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ND 216921 A

ANDA APPROVAL

Syneos Health, LLC
U.S. gent for Natco Pharma Limited
ttention: Glenda Bryant
Senior Regulatory Consultant

Dear Glenda Bryant:

This letter is in reference to your abbreviated new drug application (ND) received for review on March 23, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for Idelalisib Tablets, 100 mg and 150 mg.

Reference is also made to the complete response letter issued by this office on November 19, 2024, and to any amendments thereafter.

We have completed the review of this ND and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C ct. ccordingly the ND is **approved**, effective on the date of this letter. We have determined your Idelalisib Tablets, 100 mg and 150 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Zydelig Tablets, 100 mg and 150 mg, of Gilead Sciences, Inc. (Gilead) ND - 205858.

The RLD upon which you have based your ANDA, Gilead's Zydelig Tablets, 100 mg and 150 mg, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"): A

U.S. Patent Number	Expiration Date
8,865,730 (the '730 patent)	March 5, 2033
9,469,643 (the '643 patent)	September 2, 2033
9,492,449 (the '449 patent)	March 11, 2030
10,730,879 (the '879 patent)	March 5, 2033

Your ND contains paragraph IV certifications to each of the patents, under section 505(j)(2)( )(vii)(IV) of the FD&C ct stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Idelalisib Tablets, 100 mg A

nd 150 m g, und r this ANDA. You h v notifi d th A ncy th t N tco h rm a Limit d (N tco) compli d with th r quir m nts of s ction 505(j)(2)(B) of th FD&C Act. Liti tion w s initi t d within th st tutory 45-d y p riod inst N tco for infrin m nt of th '730, '643, '449 nd '879 p t nts in th Unit d St t s District Court for th District of D l w r [Gil d Sci nc s, Inc. nd Gil d C listo LLC. v. N tco h rm a Limit d, Civil Action No. 22-00852 nd Gil d Sci nc s, Inc. v. N tco h rm a Limit d CA No. 22-01259]. You h v lso notifi d th A ncy th t th s c s s w r dismiss d.

With r sp ct to 180-d y n ric dru xclusivity, w not th t N tco w s th first ANDA pplic nt for ld l lisib T bl ts, 100 m g nd 150 m g, to submit subst nti lly compl t ANDA with p r r ph IV c rtific tion. Th r for , with this pprov l, N tco m y b li ibl for 180 d ys of n ric dru xclusivity for ld l lisib T bl ts, 100 m g nd 150 m g. This xclusivity, which is provid d for und r 505(j)(5)(B)(iv) of th FD&C Act, would b in to run from th d t of th comm rci l m rk tin id ntifi d in s ction 505(j)(5)(B)(iv). Th A ncy not s th t N tco f il d to obt in t nt tiv pprov l of this ANDA within 30 months ft r th d t of which th ANDA w s fil d. S s ction 505(j)(5)(D)(i)(IV) of th FD&C Act (forf itur of xclusivity for f ilur to obt in t nt tiv pprov l). Th A ncy is not, how v r, m kin form l d t rmin tion t this tim of N tco's eligibility for 180-d y n ric dru xclusivity. It will do so only if subs qu nt p r r ph IV pplic nt b com es li ibl for full pprov l ( ) within 180 d ys ft r N tco b ins comm rci l m rk tin of ld l lisib T bl ts, 100 m g nd 150 m g, or (b) t ny tim e prior to th xpir tion of th '730, '643, nd '879 p t nts if N tco h s not b un comm rci l m rk tin . l s submit corr spond nc to this ANDA notifyin th A ncy within 30 d ys of th d t of th first comm rci l m rk tin of this dru product or th RLD. If you do not notify th A ncy within 30 d ys, th d t of first comm erci l marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

l s not th t if FDA r quir s Risk Ev lu tion nd Miti tion Str t y (REMS) for list d dru , n ANDA r f r ncin th t list d dru lso will b r quir d to h v REMS. S s ction 505-1(i) of th FD&C Act.

COMPENDIAL STANDARDS

A dru with n m e r co niz d in th offici l Unit d St t s h rm acop i or offici l N tion l Formul ry (US -NF) n r lly must comply with th comp ndi l st nd rd for str n th, qu lity, nd purity, unl ss th diff r nc in str n th, qu lity, or purity is pl inly st t d on its l b l (s FD&C Act § 501(b), 21 USC 351(b)). FDA typic lly c nnot sh r pplic tion-sp cific inform ation cont in d in submitt d r ul tory filin s with third p rti s, which includ s US -NF. To h lp nsur th t dru continu s to comply with comp ndi l st nd rds v pplic tion hold rs m y work dir ctly with US -NF to r vis offici l US mono r phs. Mor inform ation on th US -NF is v ilable on USP's v w bsit s https://www.uspnf.com/. v

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Und r pplic bl st tut s, r ul tions, nd uid nc s, your ANDA m ay b subj ct to c rt in r quir m ents nd r commend tions post pprov l, includin r quir m ents r rdin ch n s to pprov d ANDAs, postm ark tin r portin , promotion l m t ri ls, nd nnu l f cility f s, mon oth rs. For inform ation on post- pprov l r quir m ents nd r comm end tions for ANDAs nd list of r sourc s for ANDA hold rs, w r f r you to https://www.fd . ov/dru s/ bbr vi t d-n w-dru - pplic tion- nd /r quir m ents- nd-r sourc s- pprov d- nd s.

Sinc r ly yours,

{See appended electronic signature page}

For K ndr S. St w rt, R. h., h rm.D.
CA T, Unit d St t s ublic H lth S rvic l
Dir ctor
Offic of R ul tory Op r tions
Offic of G en ric Dru s
C nt r for Dru Ev lu tion nd R s rch

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Paul 4
Levi e 4

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