ND 216068 A

ANDA APPROVAL

Sandoz Inc.
ttention: Gregory Seitz
Head U.S. Regulatory ffairs Generics

Dear Gregory Seitz:

This letter is in reference to your abbreviated new drug application (ND) received for review on March 31, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for Enzalutamide Tablets, 40 mg and 80 mg.

Reference is also made to the tentative approval letter issued by this office on ugust 2, 2022.

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. ccordingly the ND is **approved**, effective on the date of this letter. We have determined your Enzalutamide Tablets, 40 mg and 80 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Xtandi Tablets, 40 mg and 80 mg, of stellas Pharma US, Inc. (stellas) ND - 213674.

The RLD upon which you have based your ANDA, Astellas's Xtandi Tablets, 40 mg and 80 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
7,709,517 (the '517 patent)	ugust 13, 2027
8,183,274 (the '274 patent)	ugust 24, 2026
9,126,941 (the '941 patent)	May 15, 2026 A
11,839,689 (the '689 patent)	September 11, 2033
12,161,628 (the '628 patent)	February 23, 2037
12,447,128 (the '128 patent)	September 11, 2033* A

12,502,357 (th '357 p t nt) S pt mb r 11, 2033

* only list d on th 0 m g str n th

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 Enz lut mid T bl ts, 40 m g nd 0 m g, und r this ANDA. You h v notifi d th A ncy th t S ndoz Inc. (S ndoz) 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 S ndoz for infrin m nt of th '517 nd '274 p t nts in th Unit d St t s District Court for th District of N w J rs y [Ast ll s h rm a Inc.; Ast ll s US LLC; Ast ll s h rm a US, Inc.; M ediv tion LLC; M ediv tion rost t Th r p utics LLC; Th R nts of Th Univ rsity of C liforni v. S ndoz Inc., Civil Action No. 21-13177]. You h v lso notifi d th A ncy th t this c s w s dismiss d.

With r sp ct to 1 0-d y n ric dru xclusivity, w not th t S ndoz w s th first ANDA pplic nt to submit subst nti lly compl t ANDA with p r r ph IV c rtific tion for Enz lut mid T bl ts, 40 m g nd 0 m g. Th r for , with this pprov l, S ndoz is li ibl for 1 0 d ys of n ric dru xclusivity for Enz lut mid T bl ts, 40 m g nd 0 m g. FDA not s th t ft r issu nc of this pprov l l tt r, li ibility for 1 0-d y xclusivity is subj ct to futur v nts th t m ay r sult in forf itur of xclusivity und r s ction 505(j)(5)(D) of th FD&C Act. This xclusivity, which is provid d for und r s ction 505(j)(5)(B)(iv) of th FD&C Act, b ins to run from th d t of th comm rci l m ark tin id ntifi d in s ction 505(j)(5)(B)(iv). l s submit corr spond nc to this ANDA notifyin th A ncy within 30 d ys of th d t of th first comm rci l m ark tin of this dru product or th RLD. If you do not notify th A ncy within 30 d ys, th d t of first commercial marketing will be deemed to be the date of the drug product's pprov l. S 21 CFR 314.107(c)(2).

Th RLD upon which you h v b s d your ANDA, Astellas's Xtandi Tablets, 40 mg and 0 m g, is lso subj ct to p riods of xclusivity. As not d in th Or n Book, th I-926 xclusivity is sch dul d to xpir on Nov mb r 17, 2026. You h v provid d copy of l tt r from Ast ll s th t w iv s this un xpir d xclusivity p riod ssoci t d with th RLD.

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.

COMPENDIAL STANDARDS

A dru with n m e r co niz d in th offici l Unit d St t s h rm acop i or offici l N tion l Formul ry (US -NF) n r lly must comply with th comp ndi l st nd rd for str n th, qu lity, nd purity, unl ss th diff r nc in str n th, qu lity, or purity is pl inly st t d on its l b l (s FD&C Act § 501(b), 21 USC 351(b)). FDA typic lly c nnot sh r l

pplic tion-sp cific inform ation cont in d in submitt d r ul tory filin s with third p rti s, which includ s US -NF. To h lp nsur th t dru continu s to comply with comp ndi l st nd rds, pplic tion hold rs m ay work dir ctly with US -NF to r vis offici l US mono r phs. Mor inform ation on th US -NF is available on USP's w bsit t https://www.uspnf.com/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Und r pplic bl st tut s, r ul tions, nd uid nc s, your ANDA 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 ark tin r portin , promotion l m t 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 end 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.

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

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