ATTACHMENT A

JON CLARK DECLARATION

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAXTER HEALTHCARE CORPORATION, Plaintiff, v. HOSPIRA, INC. and ORION CORP., Defendants.	Civil Action No. 18-303-RGA

DECLARATION OF JON CLARK, M.S.

I, Jon Clark, M.S., declare as follows:

I. INTRODUCTION

1. My name is Jon Clark, M.S., and I am an independent consultant with special expertise in Food and Drug Administration ("FDA") regulatory matters.

2. Plaintiff Baxter Healthcare Corporation has retained me in connection with the above-captioned litigation. Specifically, I have been asked to generally explain the processes for submitting and obtaining approval of a New Drug Application ("NDA") and Abbreviated New Drug Application ("ANDA"), and the corresponding labeling requirements. Additionally, I have been asked to detail the proceedings regarding carve-outs in generic labeling for dexmedetomidine hydrochloride injection.

3. I am being paid for my work in this litigation at the rate of $500.00 per hour, plus reimbursement of reasonable direct expenses. My compensation is not dependent on the outcome of this litigation, and it is not based on the result of any issue in this litigation. I have no personal interest in this litigation.

II. BACKGROUND AND QUALIFICATIONS

4. I received a Bachelor of Science degree in chemistry from the University of Michigan in 1980. I subsequently received my Master of Science degree in chemistry from Rutgers University in 1987. Upon completion of my Bachelor's degree, I worked as a chemist and, later, a senior chemist at Beecham Laboratories and Schering-Plough Research Institute, both simultaneous with my master's degree work. At Beecham and Schering-Plough, I specifically focused on drug manufacturing processes and synthesis.

5. I have more than thirty-five years of experience in the pharmaceutical industry, with a specific focus on drug development, research and development processes, and chemistry manufacturing and controls ("CMC") review. For more than twenty years, I worked at FDA, including as Associate Director of Program Policy with the Office of Pharmaceutical Science, where I led the development and implementation of CMC policy for the Center for Drug Evaluation and Research. I also served as a Review Chemist and Electronic Submission Expert.

6. As part of my more than twenty years of experience at FDA, I reviewed more than 200 market applications (including NDAs and ANDAs), over 500 supplements, and over 700 drug master files ("DMFs"). During my tenure at FDA, I also held several leadership roles with respect to stability guidelines for both ANDAs and NDAs.

7. My expertise in labeling requirements and carve-outs was developed as part of my role as Associate Director of Program Policy and GMP at FDA. A complete understanding of the policies and practices of each program area subordinate to the Office of Pharmaceutical Science was required to perform my role, and the Office of Generic Drugs ("OGD") is one of those subordinate program areas. These requirements were practiced on a routine basis at OGD with

periodic consultation at the Office of Pharmaceutical Science level. These consultations were generally done with my participation.

8. Since leaving FDA in 2013, I have served as Vice President of Chemical Medicines and Industry Standards Collaboration at U.S. Pharmacopeia. U.S. Pharmacopeia ("USP") is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide. I also currently serve as a consultant for NDA Partners, LLC, a global strategy firm specializing in product development and regulatory advice.

III. NEW DRUG APPLICATION

9. A person who wants to market a new drug must first submit, and obtain approval of, an application under the Federal Food, Drug, and Cosmetic Act (the "Act"). An application for a novel product is a New Drug Application ("NDA"). An NDA is submitted under section 505(b) of the Act.

10. An NDA contains, among other components, extensive scientific data and information regarding the safety and effectiveness of the drug for the conditions of use set forth in the label for which approval is sought.

11. One of the required components of an NDA is a list of patents covering the drug product and the active drug substance of the product. In addition, any patent claiming a method of use for the drug product described in the NDA is also required to be listed.

12. FDA is required to publish patent information submitted for approved NDAs. FDA does this in a publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). For the last several years, the Orange Book is a searchable database accessible on the internet.

13. After approval of an NDA, when listing a patent claiming a method of use, the NDA holder must include a description of that method of use, as required for publication. *See* 21 C.F.R. § 314.53(c)(2)(O). This description appears in the Orange Book electronic database as a link from the listing for the relevant patent. This description is commonly referred to as a "use code."

IV. ABBREVIATED NEW DRUG APPLICATION

14. A drug product approved under section 505 of the Act is known as a *listed drug*. *See* 21 C.F.R. § 314.3(b). The Act permits submission of an abbreviated new drug application ("ANDA") for approval of a generic versions of a listed drug. Unlike an NDA, which is submitted under section 505(b) of the Act, an ANDA is submitted under section 505(j) of the Act.

15. In its ANDA, an applicant must clearly identify the listed drug on which it relies for approval. This is referred to as the reference listed drug ("RLD") for that ANDA. *See* 21 C.F.R. § 314.3(b).

16. When compared to the NDA process, the ANDA process reduces the time and resources needed for approval. The principal means by which the ANDA process does this is that the ANDA applicant relies on the FDA's previous finding of safety and effectiveness for the RLD rather than requiring that the ANDA applicant independently demonstrate the safety and effectiveness of its proposed drug.

17. To successfully rely on the FDA's earlier finding of safety and effectiveness of the RLD, an ANDA must show that the proposed generic product is the same as the RLD in many fundamental respects. These include active ingredient, dosage form, strength, and route of administration. The ANDA applicant must also provide information showing that its

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