

3/4/07

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

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

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Honorable Ms Axelrad,

1. Thanks for your 1/25/07 letter and for continued consideration of our petition. There is a reason FDA requires the Expiration Dates. 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. 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. 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,

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