Product-Specific Guidances for Generic Drug Development

Disclaimer: Due to April 2019 systemwide upgrades to www.fda.gov, the filenames for product-specific guidances on this web page may not match the corresponding guidance titles. In such cases, the name on the document correctly identifies the title of the guidance. These discrepancies will be corrected as soon as possible.

To successfully develop and manufacture a generic drug product, an applicant should consider that their product is expected to be: pharmaceutically equivalent to its reference listed drug (RLD), i.e., to have the same active ingredient, dosage form, strength, and route of administration under the same conditions of use; bioequivalent to the RLD, i.e., to show no significant difference in the rate and extent of absorption of the active pharmaceutical ingredient; and, consequently, therapeutically equivalent, i.e., to be substitutable for the RLD with the expectation that the generic product will have the same safety and efficacy as its reference listed drug.

According to 21 CFR 320.24, different types of evidence may be used to establish bioequivalence for pharmaceutically equivalent drug products, including in vivo or in vitro testing, or both. The selection of the method used to demonstrate bioequivalence depends upon the purpose of the study, the analytical methods available, and the nature of the drug product. Under this regulation, applicants must conduct bioequivalence testing using the most accurate, sensitive, and reproducible approach available among those set forth in 21 CFR 320.24. As the initial step for selecting methodology for generic drug product development, applicants are referred to the following draft guidance: *Draft Guidance for Industry on Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application (ANDA)* (Dec. 2013).

To further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval, FDA publishes product-specific guidances describing the Agency's current thinking and expectations on how to develop generic drug products therapeutically equivalent to specific reference listed drugs.

FDA publishes these product-specific guidances to foster drug product development, and ANDA submission and approval, ultimately providing increased access to safe, affordable generic drugs.

These guidances are published in an incremental manner and listed below in alphabetical order according to the active ingredient's name. The most recently published guidances (new and revised) are listed below.

Additionally, as part of FDA's commitments under the Generic Drug User Fee Amendments Reauthorization of 2017 (GDUFA II), FDA will publish guidances for reference listed drugs that are (1) new chemical entities and (2) approved on or after October 1, 2017, at least 2 years prior to the earliest lawful ANDA filing date. [1] This goal does not include complex products as defined in the GDUFA II Commitment Letter. FDA will strive to issue guidance for a complex product as soon as scientific recommendations are available.

In addition to the provided information, sponsors and investigators of any Investigational New Drug (IND)-exempt pharmacokinetic (PK) studies, pharmacodynamic (PD) studies, or bioequivalence (BE) and/or bioavailability (BA) studies involving human subjects in support of an ANDA should refer to the current RLD labeling, including BOXED WARNINGS, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS and ADVERSE REACTIONS sections. This information should be considered during study design and conduct; including attention to appropriate subject screening and selection, inclusion and exclusion criteria, and appropriate clinical safety monitoring.

Some of the product-specific guidances include discussion regarding data formats. Please note that under section 745A(a) of the Federal Food, Drug, and Cosmetic Act, separate Agency-wide guidances specify the electronic formats, subject matter, and scope of applicability for certain submissions, including submissions to ANDAs. As these are finalized guidances and subject to described timetables for implementation, these guidances are binding and the electronic format(s) specified must be used for submissions to ANDAs. Questions and general information regarding the preparation of submissions in electronic format may be directed to CDER at esub@fda.hhs.gov. Questions regarding submission of datasets to CDER may be sent to edata@fda.hhs.gov.

COMMENTS: The Agency is seeking feedback and considers comments to the docket on these guidances. You may submit comments on any guidance at any time as follows: Submit electronic comments to Docket FDA-2007-D-0369. For further information on submitting electronic comments, refer to the regulations.gov website (https://www.regulations.gov/help). You may also mail your written comments to DDM (HFA-305), FDA, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All submissions received must include the Docket No. [FDA-2007-D-0369]. Please contact the Regulations.gov Help Desk at 1-877-378-5457 (toll free) for assistance

regarding submissions.

The FDA posts plans for issuing new or revised product-specific guidances on the Upcoming Product-Specific Guidances for Complex Generic Drug Product Development web page.

For additional information on development of generic drug products, please refer to FDA's biopharmaceutics guidances.

[1] GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022 (GDUFA II Commitment Letter)

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Total number of currently published PSGs: 1760

Product-Specific Guidances for Specific Products Arranged by Active Ingredient

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Search by Active Ingredient or by RLD or RS Number

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Newly Added Guidances since September 2019

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Active Ingredient (link to Specific Guidance)	Type	Route	Dosage Form	RLD or RS Number	Date Recom

Acyclovir	Draft	Oral	Suspension	019909	09/2019
Amantadine hydrochloride	Draft	Oral	Tablet, Extended Release	209410	09/2019
Amoxicillin; Clavulanate potassium	Draft	Oral	Tablet, Extended Release	050785	09/2019
Avatrombopag maleate	Draft	Oral	Tablet	210238	09/2019
Baloxavir marboxil	Draft	Oral	Tablet	210854	09/2019
Baricitinib	Draft	Oral	Tablets	207924	09/2019
Benztropine mesylate	Draft	Oral	Tablet	009193	09/2019
Chenodiol	Draft	Oral	Tablet	018513	09/2019
Chlordiazepoxide hydrochloride	Draft	Oral	Capsule	012249	09/2019
Chlorpheniramine maleate	Draft	Oral	Tablet, Extended Release	007638	09/2019

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Newly Revised Guidances since September 2019

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Active Ingredient (link to Specific Guidance)	Type	Route	Dosage Form	RLD or RS Number	Date Recomm
Acyclovir	Draft	Topical	Ointment	018604	09/2019
Armodafinil	Draft	Oral	Tablet	021875	09/2019

Bosutinib monohydrate	Draft	Oral	Tablet	203341	09/2019
Budesonide	Draft	Oral	Capsule, Extended Release	021324	09/2019
Chlorthalidone	Draft	Oral	Tablet 50 mg; 25 mg	012283	09/2019
Colesevelam hydrochloride	Draft	Oral	Powder For Suspension	022362	09/2019
Dantrolene sodium	Draft	Oral	Capsule	017443	09/2019
Diphenhydramine citrate; Ibuprofen	Draft	Oral	Tablet	021394	09/2019
Duloxetine hydrochloride	Draft	Oral	Capsule, Delayed Release Pellets	021427	09/2019
Fingolimod hydrochloride	Draft	Oral	Capsule	022527	09/2019

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