



NDA 020193/S-015

## **SUPPLEMENT APPROVAL**

Janssen Pharmaceuticals, Inc  
Attention: Jenna Giacchi, M.S.  
Associate Director, Global Regulatory Affairs  
Janssen Research & Development, LLC  
920 Highway 202  
P.O. Box 300  
Raritan, NJ 08869

Dear Ms. Giacchi:

Please refer to your supplemental new drug application (sNDA) dated and received August 21, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Elmiron (pentosan polysulfate sodium) capsules.

This Prior Approval supplemental new drug application provides for conversion of the patient labeling to a Medication Guide and associated revisions to the Prescribing Information and carton and container labeling.

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effectuated" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

### **CARTON AND CONTAINER LABELING**

We acknowledge your February 17, 2021, submission containing draft printed carton and container labeling.

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Sydney Tran, Regulatory Project Manager, at 301-796-1587.

Sincerely,

*{See appended electronic signature page}*

Catherine Sewell, M.D., M.P.H.  
Deputy Director for Safety  
Division of Urology, Obstetrics, and  
Gynecology  
Office of Rare Diseases, Pediatrics, Urologic,  
and Reproductive Medicine  
Center for Drug Evaluation and Research

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<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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CATHERINE A SEWELL  
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