



ND 217060 A

ANDA TENTATIVE APPROVAL

Lantheus Medical Imaging, Inc.
Attention: Lynn Mendonca
Senior Director, Regulatory Affairs

Dear Lynn Mendonca:

This letter is in reference to your abbreviated new drug application (ND) received for review on November 13, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Lutetium Lu 177 Dotatate Injection, 10 mCi/mL Single-Dose Vial.

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 Act. We have determined your Lutetium Lu 177 Dotatate Injection, 10 mCi/mL Single-Dose Vial to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Lutathera Injection, 10 mCi/mL Single-Dose Vial, of Advanced Accelerator Applications US, Inc. (Advanced Accelerator) ND - 208700.

However, we are unable to grant final approval to your ND at this time because of the patent issue noted below. Therefore, the ND is tentatively approved. This determination is based upon information available to the Agency 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. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the FD&C Act.

The RLD upon which you have based your ND, Advanced Accelerator's Lutathera Injection, 10 mCi/mL Single-Dose Vial, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) are currently listed in the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

Table with 2 columns: U.S. Patent Number, Expiration Date. Row 1: 10,596,276 (the '276 patent), January 25, 2039 A

10,59 ,278 (th '278 p t nt) J nu ry 25, 2039
 11,904,027 (th '027 p t nt) J nu ry 25, 2039
 12,144,873 (th '873 p t nt) J nu ry 25, 2039 I
 12,151,003 (th '1,003 p t nt) J nu ry 25, 2039
 12,1 1,732 (th '732 p t nt) J nu ry 25, 2039
 12,1 8,0 3 (th '0 3 p t nt) J nu ry 25, 2039
 12,415,003 (th '5,003 p t nt) J nu ry 25, 2039
 12,491,272 (th '272 p t nt) J nu ry 25, 2039

Your ANDA contains paragraph IV certifications to each of the products under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the products are invlid, un nforced bl , or will not be infrin d by your manufacturer, us , or s l of Lut tium Lu 177 Dot t t Inj ction, 10 mCi/mL Sin l -Dos Vi l, und r this ANDA. You h v notifi d th A ncy th t L nth us Medic l lma in , Inc. (L nth us) compli d with th r quir ments 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 L nth us for infrin ment of th '27 p t nt in th Unit d St t s District Court for th District of D l w r [Adv nc d Acc l r tor Applic tions USA, Inc. nd Adv nc d Acc l r tor Applic tions SA. v. L nth us Medic l lma in , Inc., L nth us Holdin s, Inc., oint Bioph rm USA Inc., nd oint Bioph rm Glob l Inc., Civil Action No. 24-00095].

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

1. . th xpir tion of th 30-month p riod provid d for in s ction 505(j)(5)(B)(iii) of th FD&C Act,
 - b. th d t th court d cid s¹ th t th '27 p t nt is inv lid or not infrin d I (s s ctions 505(j)(5)(B)(iii)(I), (II), nd (III) of th FD&C Act), or
 - c. th '27 p t nt h s xpir d, nd
2. Th A ncy is ssur d th r is no n w information th t would ff ct wh th r I fin l pprov l should b r nt d.

I 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. I

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

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 reporting, promotional materials, and notification of changes, among others. For information on post-approval requirements and recommendations for ANDAs and list of resources for ANDA holders, we refer you to <https://www.fda.gov/drugs/bbr/vit-d-n-w-drug-application-and-requirements-and-resources-post-approval>.

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 be eligible for final approval. A request for final approval that contains non-waivable information, or other changes to the ANDA normally requires a period of 3 months for Agency review. Accordingly, such a request for final approval should be submitted no later than 3 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 manufacturing and testing facilities’ compliance with cGMPs will be classified and reviewed according to OGD policy in effect at the time of receipt. Applicants should review applicable Agency guidance for industry related to amendments under the generic drug user fee program to determine the duration of Agency review needed to review changes submitted. As part of this consideration, applicants should monitor changes to the RLD that occur throughout 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.

The amendment requesting final approval should provide the regulatory basis for your request for final approval and should include copy of court decision, settlement or licensing agreement, or other information described in 21 CFR 314.107, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was originally approved, e.g., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of the changes were made, and it should be identified clearly in your cover letter as a “FINAL APPROVAL REQUESTED.”

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

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.

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For further information on the status of this ANDA or upon submitting a comment to the ANDA, please contact Kim Brown, Regulatory Project Manager, at (301) 794-4292.

Sincerely yours,

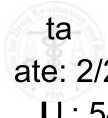
{See appended electronic signature page}

For Kندر S. Stewart, R.Ph., Pharm.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

¹ This decision may be in conflict with the 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.



Sarah G
Kurtz G



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