U.S. FOOD & DRUG ADMINISTRATION

A

ND 218578 A

ANDA TENTATIVE 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 pril 12, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for Erdafitinib Tablets 3 mg, 4 mg, and 5 mg.

Reference is also made to the complete response letter issued by this office on June 25, 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. We have determined your Erdafitinib Tablets, 3 mg, 4 mg, and 5 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Balversa Tablets, 3 mg, 4 mg, and 5 mg, of Janssen Biotech, Inc. (Janssen), ND – 212018.

However, we are unable to grant final approval to your ND at this time because of the patent issue noted below. Therefore, the ND is **tentatively approved**. This determination is based upon information available to the gency at this time (e.g., information in your ND and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the FD&C ct.

The RLD upon which you have based your ND , Janssen's Balversa Tablets, 3 mg, 4 mg, and 5 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
8,895,601 (the '601 patent) A	pril 12, 2033 A

9,464,0 1 (th '0 1 p t nt)	April 28, 2031
9,902, 14 (th ' 14 p t nt) l	M arch 26, 2035
10,898,482 (th '482 p t nt)	F bru ry 9, 2036
11,0 ,106 (th '106 p t nt)	F bru ry 2, 2038
11,684,620 (th '620 p t nt)	F bru ry 9, 2036
10,4 8,494 (th ‘494 p t nt)	Au ust 13, 2036
12,03 ,644 (th '644 p t nt)	Octob r 18, 2035

With r sp ct to th '601 nd '0 1 p t nts, your ANDA cont ins p r r ph III c rtific tions to ch of th p t nts und r s ction 505(j)(2)(A)(vii)(III) of th FD&C Act st tin th t N tco h rm a Limit d (N tco) will not m ark t Erd fitinib T bl ts, 3 m , 4 m g, nd 5 m g prior to th xpir tion of th p t nts. Th r for , fin l pprov l of your ANDA m ay not b r nt d pursu nt to s ction 505(j)(5)(B)(ii) of th FD&C Act until th '601 p t nt h s xpir d, curr ntly April 12, 2033.

Your ANDA cont ins p r r ph IV c rtific tions to th ' 14, '482, '106, '620, nd '644 p t nts und r s ction 505(j)(2)(A)(vii)(IV) of th FD&C Act st tin th t th p t nts r inv lid, un nforc bl , or will not b infrin d by your m anuf ctur , us , or s l of Erd fitinib T bl ts, 3 m g, 4 m g, nd 5 m g, und r this ANDA. You h v notifi d th A ncy th t N tco compli d with th r quir m ents 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 ' 14 nd '106 p t nts in th Unit d St t s District Court for th District of N w J rs y [J nss n h rm ac utic NV, J nss n Biot ch, Inc., nd Ast x Th r p utics Ltd., v. N tco h rm a Ltd. Civil Action No. 23-03959].

Th r for , fin l pprov l c nnot b r nt d until:

1. . th xpir tion of th .5-y r p riod provid d for in s ctions 505(j)(5)(B)(iii) l nd 505(j)(5)(F)(ii) of th FD&C Act,

   b. th d t th court d cid s[1] th t th ' 14 nd '106 p t nts r inv lid or not infrin d (s s ctions 505(j)(5)(B)(iii)(I), (II), nd (III) of th FD&C Act), or

   c. th '601, '0 1, ' 14, nd '106 p t nt h v xpir d, nd

2. Th A ncy is ssur d th r is no n w inform ation th t would ff ct wh th r l fin l pprov l should b r nt d.

With respect to the ‘494 p t nt, th A ncy h s d t rmin d th t inform ation on this p t nt w s submitt d to th A ncy by th n w dru pplic tion (NDA) hold r ( ) ft r

th d t of th submission of your ANDA, nd (b) mor th n 30 d ys ft r th p t nt w s r quir d to b submitt d und r 21 CFR 314.53. Th r for , und r 21 CFR 314.94( )(12)(vi), no p rson with n ppropri t p t nt c rtific tion t th tim e of th submission of th p t nt w s r quir d to submit n m end d p t nt c rtific tion to address the '494 p t nt. You l ct d not to submit n m end d p t nt c rtific tion with r sp ct to this p t nt.

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.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Und r pplic bl st tut s, r ul tions, nd uid nc s, if your ANDA r c iv s fin l pprov l, it m ay b subj ct to c rt in r quir m ents nd r comm nd tions post pprov l, includin r quir m ents r rdin ch n s to pprov d ANDAs, postm rk tin r portin , promotion l m at 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 commend 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.

RESUBMISSION

To request final approval, please submit an amendment titled "FINAL APPROVAL REQUESTED" with enough time to permit FDA review prior to the date you believe that your ANDA will b li ibl for fin l pprov l. A r qu st for fin l pprov l th t cont ins no n w d t , inform ation, or oth r ch n s to th ANDA n r lly r quir s p riod of 3 months for A ncy r vi w. Accordin ly, such r qu st for fin l pprov l should b submitt d no l t r th n 3 months prior to th d t on which you s k pprov l. A r qu st for fin l pprov l th t cont ins subst ntiv ch n s to this ANDA or ch n s in the status of the manufacturing and testing facilities' compliance with cGMPs will be cl ssifi d nd r vi w d ccordin to OGD policy in ff ct t th tim e of r c ipt. Applic nts should r vi w v il bl ncy uid nc for industry r l t d to m endm ents und r th n ric dru us r f pro r m to d t rmin th dur tion of A ncy r vi w n d d to r vi w th ch n s submitt d. As p rt of this consid r tion, pplic nts should monitor ny ch n s to th RLD th t occur ft r t nt tiv pprov l, includin ch n s in l b lin , p t nt or xclusivity inform ation, or m ark tin st tus. Th submission of multipl m endm ents prior to fin l pprov l m ay lso r sult in d l y in th issu nc of th fin l pprov l l tt r.

Th m endm ent r qu stin fin l pprov l should provid th l l/r ul tory b sis for your r qu st for fin l pprov l nd should includ copy of court d cision, s ttl m ent or lic nsin r m ent, or oth r inform ation d scrib d in 21 CFR 314.10 , s pproprí t . It should lso id ntify ch n s, if ny, in th conditions und r which th ANDA w s t nt tiv ly pprov d, . ., upd t d inform ation such s fin l-print d l b lin , ch mistry, m anuf cturin , nd controls d t s ppropri t . This m endm ent should b a

submitt d v n if non of th s ch n s w r m ad , nd it should b d si n t d clearly in your cover letter as a "FINAL APPROVAL REQUESTED."

In ddition to th m endm ent r qu st d bov , th A ncy m ay r qu st, t ny tim e prior to th d t of fin l pprov l, th t you submit n ddition l m endm ent cont inin inform ation s sp cifi d by th A ncy. F ilur to submit ith r or, if r qu st d, both typ s of m endm ents d scrib d bov m ay r sult in d l y in th issu nc of th fin l pprov l l tt r.

This dru product m ay not b m ark t d without fin l A ncy pprov l und r s ction 505(j) of th FD&C Act. Th introduction or d liv ry for introduction into int rst t comm rc of this dru product b for th fin l pprov l d t is prohibit d und r s ction 301 of th FD&C Act. Also, until th A ncy issu s th fin l pprov l l tt r, this dru a product will not b d m ed pprov d for m ark tin und r s ction 505(j) of th FD&C Act, nd will not b list d in th Or n Book.

For furth r inform ation on th st tus of this ANDA or upon submittin n m endm ent to th ANDA, pl s cont ct Xu n-M ai N uy n, R ul tory roj ct M an r, t (301) 96 - 9453.

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
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 a

[1] This d cision m ay b ith r d cision of th district court or th court of pp ls, which v r court is a th first to d cid th t th p t nt is inv lid or not infrin d.

Paul 4
Levi e 4

i i a l si ed b Paul Levi e
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