ND 219602 A

ANDA APPROVAL

Glenmark Pharmaceuticals Inc., US
U.S. gent for Glenmark Specialty S
ttention: Thomas Callaghan
Executive Director - Regulatory ffairs

Dear Thomas Callaghan:

This letter is in reference to your abbreviated new drug application (ND) received for review on May 24, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for Fluticasone Propionate Inhalation erosol USP, 44 mcg per actuation.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the complete response letter issued by this office on May 27, 2025, 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. ccordingly the ND is **approved**, effective on the date of this letter. We have determined your Fluticasone Propionate Inhalation erosol USP, 44 mcg per actuation to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Flovent HF Inhalation erosol, 44 mcg, of GlaxoSmithKline Intellectual Property Ltd. England ND - 021433.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated July 22, 2024.

We note that Glenmark Specialty S (Glenmark) was granted a Competitive Generic Therapy (CGT) designation for Fluticasone Propionate Inhalation erosol USP, 44 mcg per actuation. Glenmark is the "first approved applicant" for Fluticasone Propionate Inhalation erosol USP, 44 mcg per actuation, as defined in section 505(j)(5)(B)(v)(III) of the FD&C ct. Therefore, with this approval, Glenmark is eligible for 180 days of CGT exclusivity for Fluticasone Propionate Inhalation erosol USP, 44 mcg per actuation, under section 505(j)(5)(B)(v) of the FD&C ct. This exclusivity begins to run from the date of the first commercial marketing of the CGT (including the commercial marketing of the listed drug) by Glenmark, as specified in section 505(j)(5)(B)(v) of the FD&C ct. Furthermore, in accordance with section 505(j)(5)(B)(v)(I) of the FD&C ct, this 180-day A

CGT xclusivity will not block pprov l of oth r pplic tions until Gl nm ark h s comm nc d dcomm rcil l m ark tin . l s submit corr spond nc to this ANDA informin th A ncy of th d t you b in comm rci l m ark tin . l s lso submit notic of first comm rci l m ark tin vi -m ail to th t nt nd Exclusivity T m t CDER-OGD ET@fd .hhs. ov. This -m ail should b s nt th s m e d y you comm nc comm rci l m ark tin . R f r nc is lso m ad to th Sp ci l Forf itur Rul for Comp titiv G en ric Th r py in s ction 5 5(j)(5)(D)(iv) of th FD&C Act. l s b w r th t, pursu nt to this forf itur rul , you will forf it your li ibility for th 18 -d y CGT xclusivity p riod for Flutic son ropion t Inh l tion A rosol US , 44 mc p r ctu tion, if you f il to m ark t this CGT within 75 d ys ft r th d t on which th pprov l of this pplic tion is m ad ff ctiv .

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 5 5-1(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 § 5 1(b), 21 USC 351(b)). FDA typic lly c nnot sh r 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 s https://www.uspnf.com/.

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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

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