

Cover letter

January 1, 2021

Editorial Department of Indian Journal of Medical Ethics

Dear Editor of IJME,

We wish to submit a new manuscript for consideration of publication in Indian Journal of Medical Ethics. The manuscript is entitled “Expedited Drug Review Processes for Approval in US and EU with Consequences and Case Reports”. All authors have participated in the work sufficiently to meet the ICMJE guidelines for authorship. All have read and approved the manuscript.

The submission is not under consideration for publication in any other journal.

Regulatory authorities and pharmaceutical companies are pursuing a strategy that facilitate and expedite the development and approval of new drug products to treat serious or life-threatening diseases and address an unmet medical need. It was found that some of the products which are approved through the expedited process have gone unpredicted and withdrawn from the market because of inadequate review time and lack of long-term safety studies. In this article, it is presented with different expedited approval processes, examples, timeline, and case report that support the consequences that occurred through these speedy approval processes.

We have read the terms and conditions of authorship of IJME and accept them.

Thank you very much for your consideration.

Please address all correspondence concerning this manuscript to me at balakrishnachilukuri@gmail.com

Yours Sincerely,

Ch. S S N D Balakrishna*

Shri Vishnu College of Pharmacy

Affiliated to Andhra University

Vishnupur, Bhimavaram -534202

Andhra Pradesh, India.

Phone: +91 9493069348

E-mail: balakrishnachilukuri@gmail.com

Sai Pavan Dwarapudi
Department of Regulatory Affairs,
Shri Vishnu College of Pharmacy
Affiliated to Andhra University
Phone: +91 9110766466
E-mail: dwarapudisaipavan@gmail.com

Dr. Ravi Kumar Reddy Juturi,
Department of Regulatory Affairs (HOD)
Shri Vishnu College of Pharmacy
Affiliated to Andhra University
Phone: +91 7702229333
E-mail: ravikumarreddy.j@svcp.edu.in

Dr. Venkateswara Raju k
Department of Regulatory Affairs (Assistant Professor)
Shri Vishnu College of Pharmacy
Affiliated to Andhra University
Phone: +91 7702718782
E-mail: venkateswararaju.k@svcp.edu.in