

Reference: FDA-2020-P-0963


Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFV-305
Rockville, MD 20852

SUITABILITY PETITION AMENDMENT

Aurora Pharmaceutical, Inc. would like to amend the Suitability Petition for the proposed generic Deracoxib Solution 1.80% w/v (docket ID FDA-2020-P-0963) providing the following statements:

1. Aurora Pharmaceutical, Inc. will supply the proposed generic product in container size(s) appropriate to the labeled indications and dosing directions. The specific container size(s) will be agreed upon with CVM during the approval process.
2. Aurora Pharmaceutical, Inc. will include detailed dosing and administration directions in the labeling of the proposed generic product to ensure accurate dosing and prevent dosing errors. The specific language used in labeling will be agreed upon with CVM during the approval process.
3. Aurora Pharmaceutical, Inc. will include comprehensive user safety language on the labeling to ensure appropriate information regarding safety to humans that are handling, administering, and exposed to the proposed generic product. The specific language used in labeling will be agreed upon with CVM during the approval process.

Sincerely,

 03/27/2020 10:10:35 am SigPlot

Alina Garbar, PhD
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Date