DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 29, 2020

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Sent via email to: drosen@foley.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA:

1. Refrain from filing or approving any Abbreviated New Drug Application ("ANDA") or 505(b)(2) New Drug Application ("NDA") for a generic version of Lonsurf ® Tablets, 15 mg trifluridine/6.14 mg tipiracil and 20 mg trifluridine/8.19 mg tipiracil that does not reference Lonsurf and include certifications to the all of the patents listed in FDA's *Orange Book* for Lonsurf.

2. Refrain from approving any ANDA or 505(b)(2) application for a generic version of Lonsurf Tablets, 15 mg trifluridine/6.14 mg tipiracil and 20 mg trifluridine/8.19 mg tipiracil product, if the application includes a statement pursuant to Section 505(j)(2)(A)(viii) of the FD&C Act (Section 21 CFR 314.94(8)(iv) of FDA's implementing regulations) stating that the applicant is not seeking approval of an application that contains an indication or other aspect of labeling protected by patent or accorded exclusivity under section 505(j)(5)(F) of the FD&C Act.

3. Require the labeling for any generic version of Lonsurf Tablets, 15 mg trifluridine/6.14 mg tipiracil and 20 mg trifluridine/8.19 mg tipiracil product to include all information related to Warnings, recautions and other safety related information that is included in the Lonsurf labeling, including relevant dose adjustments in severe renally impaired patients needed to prevent unnecessary toxicity

Your petition was received on 04/28/2020. It was assigned docket number FDA-2020-P-1312. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby

Digitally signed by
Dynna Bigby
Date: 2020.04.30
17:05:45 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of Operations (OO)