities on the RLD.
- Daraprim was on the [list of off-patent, off-exclusivity drug products without an approved generic](#) to improve transparency and encourage the development and submission of applications for drugs with limited competition.
- [Draft product-specific guidance for pyrimethamine Tablets](#) published in 3/2015.

Read more about our public health impact in

OGD's 2019 Annual Report



FDA Drug Information @FDA_Drug_Info · 22h

FDA's Office of Generic Drugs (OGD) releases its fifth annual report of OGD's activities, which resulted in more treatment choices and greater access to affordable medicines for patients with a wide range of medical conditions: go.usa.gov/xdUBs



OFFICE OF GENERIC DRUGS 2019 ANNUAL REPORT

Ensuring Access to Safe, Affordable, and Effective Generic Drugs



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1,014

Approved or tentatively approved Abbreviated New Drug Applications (ANDAs).

107

First generic drugs were approved, which provided access to needed therapies that treat a wide range of medical conditions where little or no competition has previously existed.

110

Complex generic drugs were approved totaling 11% of the generic drug product approvals in 2019.

269

Product-specific guidances (PSGs) were published along with 4 new or revised guidances for industry and 1 manual of policies and procedures (MAPP) for stakeholders.

2,311

Complete response letters were issued detailing important items that applicants needed to resolve before FDA could grant an approval.

3,274

Controlled correspondence inquiries, an important tool used to communicate with prospective generic drug applicants, were submitted by industry in 2019.

105

Pre-ANDA meeting requests to discuss product development and/or pre-submission issues were received in 2019.

FDA

OGD and the COVID-19 Pandemic



OGD takes our mission of ensuring that the American public has access to safe and effective generic medicines very seriously, especially now, during a time of crisis.

Application Assessment:

- The COVID-19 pandemic has not delayed our ability to work on applications to date.
- Our staff is working at full capacity, and we continue to move generic drug applications forward.
- OGD is working diligently to address challenges related to the pandemic and to carry out our ongoing duty of safeguarding the public health, while helping to ensure that safe and effective, high-quality generic drugs are available to the public.

FDA and the Generics Industry:

- FDA and the generics industry are doing incredible and valuable work to address the COVID-19 pandemic.
- We are in close contact with companies and appreciate that they are taking their role as partners in the defense of public health seriously, many reprioritizing their work around the COVID-19 response.

Drug Competition Action Plan (DCAP)

Increasing access to safe, high-quality, affordable generics while

- maintaining FDA's gold standard for rigorous, science-based regulation and
- continuing to encourage and support the development of new innovative products as Congress intended

DCAP goes **beyond** abbreviated new drug application (ANDA) **approval numbers** to focus resources on initiatives with the greatest potential for **public health impact**.

DCAP Enhances Access to Generic Drugs

- Closes **loopholes** that delay generic competition
 - [List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic](#)
 - [Access to Product Samples: The CREATES Act](#)
- Improves the **efficiency** of the generic drug development, assessment, and approval process
 - [Patent Certifications and Suitability Petitions](#)
- Maximizes scientific and regulatory **clarity** with respect to complex generic drugs
 - [Upcoming Product-Specific Guidances for Complex Drug Product Development](#)
 - [Product-Specific Guidances](#), as well as many other draft and final guidances
 - Regulatory science workshops to support complex generic drug development
- Drives global **harmonization** on scientific and technical standards for generic drugs
- Supports continued **availability** of safe, effective, and high-quality generic drugs through surveillance projects and engagement



GDUFA II Enhances Access to Generic Drugs

Goals and commitments include:

- [Pre-ANDA program](#) to better facilitate development and assessment of ANDAs for complex generic products
 - Clarify regulatory expectations for prospective applicants early in product development
 - Help applicants develop more complete submissions
 - Promote a more efficient and effective review process
 - Reduce the number of review cycles necessary to obtain ANDA approval of complex products
- New review goals for priority ANDA submissions
- Greater accountability and reporting, a modified user fee structure, and relief for small businesses

GDUFA II is critical to facilitating access by:

1. Reducing the number of assessment cycles to approval
2. Increasing approvals of safe, high-quality, and lower-cost generic drugs

GDUFA Regulatory Science



Guidance on complex products



Internal alignment on complex issues



Confidence in generic substitution



Review tool development



Faster and smarter generic drug development and review

Annual GDUFA Research and Science Reports



FDA Drug Information @FDA_Drug_Info · Feb 18

FDA releases FY2019 GDUFA Science and Research Report to provide detailed results for 13 areas of focus, including research activities and comprehensive lists of grants and contracts that the GDUFA Science and Research program awarded in FY2019: go.usa.gov/xdQnt.



Major Web Page Enhancements

- Competitive Generic Therapy (CGT) Approvals, featuring
 - a list of all approved ANDAs for drug products that received a CGT designation and notes which ANDAs on this list cover drug products that were also eligible for CGT exclusivity
- FDA Drug Competition Action Plan (DCAP), featuring
 - news and information about DCAP, FDA efforts and accomplishments under DCAP, and related updates.
- Upcoming Product-Specific Guidances (PSGs) for Complex Generic Drug Product Development, featuring
 - information related to upcoming new and revised PSGs to support the development and approval of safe and effective complex generic drug products.



Opportunities for collaboration: during development



- Pre-ANDA program
 - FDA's pre-submission process shows early collaboration helps longer term success
 - **Controlled correspondence** inquiries that address specific development questions from potential generic applicants
 - **Pre-ANDA meeting requests for complex generics**
- Guidances
 - Enhanced communications with and transparency to industry through PSGs and guidance documents = **significant improvement in the adequacy of applications on receipt**
 - **Industry can engage in ideas for guidance development**
 - Submit comments to public dockets
 - Participate in public workshops



Opportunities for collaboration: during assessment

Mutual commitment to the assessment process has shown clear value

More clear communications from FDA, and complete, timely responses from applicants significantly enhances process

Maximizing GDUFA II mechanisms is critical



Opportunities for collaboration: through timely actions/responses

- Withdraw ANDAs industry does not intend to pursue
- Proactively update ANDAs to reflect RLD changes and/or changes to patent and exclusivity information
- Provide timely responses to communications (e.g., Information Requests, Complete Response Letters)



Opportunities for collaboration: at FDA public workshops

- May 4, FY20 Generic Drug Regulatory Science Initiatives Public Workshop
- September 29-30, Generic Drug Product Development Workshop
- Orange Book 40th Anniversary



**Thank You
to our FDA
partners in
the Generic
Drug Program**

Office of Communications
Office of Compliance
Office of Management
Office of Medical Policy
Office of New Drugs
Office of Pharmaceutical Quality
Office of Regulatory Policy
Office of Strategic Programs
Office of Surveillance and
Epidemiology

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Generic Drug Program



