

ANDA Efforts Related to COVID-19

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Objective

- Current and future applicants will be able to describe the Generic Drug Program's efforts to facilitate marketing of generic drug products for potential treatment and supportive therapies for patients with COVID-19.

COVID-19 Effects on OGD's work

- Public Health Emergency declared on January 31, 2020
- OGD shifted to a largely telework based staff
- OGD continued to meet (often exceed) key GDUFA¹ commitments

¹GDUFA – Generic Drug User Fee Amendments

OGD COVID-19 efforts

- Abbreviated new drug applications (ANDAs) that could help address COVID-19 are prioritized based on CDER's Manual of Policies and Procedures 5240.3 Rev.5 *Prioritization of the Review of Original ANDAs, Amendments, and Supplements*. As part of its evaluation of whether a submission could help address the current public health emergency, FDA will consider whether the ANDA is (1) for a drug being investigated to treat or prevent COVID-19, but is not labeled for this use, or (2) for a drug being used for its labeled use to treat or prevent secondary conditions associated with COVID-19.²
- Some approvals were issued in GDUFA-era record time - as short as a few months.

² Guidance for Industry: *Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications* — Questions and Answers (May 2020)

OGD COVID-19 efforts

- ANDAs Approved and Controlled Correspondences answered as part of the COVID-19 Effort as of 05/01/2021:
 - 60+ Originals
 - 750+ Supplements
 - 300+ Controlled Correspondences

ANDA COVID-19 Guidances

- Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications — Questions and Answers, May 2020
 - FDA developed this guidance to provide answers to frequently asked questions relating to applications and the COVID-19 pandemic.
- Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers, August 2020 (Updated January 29, 2021)
 - FDA issued this guidance to provide answers to frequently asked questions about regulatory and policy issues related to inspections, pending drug applications, and changes in manufacturing facilities for approved pharmaceutical products.

ANDA COVID-19 Guidances



- Review Timelines for Applicant Responses to Complete Response Letters When a Facility Assessment Is Needed During the COVID-19 Public Health Emergency, December 2020
 - FDA issued this guidance to provide information pertaining to review timelines that FDA will use during the COVID-19 public health emergency for the following applicant responses to complete response (CR) letters when a facility assessment is necessary before FDA can take action on a marketing application: Amendments to original and supplemental abbreviated new drug applications (ANDAs) submitted to FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)...

ANDA COVID-19 Guidances



- Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID-19 Public Health Emergency, January 2021
 - FDA issued this guidance to provide recommendations to prospective applicants of ANDAs on ensuring the protection of participants when resuming or initiating bioequivalence (BE) studies conducted to support the approval of an ANDA that have been disrupted during the COVID-19 public health emergency.

ANDA COVID-19 Guidances

- Development of Abbreviated New Drug Applications During the COVID-19 Pandemic - Questions and Answers, April 2021
 - FDA issued this guidance to provide general recommendations to prospective applicants and applicants of ANDAs related to generic drug product development and regulatory submissions in the form of questions and answers that have been received and addressed by FDA during the COVID-19 public health emergency.

Challenge Question

What is the focus of the Generic Drug Program's efforts related to COVID-19?

- A. facilitate the approval of new generic drugs
- B. facilitate increased supply and market access through approval of supplements
- C. A and B

