ND 220327 A

ANDA TENTATIVE APPROVAL A

ppco Pharma LLC
ttention: Peddanna Gumudavelli
Chief Operating Officer

Dear Peddanna Gumudavelli:

This letter is in reference to your abbreviated new drug application (ND) received for review on March 26, 2025, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for Sodium Sulfate, Magnesium Sulfate, and Potassium Chloride Tablets, 1.479 g/0.225 g/0.188 g.

Reference is also made to any amendments submitted prior to the issuance of this letter.

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 Sodium Sulfate, Magnesium Sulfate, and Potassium Chloride Tablets, 1.479 g/0.225 g/0.188 g to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Sutab Tablets, 1.479 g/0.225 g/0.188 g, of zurity Pharmaceuticals, Inc. (zurity; ND – 213135).

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 reference listed drug (RLD) upon which you have based your ND , zurity's Sutab Tablets, 1.479 g/0.225 g/0.188 g, 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 A Book"):

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U.S. t nt Numb r v	Expir tion D t v
10,143,656 (th '656 p t nt)	Au ust 4, 2037
11,033,498 (th '498 p t nt)	Au ust 4, 2037
11,382,864 (th '864 p t nt)	Au ust 4, 2037
11,638,697 (th '697 p t nt)	Au ust 4, 2037

Your ANDA cont ins p r r ph IV c rtific tions to ch of th 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 Sodium Sulf t , M a n sium Sulf t , nd ot ssium Chlorid T bl ts, 1.479 /0.225 /0.188 , und r this ANDA. You h v notifi d th A ncy th t Appco h rm a LLC (Appco) 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 Appco for infrin m ent of th '656, '498, '864 nd '697 p t nts in th Unit d St t s District Court for th District of N w J rs y [B i tr L bor tor , Inc. nd S b l US Inc., v. Appco rm a LLC., nd Som ers t T r p utic LLC, Civil Action No. 25-10876]. 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. rior to th submission of your ANDA, noth r pplic nt or pplic nts submitt d subst nti lly compl t ANDA providin for Sodium Sulf t , M a n sium Sulf t , nd ot ssium Chlorid T bl ts, 1.479 /0.225 /0.188 , 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.

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 314.107, 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.

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 C ss ndr M etu, R ul tory roj ct M an r, t (2 0) 02 - 68 7.

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

Paul c
Levi e c

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