ND 219409 A

ANDA APPROVAL

Cipla US , Inc.
U.S. gent for Cipla Limited
ttention: Michele Crawley
Director, Regulatory ffairs

Dear Michele Crawley:

This letter is in reference to your abbreviated new drug application (ND) received for review on December 2, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic ct (FD&C ct) for lbuterol Sulfate Inhalation erosol, 90 mcg (base) 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 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. ccordingly the ND is **approved**, effective on the date of this letter. We have determined your lbuterol Sulfate Inhalation erosol, 90 mcg (base) per actuation to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Ventolin HF Inhalation erosol, 90 mcg (base) per actuation, of GlaxoSmithKline Intellectual Property Management Ltd. England, ND - 020983.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated March 18, 2024.

We note that Cipla Limited (Cipla) was granted a Competitive Generic Therapy (CGT) designation for lbuterol Sulfate Inhalation erosol, 90 mcg (base) per actuation. Cipla is the "first approved applicant" for Albuterol Sulfate Inhalation Aerosol, 90 mcg (base) per actuation, as defined in section 505(j)(5)(B)(v)(III) of the FD&C ct. Therefore, with this approval, Cipla is eligible for 180 days of CGT exclusivity for lbuterol Sulfate Inhalation erosol, 90 mcg (base) 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 A of the CGT (including the commercial marketing of the listed drug) by Cipla, 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 CGT exclusivity will not block approval of other applications until Cipla has commenced commercial marketing. Please submit a A

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 Albut rol Sulf t Inh l tion A rosol, 9 mc (b s) 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 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, l 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