ND 210804 A

ANDA TENTATIVE APPROVAL

MSN Pharmaceuticals Inc.
U.S. gent for MSN Laboratories Private Limited
ttention: Kondal Reddy Bairy
Senior Vice President

Dear Kondal Reddy Bairy:

This letter is in reference to your abbreviated new drug application (ND) received for review on July 12, 2017, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for fatinib Tablets, 20 mg, 30 mg, and 40 mg.

Reference is also made to the tentative approval letter issued by this office on February 14, 2023, 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 fatinib Tablets, 20 mg, 30 mg, and 40 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Gilotrif Tablets, 20 mg, 30 mg, and 40 mg, of Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer), ND - 201292.

However, we are unable to grant final approval to your ND at this time because of the exclusivity 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 reference listed drug (RLD) upon which you have based your ND , Boehringer's Gilotrif Tablets, 20 mg, 30 mg, and 40 mg, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic* A *Equivalence Evaluations* (the "Orange Book"):

U.S. Food & dminist ation
Silve Sp in , M D20993
www.fda. ov

U.S. t nt Numb r l	Expir tion D t l
8, 26,586 (th '586 p t nt)	April 10, 2030
8,5 5,88 (th '88 p t nt)	Jun 19, 2030
9,539,258 (th '258 p t nt)	M ay 9, 2027
10,00 ,7 3 (th '7 3 p t nt)	J nu ry 5, 2031
RE 3, 31 (th ' 31 p t nt)	July 13, 2026

Your ANDA cont ins p r r ph IV c rtific tions to th '586, '884, '258, and '743 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 Af tinib T bl ts, 20 m g, 30 m g, nd 0 m g, und r this ANDA. You h v notifi d th A ncy th t MSN L bor tori s riv t Limit d (MSN) 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 5-d y p riod inst MSN for infrin m ent of th '586 p t nt in th Unit d St t s District Court for th District of N w J rs y [Bo hrin r In lh im h rm ac utic ls, Inc. nd Bo hrin r In lh im Int rn tion l GmbH, v. MSN L bor tori s riv t Limit d nd MSN h rm ac utic ls, Inc., Civil Action No. 3:17-cv-08399]. You h v lso notifi d th A ncy th t this c s w s dismiss d.

The RLD upon which you have based your ANDA, Boehringer's Gilotrif Tablets, 20 mg, 30 m g, nd 0 m g, is subj ct to p riod of xclusivity. As not d bov , th p di tric xclusivity p riod ssoci t d with th ' 31 p t nt is sch dul d to xpir on July 13, 2026.[1] Th r for , fin l pprov l c nnot b r nt d until xpir tion of th p di tric xclusivity p riod ssoci t d with th ' 31 p t nt. S s ction 505A(b)(1)(B)(i) of th FD&C Act.[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.

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 l 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 A ROVAL 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 31 .107, s ppropri 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 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 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.

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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 Wilb rt F r uson III, R ul tory roj ct M an r, t (2 0) 02 - 687. l

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 l

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[1] We not th t this ANDA curr ntly is li ibl for pprov l th d y ft r xpir tion of th p di tric xclusivity p riod. S S ction 505A(b)(1)(B) of th FD&C Act. If this d y f lls on S turd y, Sund y, or F d r l holid y, it will b li ibl for pprov l th n xt busin ss d y.

[2] Althou h your ANDA pr viously cont in d p r r ph IV c rtific tion to th ' 31 p t nt, upon xpir tion of th t p t nt on J nu ry 13, 2026, your c rtific tion to th ' 31 p t nt is d m ed to b p r r ph II c rtific tion.

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Paul c
Levi e c

i i a l si ed b Paul Levi e
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