CDER Small Business and Industry Assistance (SBIA)
CHRONICLES

DECEMBER 19TH, 2019

Improving Regulatory Communication via the CDER NextGen Portal

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Resources:

1. CDER NextGen Portal
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3. Requesting a Pre-Assigned Application number web page
4. Pre-ANDA Program webpage
5. FAQ's for Pre-ANDA Meeting Requests
6. Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA - Guidance for Industry
7. Controlled Correspondences webpage
8. Controlled Correspondence Related to Generic Drug Development - Guidance for Industry
9. GDUFA webpage

Upcoming Events:

1. REdI Generic Drug Forum – April 15-16, 2020 – College Park MD

2. REdI Annual Conference – May 12-13, 2020 – Rosemont IL (Registration to open in 2020)

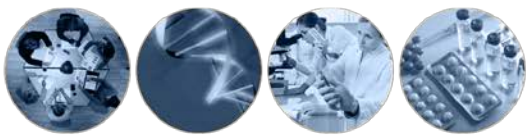
The CDER NextGen Portal (or the "Portal" for short) has made it easier than ever for regulated industry to communicate with the FDA. Now, an applicant, prospective applicant, or authorized U.S. agent can submit, receive, review, and respond to FDA communications in real time with receipt confirmation, two-way communications, and a communication history in one convenient centralized location. The Portal also uses multi-factor authentication to ensure data security.

Since its introduction in 2017, the Portal has been gaining functionality, and it now allows industry to perform a variety of functions, as detailed below.

Submit pre-assigned ANDA, NDA, BLA, IND, and MF number requests: Companies may submit pre-assigned abbreviated new drug application (ANDA), new drug application (NDA), biologics license application (BLA), investigational new drug application (IND), and master file (MF) number requests though the Portal. Although applicants may still request pre-assigned numbers by applying for secure email, we encourage use of the Portal for this function via the 'Pre-Assignment' tab. Once requested, the pre-assigned number is issued within three business days and does not expire. For ANDAs, the reference listed drug (RLD) will be needed for the request. *Note that the Portal is only for CDER documents and not for CBER documents.* All CBER application requests should be sent to CBERRIMS@fda.hhs.gov. Details are located on FDA's Requesting a Pre-Assigned Application number web page.

Request pre-ANDA meetings for complex generic drugs: The Portal allows for submission of supporting documents (such as the cover letter, meeting package, information requests, preliminary responses for pre-ANDA meetings, & updated agenda and presentation materials from the applicant); requests for additional information made by the FDA; post-meeting comments from the applicant within seven days of the meeting; and final meeting minutes from the FDA. A meeting package must be added in order to proceed. *Note that that the Portal should not be used to request mid-review-cycle meetings, as FDA will notify applicants if they are eligible.*

Before submitting the request, the applicant has the option of saving the draft meeting request to edit it later. Note that FDA cannot see saved meeting requests. All requests should be reviewed for accuracy, and the applicant can delete a meeting request if they have not yet submitted it. Details are located on FDA's Pre-ANDA Program webpage and in the FAQ's for Pre-ANDA Meeting Requests.



CDER Small Business and Industry Assistance (SBIA)
Division of Drug Information | Office of Communications
10001 New Hampshire Avenue | Hillandale Bldg, 4th Floor | Silver Spring, MD 20993
(866) 405-5367 or (301) 796-6707
CDERSBIA@fda.hhs.gov
www.fda.gov/cdersbia

Pre-ANDA meeting requests can still be submitted to genericdrugs@fda.hhs.gov per the Guidance for Industry - Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA.

Send controlled correspondence: After submitting a controlled correspondence via the Portal, the requestor will receive an email with a confirmation, and after FDA review, will receive a response via the Portal. The Portal also provides real-time status updates and notifications about controlled correspondence submissions to FDA personnel.

A pre-assigned ANDA number is not needed to submit a controlled correspondence through the Portal. The submission should include the detailed question and a letter of authorization if submitting on behalf of another company. You will need to specify the RLD listed in the Orange Book, even if the RLD has been discontinued. If there is no RLD, you may choose the reference standard (RS). Note that post-approval changes controls do not need to specify an RLD or RS. Find details on the Controlled Correspondences webpage and refer to FDA's draft guidance for industry, Controlled Correspondence Related to Generic Drug Development for additional information.

Submit a list of approved ANDAs to the FDA for the remainder of GDUFA II (2020-2022): In preparation for the Fiscal Year 2021, FDA has asked ANDA applicants to use the Portal to confirm their affiliates along with the approved ANDAs owned by the company and affiliates. Companies can log in to the Portal to set up and view their company portfolio, including their affiliates and all corresponding ANDAs to ensure the company is aligned with the correct Program Fee tier. Submissions are due by April 1, 2020. All actions regarding any submissions should be officially requested through the Electronic Submissions Gateway (ESG). Details are available on FDA's GDUFA webpage.

Send FDA Drug Shortage and Supply Notifications: Manufacturers and applicants can utilize the Portal to notify FDA of drug shortages, new discontinuances, good manufacturing practice issues, increases in product demand, recalls, supply interruptions, or other events.

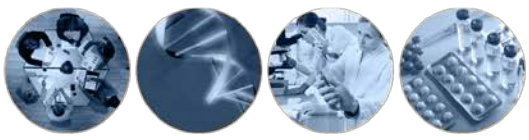
In general, when submitting via the Portal, non-U.S. applicants will need to utilize a U.S. agent. Agents should create an account and fill in the applicant's information, including applicant contact information. If a foreign applicant does not have a U.S. agent, they should not enter themselves as an agent. However, this does not apply to companies viewing or changing their portfolio in the Portal.

So, why use the Portal when the submissions and requests described above are still possible via mail and email? The Portal allows for greater consistency, faster triage, simplified acknowledgement, and easier tracking. It also allows FDA and applicants to view the request and history all in one place. The Portal is continuously gaining functionality, and at some point the Office of Generic Drugs will migrate to full utilization of the Portal. Please refer to the Portal Login Frequently Asked Questions at for additional information. Schedule some time today to visit the CDER NextGen Portal and create your account!

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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