

8/28/07

Lohiya's Petition Docket # 2006P-0307/CP1

Ms Jane A. Axelrad,  
Associate Director for Policy, CDER, FDA  
Rockville MD 20857

Phone 301 827 6857, 60/ Fax 13018276870

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Honorable Ms Axelrad,

1. Thanks for your 1/25/07 letter and for continued consideration of our petition. FDA mandates Expiration Dates on drugs for consumer safety reasons. What good are those date inscriptions if they can not be read!
2. Federalism issues (approval from all 50 states) do not apply to this petition because FDA currently has minimum legibility requirements in other areas; for example:
  - a. Minimum font size 8 for prescription drug labels (Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products. Final Rule. 21CFR,201,314,601. Food and Drug Administration.  
[www.fda.gov/ohrms/dockets/98fr/06-545.pdf](http://www.fda.gov/ohrms/dockets/98fr/06-545.pdf). Accessed January 31, 2007).
  - b. For Pharmaceutical Marketing Applications, FDA recommends 'Times New Roman 12 point' (Common Technical Document. Submitting Marketing Applications.  
[www.fda.gov/cder/guidance/4707dft.pdf](http://www.fda.gov/cder/guidance/4707dft.pdf). Accessed January 31, 2007).
3. No such font-size criteria exist for Expiration Dates on drug containers - occasionally we overlook the obvious!
4. Our research and petition underscore a critical need to improve Expiration Date legibility via regulatory or industry action.
5. We brought this issue to the attention of the Pharmaceutical Research Manufacturers' Association thrice. They did not even reply. In view of their apathy, we have had to file this petition.
6. Could you kindly add Sonia Lohiya. as an additional petitioner.  
We hope you will approve our petition.

Yours Respectfully,

SAPNA LOHIYA (Student, University of California, Los Angeles CA)  
SONIA LOHIYA (Student, David Geffen School of Medicine, University of California,  
Los Angeles CA)  
Correspondence: [lohiyas@ucla.edu](mailto:lohiyas@ucla.edu)  
Royal Medical Group 1120 W. Warner Av, #A, Santa Ana Ca 92707  
PHONE 714 444 4448 FAX 714 444 9892

Copy: Marjorie Bowman MD Fax 13135773070, Phone 313 577 5205  
Editor, Journal of the American Board of Family Medicine  
Department of Family Medicine, Wayne State University  
101 E. Alexandrine #249  
Detroit MI 48201

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