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ND A220143 A

ANDA TENTATIVE APPROVAL A

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Hetero US A Inc. A

U.S. Agent for Hetero Labs Limited Unit V A

Attention: Dr. Soma Raju Indukuri A

A Vice President, Regulatory Affairs A

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Dear Dr. Soma Raju Indukuri: A

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This letter is in reference to your abbreviated new drug application (ND A) received for A
review on December 18, 2024, submitted pursuant to section 505(j) of the Federal A
Food, Drug, and Cosmetic Act (FD&C Act) for Relugolix Tablets, 120 mg. A

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

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We have completed the review of this ND A and have concluded that adequate A
information has been presented to demonstrate that the drug meets the requirements A
for approval under the FD&C Act. We have determined your Relugolix Tablets, 120 mg, A
to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), A
Orgovyx Tablets, 120 mg, of Sumitomo Pharma America, Inc. (Sumitomo) A A
ND A- 214621. A

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However, we are unable to grant final approval to your ND A at this time because of A
the patent issue noted below. Therefore, the ND A is **tentatively approved**. This A
determination is based upon information available to the Agency at this time (e.g., A
information in your ND A and the status of current good manufacturing practices A
(cGMPs) of the facilities used in the manufacturing and testing of the drug product). This A
determination is subject to change on the basis of new information that may come to our A
attention. This letter does not address issues related to the 180-day exclusivity A
provisions under section 505(j)(5)(B)(iv) of the FD&C Act. A

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The reference listed drug (RLD) upon which you have based your ND A Sumitomo's A
Orgovyx Tablets, 120 mg, is subject to periods of patent protection. The following A
patents and expiration dates are currently listed in the Agency's publication titled A
Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange A
Book"): A

A	A	A	A
A	<u>U.S. Patent Number</u>	A	<u>Expiration Date</u>
A	A	A	A
	7,300,935 (the '935 patent)	A	January 28, 2029

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10, 50,170 (th I'170 p I nt) I F lbru ly 25, 20 16 I
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10,449,191 (th I'191 p I nt) I S lpt mb lr 29, 20 17 I
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10,786,501 (th I'501 p I nt) I S lpt mb lr 29, 20 17 I
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11,58 1,526 (th I'526 p I nt) I S lpt mb lr 29, 20 17 I
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11,795,178 (th I'178 p I nt) I S lpt mb lr 27, 20 1 I
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12,097,198 (th I'198 p I nt) I S lpt mb lr 29, 20 17 I
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12,144,809 (th I'809 p I nt) I S lpt mb lr 29, 20 17 I
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12, 25,714 (th I'714 p I nt) I S lpt mb lr 27, 20 1 I
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12, 16,990 (th I'990 p I nt) I S lpt mb lr 29, 20 17 I

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With r sp ct to th '9 5 p t nt, your ANDA cont ins p r Ir ph III c rtific tion to th I
p t nts und r s ction 505(j)(2)(A)(vii)(III) of th FD&C Act st tin th t H lt ro L bs I
Limit d Unit V (H t ro) will not mark t R lu olix T bl ts, 120 mg prior to th xpir tion I
of th p t nts. Th r for , fin l pprov l of your ANDA may not b r nt d pursu nt to I
s ction 505(j)(5)(B)(ii) of th FD&C Act until th '9 5 p t nt h s xpir d, curr ntly I
J nu ry 28, 2029. I

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Your ANDA cont ins p r Ir ph IV c rtific tions to th '170, '191, '501, '526, '178, '198, I
'809, '714 nd '990 p t nts und r s ction 505(j)(2)(A)(vii)(IV) of th FD&C Act st tin I
th t th p t nts r inv lid, un nforc I bl , or will not b infrin I d by your manuf ctur , I
us I or s l of R lu olix T bl ts, 120 mg, und r this ANDA. You h v notifi d th I
A lncy th t H lt ro compli d with th r quir ments of s ction 505(j)(2)(B) of th FD&C I
Act. Liti tion w ls initi t d within th Ist tutory 45-d ly p riod I inst H lt ro for I
infrin I ment of th I'178, '198 nd '809 p I nts in th I Unit d St t s District Court for th I I
District of D ll w lr [Sumitomo h rma Switz rl nd GMBH, Sumitomo h rma II
Ameri c , Inc., T k d h rma l utic l Comp ny Limit d, T k d h rma l utic ls I
Int rn tion l AG, nd fiz r Inc. v. H lt ro L bs Limit d, H lt ro L bs Limit d Unit-V, I
H lt ro USA, Inc., nd C lmb r h rma l utic ls, Inc., Civil Action No. 25-00 44]. I

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Th r for , fin l pprov l c nnot b r nt d until: I

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1. I. th xpir tion of th 7.5-y l r p riod provid d for in s ctions 505(j)(5)(B)(iii) I
nd 505(j)(5)(F)(ii) of th FD&C Act, I
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I b. th d t th court d cid s' th t th '178, '198 nd '809 p t nts r inv lid or I
not infrin I d (s l s ctions 505(j)(5)(B)(iii)(I), (II), nd (III) of th FD&C Act), I
or I

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1c. the '178, '198, '9 5 and '809 patents have expired, and 1

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2. The Agency is assured that there is no new information that it would affect whether it should be granted. 1

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It is not that if FDA requires Risk Evaluation and Mitigation Strategy (REMS) for listed drug, an ANDA for the same listed drug also will be required to have REMS. Section 505-1(i) of the FD&C Act. 1

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REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL 1

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Under applicable statutes, regulations, and guidelines, if your ANDA receives final approval, it may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing promotion materials, and notification of changes. For information on post-approval requirements and recommendations for ANDAs and list of resources for ANDA holders, visit you to: <https://www.fda.gov/drugs/bbr/visit-and-drug-application-and-requirements-and-resources-post-approval>. 1

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RESUBMISSION 1

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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 be eligible for final approval. A request for final approval that contains new data, information, or other changes to the ANDA in the 12-month period of 12 months for Agency review. Accordingly, such a request for final approval should be submitted no later than 12 months prior to the date on which you seek approval. A request for final approval that contains substantive changes to this ANDA or changes in the status of the manufacturer and testing facilities' compliance with cGMPs will be classified and reviewed according to OGD policy in effect at the time of receipt. Applications should review applicable Agency guidance for industry related to amendments under the Inactive Drug Substances Program to determine the duration of Agency review and lead to review with changes submitted. As part of this consideration, applicants should monitor any changes to the RLD that occur after final approval, including changes in labeling, patent or exclusivity information, or marketing status. The submission of multiple amendments prior to final approval may also result in delay in the issuance of the final approval letter. 1

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The amendment requesting final approval should provide the following regulatory basis for your request for final approval and should include a copy of the court decision, settlement or licensing agreement, or other information described in 21 CFR 14.107, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was previously approved, e.g., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be 1

submitted even if none of the channels were made, and it should be designated clearly in your cover letter as a "FINAL APPROVAL REQUESTED." 1

In addition to the amendments requested above, the Agency may request, at any time prior to the date of final approval, that you submit in addition to amendments containing information specified by the Agency. Failure to submit either or, if requested, both types of amendments described above may result in delay in the issuance of the final approval letter. 1

This drug product may not be marketed without final Agency approval under section 505(j) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the FD&C Act. Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505(j) of the FD&C Act, and will not be listed in the Orange Book. 1

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Honorable L. R. Mulroney, Regulatory Project Manager, at (240) 402-4600. 1

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Sincerely yours, 1

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{See appended electronic signature} 1

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For K. Linda S. Stewart, R. h., Pharm.D. 1
CAIT, United States Public Health Service 1
Director 1
Office of Regulatory Operations 1
Office of Generic Drugs 1
Center for Drug Evaluation and Research 1

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¹ This decision may be with a decision of the district court or the court of appeals, which ever court is the first to decide that the patent is invalid or not infringed. 1



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