



July 25, 2022

Deborah Droza
Chem IQ FZCO
Unit No HD-03, 25th Floor
Sheikh Rashid Tower
Dubai World Trade Centre
Dubai
United Arab Emirates

Sent via email to: asg.dxb@chemiqglobal.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug respectfully take the following actions considering the risks presented by a high amount of organic impurities in Indomethacin Suppositories:

- (1) Ensure that the currently marketed RS for Indomethacin Suppositories, 50 mg, approved under ANDA 073314 complies with ICH guidelines and established impurity acceptance criteria: and
- (2) FDA should refrain from approving any ANDAs which justifies higher impurities levels citing results of current marketed RS Indomethacin suppositories (ANDA 073314) rather than complying with ICH guidelines, FDA regulations and established acceptance criteria with respect to impurities.

This petition was received and processed under CFR 10.30 by this office on 07/25/2022.

It was assigned docket number FDA-2022-P-1667. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)