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RESEARCH**

APPLICATION NUMBER:

217569Orig1s000

CLINICAL REVIEW(S)

NDA: 217569, 505(b)(2)

Drug: Vasopressin in 0.9% Sodium Chloride injection, 20 units/100 mL and 40 units/100 mL

Applicant: Baxter Healthcare Corporation

Indication: To increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines.

Letter date: 11/30/2022

Receipt date: 11/30/2022

60-day Filing date: 1/29/2023

Day 74 Letter due: 2/12/2023

Medical Reviewer: Maryann Gordon, MD

Conclusion

I have reviewed 20 articles, including clinical trial and review articles, one Baxter Pharmaceutical Plan for Vasopressin Premix and one Rowe 2006 Handbook of Pharmaceutical Excipients. In conclusion, I have found no obvious new evidence of a safety issue that is not addressed in the label.

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/s/

MARYANN GORDON
02/02/2023 08:43:48 AM

FORTUNATO F SENATORE
02/02/2023 09:44:05 AM