ND A219218

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 A) received for review on December 26, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for Ubrogepant Tablets, 50 mg and 100 mg.

We have completed the review of this ND Aand 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 Ubrogepant Tablets, 50 mg and 100 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Ubrelvy Tablets, 50 mg and 100 mg, of bbVie Inc. (bbVie) ND A- 211765.

However, we are unable to grant final approval to your ND Aat this time because of the patent issue noted below. Therefore, the ND Ais **tentatively approved**. This determination is based upon information available to the gency at this time (e.g., information in your ND Aand 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 A, bbVie's Ubrelvy Tablets, 50 mg and 100 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"):

U.S. Patent Number	Expiration Date
8,754,096 (the '096 patent)	July 19, 2032
8,912,210 (the '210 patent)	December 23, 2033

ANDA 219218 v
2 v

9,499,545 (th '545 p t nt) v	Nov mb r 10, 2031 v
9,833,448 (th '448 p t nt) v	Nov mb r 10, 2031 v
10,117,836 (th '836 p t nt) v	J nu ry 30, 2035 v
11,717,515 (th '515 p t nt) v	D c mb r 22, 2041* v
11,857,542 (th '542 p t nt) v	D c mb r 22, 2041* v
11,925,709 (th '709 p t nt) v	J nu ry 30, 2035 v
12,070,450 (the '450 patent) v	D c mb r 22, 2041** v
12,168,004 (th '004 p t nt) v	J nu ry 30, 2035 v
12,194,030 (th '030 p t nt) v	D c mb r 22, 2041* v
12,220,408 (th '408 p t nt) v	J nu ry 30, 2035 v
12,310,953 (th '953 p t nt) v	J nu ry 30, 2035 v
12,329,750 (th '750 p t nt) v	D c mb r 22, 2041* v
12,458,632 (th '632 p t nt) v	J nu ry 30, 2035 v
12,458,633 (th '633 p t nt) v	J nu ry 30, 2035 v

*50 m g str n th only v
** 100 m g str n th only v
v

With r sp ct to th '096, '210, '545 nd '448 p t nts, your ANDA cont ins p 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 MSN L bor tori s riv t Limit d (MSN L bs) will not m rkt Ubro p nt T bl ts, 50 m g nd 100 m g prior to th xpir tion of th p t nts. Th for , fin l pprov l of your ANDA m y not b r nt d pursu nt to s ction 505(j)(5)(B)(ii) of th FD&C Act until th '210 p t nt h s xpir d, curr ntly D c mb r 23, 2033. v

Your ANDA contains paragraph IV certifications to the '836, '515, '542, '709, '450, '004, '030, '408, '953, '750, '632 nd '633 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 nuf ctur , us , or s l of Ubro p nt T bl ts, 50 m g nd 100 m g, und r this ANDA. You h v notifi d th A ncy th t MSN L bs 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 v inst MSN L bs for infrin m nt of th '836 nd '515 p t nts in th Unit d St t s District Court for th District of N w J rs y [AbbVi Inc., All r n v

h rm ac l utic ls Int rn tion l Limit d, nd M erdk Sh rp & Dohm e LLC, v. MSN h rm ac l utic ls Inc., MSN L bor tori s riv t Limit d, nd MSN Lif Sci nc riv t Limit d, Civil Action No. 24-04662].

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

1. l. th xpir tion of th 7.5-y l r p riod provid d for in s ctions 505(j)(5)(B)(iii) nd 505(j)(5)(F)(ii) of th FD&C Act,

lb. th d t th court d cid s[1] th t th '8 6 nd '515 p t nts r inv lid or not infrin l d (s l s ctions 505(j)(5)(B)(iii)(I), (II), nd (III) of th FD&C Act), or

lc. th '096, '210, '545, '448, '8 6 nd '515 p t nts h v xpir d, nd

2. Th lA l ncy is ssur d th r is no n lw inform tion th t would ff ct wh th r fin l pprov l should b r nt d.

l ls not th t if FDA r quir s Risk Ev lu tion nd Miti ltion Str t ly (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 l 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 ayl b subj ct to c rt in r quir m entls nd r comml nd tions post pprov l, includin r quir m entls r rdin ch n l s to pprov d ANDAs, postm arkl tin r portin l, promotion l m at lri ls, nd nnu l f cility f ls, mon loth rs. For inform tion on post- pprov l r quir m entls nd r commerld tions for ANDAs nd list of r sourc s for ANDA hold rs, w l r f r you to https://www.fd l ov/dru ls/ bbr vi t d-n lw-dru l- pplic tion- nd /r quir m entls- 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 lw d t , inform tion, or oth r ch n l s to th lANDA ln r lly r quir s p riod of months for A l 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 months prior to th d t on which you s l k pprov l. A r qu st for fin l pprov l th t cont ins subst ntiv ch n l s to this ANDA or ch n l s in the status of the manufacturing and testing facilities’ compliance with cGMPs will be cl ssifi d nd r vi w ld ccordin to OGD policy in ff ct t th time df r c ipt. Applic nts should r vi w v il bl l ncy uid nc for industry r l t d to m endm entls und r th ln ric dru us r f l pro r m to d t rmin th dur tion of A l ncy r vi w n l d d to r vi w th ch n l s submitt d. As p rt of this consid r tion, pplic nts should monitor ny ch n l s to th RLD th t occur ft r t nt tiv pprov l, includin

changes in labeling, patent or exclusivity information, or marketing status. The submission of multiple amendments prior to final approval may also result in delay in the issuance of the final approval letter.

The amendment requesting final approval should provide the legal/regulatory basis for your request for final approval and should include a copy of court decision, settlement or licensing agreement, or other information described in 21 CFR 314.107, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a "FINAL APPROVAL REQUESTED."

In addition to the amendment requested above, the Agency may request, at any time prior to the date of final approval, that you submit an additional amendment containing information specified by the Agency. Failure to submit either, if requested, both types of amendments described above may result in delay in the issuance of the final approval letter.

This drug product may not be marketed without final Agency approval under section 505(j) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the FD&C Act. Also, until the Agency issues the final approval letter, this drug product will not be considered approved for marketing under section 505(j) of the FD&C Act, and will not be listed in the Orange Book.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Devon Lee, Regulatory Project Manager, at (301) 837-7615.

Sincerely yours,

{See appended electronic signature page}

For Kendra S. Stewart, R.Ph., PharmD.
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

Joe 1
Shin 1

Di i 1 si ned b Joe Shin 1
D 1e: 6/24/2026 05:03:22PM 1
GUID: 548b4db50000 00809e4 9b42 823e26 1