

CHRONICLES

Competitive Generic Therapies

MAY 23RD, 2019

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Featuring LCDR Rinku Patel,
Pharm.D., Patent & Exclusivity Team,
Office of Generic Drugs Policy

Resources:

1. [Competitive Generic Therapies – Draft Guidance for Industry](#)

Upcoming Events:

1. [REdI Annual Conference – May 29-30 – Boston, MA \(in-person registration closed; live webcast available\)](#)

2. [SBIA Webinar - Financial Incentives for CDER Medicinal Products – June 10 \(10 AM – 3 PM\)](#)

3. [SBIA Webinar - CDER/CBER: Identification of Medicinal Products Initiative – June 13 \(1 PM – 2:30 PM\)](#)

4. [SBIA Webinar: An FDA Perspective on the Bioanalytics Method Validation – June 17 \(10 AM – 2 PM\)](#)

5. [Complex Generic Drug Product Workshop – Sept. 25-26 – College Park, MD \(Live webcast available\)](#)

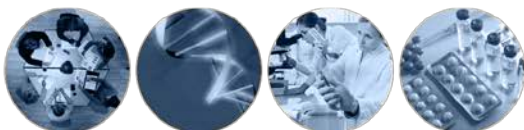
Drug development can be more challenging for products with limited markets, complex formulations or modes of delivery. This may translate into single source drugs with no generic competition for products with these characteristics. FDA recognizes this and has taken steps to incentivize generic competition for drugs with these challenges to help ensure patients have more access to affordable and high-quality generic drugs. One important part of these efforts is the new Competitive Generic Therapies (CGT) pathway, which is intended to stimulate generic drug development where inadequate generic competition exists.

The CGT pathway is a key component of FDA's [Drug Competition Action Plan](#), which aims to encourage robust and timely market competition for generic drugs so that patients can get access to the safe and effective medicines they need at affordable prices. Created under the FDA Reauthorization Act of 2017 (FDARA), the CGT pathway established a process through which FDA may, at the request of an applicant, designate a drug with "inadequate drug competition" as a CGT and may also expedite the development and review of the abbreviated new drug application (ANDA) for that drug. The pathway also includes a new type of 180-day exclusivity for the first approved applicant of a drug with a CGT designation for which there were no unexpired patents or exclusivities listed in the Orange Book at the time of the original submission of the ANDA. FDA recently issued a [draft guidance on CGTs](#) to provide generic drug applicants with information on how to request a CGT designation and whether they may be eligible for CGT exclusivity.

The success of the program to date is in the numbers. As of March 2019, the FDA has received more than 245 CGT requests, of which over 70% have been granted. FDA has also approved seven ANDAs for generic drugs designated as CGTs that qualified for 180-day CGT exclusivity. FDA's [quarterly CGT application reports](#) provide transparency on the numbers of ANDAs with a CGT designation.

Designation of a drug as a CGT. The applicant may request that a drug be designated as a CGT concurrently with, or any time prior to, the original ANDA submission. FDA must then determine that there is "inadequate generic competition" for the drug for it to be designated as a CGT. To qualify, there cannot be more than one approved drug in the active section of the Orange Book at the time FDA makes its determination. This may include the reference listed drug (RLD) or a generic drug that references the same RLD as the drug for which designation as a CGT is sought. FDA intends to make a determination within 60 calendar days of receipt of the request.

In the cover letter accompanying the request for designation, the applicant should include a pre-assigned ANDA number, a statement supporting the request for designation (details in the [guidance](#)), and information supporting the claim that there is inadequate generic competition for the drug. If the request for CGT designation is made prior to ANDA submission and the applicant plans to request a pre-ANDA meeting for the same drug, the applicant should submit the request for CGT designation before submitting the pre-ANDA meeting request. Whether or not the request for designation is being made prior to ANDA submission or concurrently with the original ANDA submission, the cover letter identifying the request should be included in Module 1 of the electronic Common Technical Document, and the request should be transmitted through FDA's Electronic Submission Gateway.



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Expedited Drug Development and Review of CGTs. If an applicant's drug is designated as a CGT, the applicant may request expedited development and review of its ANDA. This may entail:

- *Product development meetings* – The applicant may discuss specific scientific issues or questions with FDA (e.g., a proposed study design, alternative approach, or additional study expectations) and receive targeted feedback regarding an ongoing ANDA development program.
- *Pre-submission meetings* – The applicant may discuss and explain the format and content of the ANDA to be submitted (e.g., the types of data that will be contained in the ANDA or the data that will support equivalence claims).
- *Mid-review-cycle meetings* – FDA may discuss issues identified during review with the applicant.
- *Coordinated review of CGTs* – FDA may involve experienced staff in a collaborative, cross-disciplinary review of the ANDA. Senior management will be involved in the review consistent with the processes described in [MAPP 5241.3 - Good Abbreviated New Drug Application Assessment Practices](#).
- *Good ANDA assessment practices* – FDA is committed to improving the predictability and transparency of ANDA assessments to help minimize the number of review cycles necessary for approval (See [Good ANDA Submission Practices Draft Guidance](#)).

FDA will consider requests for meetings that may expedite the development of a drug on a case-by-case basis. The agency considers factors such as the complexity of developing an application for the drug, the potential public health impact of the drug, and the impact on FDA resources and other existing workload commitments. FDA generally intends to expedite the review of ANDAs for drugs designated as CGTs when the applicant has participated in the pre-ANDA meeting program prior to the submission of the ANDA (e.g. when the drug is a complex product). However, FDA generally does not intend to expedite the review of ANDAs covering CGTs if unexpired patents or exclusivities were listed in the Orange Book for the RLD at the time of submission. Under expedited review, FDA will strive to act on the ANDA as soon as possible, including prior to the GDUFA goal date.

CGT Exclusivity. A 180-day period of marketing exclusivity (CGT exclusivity) may be granted to the *first approved applicant* that:

- Obtains approval of an ANDA for a drug that has been designated as a CGT and for which there were no unexpired patents or exclusivities listed in the Orange Book for the relevant RLD at the time the applicant submitted the original ANDA; and
- Commercially markets the drug within 75 calendar days after the approval of the ANDA.

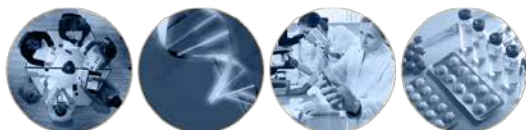
How can an applicant qualify as a “first approved applicant”? The applicant must obtain approval of its ANDA for a CGT on the first day that the FDA approves an ANDA for that particular CGT. There may be multiple ANDA applicants approved on the same day for the same CGT, which means that there may be multiple “first approved applicants”. “First approved applicant” in terms of CGT exclusivity does not necessarily mean the first applicant to have their ANDA approved for the drug product. In some cases, there may be an already approved ANDA that references the same RLD, but that did not receive a CGT designation. In this situation, when FDA approves the first ANDA for that drug product that has been designated as a CGT, the applicant for that ANDA may still qualify as a “first approved applicant”.

An ANDA would not qualify for CGT exclusivity if it is also eligible for [180-day patent challenge exclusivity](#), which is the exclusivity that the first generic drug applicant who submits a substantially complete ANDA containing a paragraph IV certification to a patent listed in the Orange Book may qualify for. A first approved applicant would forfeit its eligibility for CGT exclusivity if the applicant fails to market the CGT within 75 days after the date on which approval of its ANDA for the CGT is made effective. It is the responsibility of the applicant to notify FDA of the date of the first commercial marketing of the CGT. For detailed information about CGT designation and exclusivity, read the full draft guidance for industry titled, [‘Competitive Generic Therapies’](#).

Cheers,
Renu Lal, Pharm.D.
CDER Small Business and Industry Assistance

Issues of this newsletter are archived at <http://www.fda.gov/cdersbiachronicles>

This communication is consistent with 21CFR10.85(k) and constitutes an informal communication that represents our best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.



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