MEMORANDUM

TO: **Division of Dockets Management, HFA-305**

FROM: **Division of Filing Review, Office of Regulatory Operations, Office of Generic Drugs**

RE: **Docket No. FDA-2006-P-0395**

DATE: **August 21, 2023**

Please consider the suitability petition in the above-referenced docket to have been voluntarily withdrawn without prejudice to resubmission. The citizen petition, dated November 20, 2006, was submitted by Strides Pharma, Inc.

On July 13, 2023, the Food and Drug Administration sent a letter via certified mail to the petitioner requesting that the petitioner respond if the petitioner wished to keep the petition active. The letter stated that if we do not receive a written response within 30 days from the date of the letter, a copy of the letter would be filed in the docket with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

The letter was received by Strides Pharma, Inc. To date, the Agency has not received a response to the letter. In light of the above, we are considering the petition to be voluntarily withdrawn without prejudice, and we request closure of this docket.

The letter and signed return receipt are attached to this memorandum.

Attachments:
2006-P-0395_Letter_of_Interest
FDA-2006-P-0395_ReturnReceipt

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

July 13, 2023

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Strides Pharma, Inc.
2 Tower Center Blvd
Suite 1102
East Brunswick, NJ 08816

Re: Docket Number: FDA-2006-P-0395
(Legacy Number 2006P-0469)

Dear Petitioner:

We are contacting you concerning the petition referenced above. According to the records of the Food and Drug Administration's (FDA's) Division of Dockets Management, this petition has not been resolved.

The Agency and industry agreed to certain commitments related to Suitability Petitions as part of the reauthorization of the Generic Drug User Fee Amendments and as described in "GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023- 2027" (GDUFA III commitment letter). We note that, in accordance with the GDUFA III commitment letter, FDA agreed to certain goals and procedures for the review of suitability petitions. FDA agreed to take appropriate action prior to FY 2024 to determine if petitioners who submitted suitability petitions prior to FY 2023 remain interested in a response. FDA also agreed that any suitability petition submitted in FY 2024-2027 will receive a goal date. More details about these goal dates are included in the GDUFA III commitment letter. Any suitability petitions submitted to FDA prior to FY 2024 will not receive a goal date. If a petitioner wants to receive a goal date on a suitability petition submitted prior to FY 2024, the petitioner may withdraw and submit a new suitability petition in FY 2024-2027.

To fulfill the Agency's commitment to determine if petitioners who submitted suitability petitions prior to FY 2023 remain interested in a response, the Center for Drug Evaluation and Research (CDER) has reviewed unresolved suitability petitions.

The referenced petition was submitted more than 5 years ago by Strides, Inc. Given the length of time since the petition was submitted and developments since that time, we are uncertain as to whether the petitioner remains interested in a response.

Accordingly, we have enclosed a copy of the petition and would appreciate it if you would review the petition and respond to the docket number listed above if you wish to keep this

petition active. Your response should reference the docket number and be sent to the Food and Drug Administration, Division of Dockets Management, Room 1061, 5630 Fishers Lane, Rockville, MD 20852; or submitted electronically at www.regulations.gov. If we do not receive a written response from you within **30 days** from the date of this letter, a copy of this letter will be filed in Docket No. FDA-2006-P-0395 (Legacy Number 2006P-0469) with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

If you have any questions, please contact ANDAFiling@fda.hhs.gov. Thank you for your attention to this matter.

Sincerely,

Rosanne R. Pagaduan -S

Digitally signed by Rosanne R. Pagaduan -S
Date: 2023.07.13 14:29:31 -04'00'

Rosanne Pagaduan, Pharm.D.
Supervisory Pharmacist
Division of Filing Review
Office of Regulatory Operations
Office of Generic Drugs

Tracking Number:

70133020000149590422

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EAST BRUNSWICK, NJ 08816
July 17, 2023, 1:50 pm

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