



NDA 218475/S-001

TENTATIVE APPROVAL

Baxter Healthcare Corp
Attention: Ravi Bhalodia
Senior Manager, Regulatory Affairs
One Baxter Parkway
Deerfield, IL 60015

Dear Ravi Bhalodia:

Please refer to your Supplemental New Drug Application (sNDA) dated May 29, 2025, received May 29, 2025, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Epinephrine Injection.

This supplemental new drug application provides for [REDACTED] (b) (4)

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the submitted labeling (text for the prescribing information submitted May 29, 2025, carton and immediate container labels submitted May 29, 2025). This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

Final approval of your application is subject to expiration of the 30-month period provided for in section 505(c)(3)(C) of the FD&C Act. Therefore, final approval of your application may not be granted at this time.

Section 505(c)(3)(C) of the FD&C Act provides, in relevant part, that there generally will be a 30-month stay of approval of a 505(b)(2) application if patent infringement litigation was initiated within the 45-day period after receipt of notice of a paragraph IV certification for a patent for which information was submitted to the Secretary before the date on which the application (excluding an amendment or supplement to the application) was submitted.

Your 505(b)(2) application contained a certification(s) to one or more patents under section 505(b)(2)(A)(iv) of the FD&C Act stating that the patent(s) is/are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application ("paragraph IV certification"). You notified us that you complied with the notice requirements of section 505(b)(3) of the FD&C Act. In addition,

you have notified the Agency that the patent owner and/or NDA holder has initiated a patent infringement suit against you with respect to U.S. Patent No. 11,207,280 (the '280 patent), U.S. Patent No. 12,133,837 (the '837 patent), U.S. Patent No. 10,653,646 (the '646 patent), and U.S. Patent No. 11,083,698 (the '698 patent) in the United States District Court for the District of Delaware (1:25-cv-00861). Such patent infringement action was initiated on July 10, 2025, prior to the expiration of the 45-day period provided for in section 505(c)(3)(C). Accordingly, based on the timely initiated patent infringement action following the patent owner and/or NDA holder's receipt of your notice of paragraph IV certifications to the '280 patent, the '646 patent, and the '698 patent, your application is subject to a 30-month stay of approval and final approval cannot be granted until:

(1)

- expiration of the 30-month period provided for in section 505(c)(3)(C) beginning on the later of the date of receipt by any owner of the listed patent or application holder of the notice required under section 505(b)(3), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or
- the date of a court action or other circumstance described in section 505(c)(3)(C) of the FD&C Act or 21 CFR 314.107(b)(3) that terminates the 30-month stay, or
- the listed patent(s) has/have expired, and

(2) we are assured there is no new information that would affect whether final approval should be granted.

On September 16, 2025, you submitted an amendment withdrawing your paragraph IV certifications to the '280 patent, the '646 patent, the '698 patent, and the '837 patent. Even though your application no longer contains a paragraph IV certification, the statute and FDA's regulations do not provide that withdrawal of a paragraph IV certification terminates a 30-month stay and the 30-month stay on approval of your application remains in effect. We are also not aware of a specified court decision or other circumstance under 505(c)(3)(C) and 21 C.F.R. 314.107(b)(3) that terminated the 30-month stay.

To obtain final approval of this application, submit an amendment two or six months prior to the date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as "REQUEST FOR FINAL APPROVAL". This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If

there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this supplemental NDA is not approved. If you believe that there are grounds for issuing the final approval letter before the expiration of the patent(s) and/or exclusivity protection, you should amend your application accordingly.

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If you have any questions, contact Rajani Ranga, Regulatory Business Process Manager, at Rajani.Ranga@fda.hhs.gov or 2404025041.

Sincerely,

{See appended electronic signature page}

Julia Pinto, Ph.D.
Supervisor, Division of Product Quality Assessment VIII
Office of Product Quality Assessment II
Office of Pharmaceutical Quality

ENCLOSURE(S):

Content of Labeling

Carton and Container Labeling



Julia
Pinto

Digitally signed by Julia Pinto

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