ND 215155 A

ANDA TENTATIVE APPROVAL A

scend Laboratories, LLC
U.S. gent for lkem Laboratories Limited
ttention: Hindy Schiff
Vice President, Regulatory ffairs

Dear Hindy Schiff:

This letter is in reference to your abbreviated new drug application (ND) received for review on July 27, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for Sitagliptin Tablets USP, 25 mg, 50 mg, and 100 mg.

Reference is also made to the tentative approval letter issued by this office on pril 8, 2022, the complete response letter issued by this office on July 11, 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 Sitagliptin Tablets USP, 25 mg, 50 mg, and 100 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Januvia Tablets, 25 mg, 50 mg, and 100 mg, of Merck Sharpe & Dohme Corp. (Merck) ND - 021995.

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.

The RLD upon which you have based your ND , Merck's Januvia Tablets, 25 mg, 50 mg, and 100 mg, is subject to a period of patent protection. The following patent and expiration date (with pediatric exclusivity added) is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"): A

U.S. P t nt Numb r e	Expir tion D t
7,326,708 (th '708 p t nt)	M ay 24, 2027

Your ANDA cont ins p r r ph IV c rtific tion to th '708 p t nt und r s ction 505(j)(2)(A)(vii)(IV) of th FD&C Act st tin th t th p t nt is inv lid, un nforc bl , or will not b infrin d by your m anuf ctur , us , or s l of Sit liptin T bl ts USP, 25 m g, 50 m g, nd 100 m g, und r this ANDA. You h v notifi d th A ncy th t Alk m L bor tori s Limit d (Alk m) 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 Alk m for infrin m ent of th '708 p t nt in th Unit d St t s District Court for th District of D l w r [M erck Sh rp & Dohm e Corp. v. Alk m L bor tori s Ltd. nd S&B Ph rm a, Inc., Civil Action No. 21-00824]. You h v lso notifi d th A ncy th t this c s w s dismiss d.

How v r, w r un bl to r nt fin l pprov l to your ANDA t this tim e. Prior to th submission of your ANDA, noth r pplic nt or pplic nts submitt d subst nti lly compl t ANDA providin for Sit liptin T bl ts USP, 25 m g, 50 m g, nd 100 m , nd cont inin p r r ph IV c rtific tion. Your ANDA will b li ibl for fin l pprov l on th d t th t is 180 d ys ft r th comm rci l m ark tin d t id ntifi d in s ction 505(j)(5)(B)(iv) of th FD&C Act.

Pl 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 comm nd 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 e 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 e

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 14.107, 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 01 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.

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 M e nu Sh rm a, R ul tory Proj ct M an r, t (01) 796 - 691.

Sinc r ly yours,

{See appended electronic signature page}

For K ndr S. St w rt, R.Ph., Ph rm.D.
CAPT, Unit d St t s Public H lth S rvic v
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

Paul 7
Levi e 7

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