

4/10/08

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

Honorable Ms Axelrad,

Thanks for a phone call from your office on 1/23/08 advising us to separate this petition from our other petition [2007P-0456/CP1]. We authorized you to do so on 1/23/08 but have not heard back from you. We hope you will find our petition worthy of approval. We have also attached two letters of support we received recently.  
Yours Respectfully,

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

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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**FDA-2006-P-0135**

**LET**

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

Ms Jane A. Axelrad, Associate Director for Policy, CDER, FDA, Rockville MD 20857  
Ms. Carolyn Kachovec Phone 301 827 6857, 60/ Fax 13018276870

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 miss 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.
- Yours Respectfully,

SAPNA LOHIYA (Student, 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

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*The Journal of the  
American Board of  
Family Medicine*

March 15, 2004

Sapna Lohiya  
Royal Medical Group  
1120 W. Warner Avenue, #A  
Santa Ana, CA 92707

Re: MS 14-04 "Location, Content and Legibility of Expiration-Dates on Medicines"

Dear Ms. Lohiya:

Your manuscript has been received in this office and I am delighted to inform you it has been accepted for publication in *The Journal of the American Board of Family Practice*.

Since your article is tentatively scheduled for publication in a 2004 issue of *The Journal of the American Board of Family Practice*, you will be hearing from us further regarding your manuscript as it completes the editorial process.

I would also suggest that after your manuscript has been published, you should consider sending it to the FDA.

Thank you for your work on this interesting paper.

Sincerely,



Marjorie Bowman, MD, MPH  
Editor  
*Journal of the American Board of Family Practice*  
Department of Family Medicine  
Wayne State University  
101 E. Alexandrine, Room 241  
Detroit, MI 48201

Exhibit 2

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**Support Letter:**

Date: Sat, 19 Jan 2008 18:02:55 EST

From: MarkH38514@aol.comReply-To: MarkH38514@aol.com

Subject: Your JABFM article

To: slohiya@ucla.edu

Hello Sonia:

I just came across your splendid research letter on "The suboptimal legibility of prescribing information in pharmaceutical advertisements." I really liked it.

I've done quite a bit of readability research, including DTC consumer drug ads, and I suspect that not only was the prescribing information illegible, but probably unreadable, too. I've seen pharmaceutical ads in consumer magazines that were written at a graduate school reading level. My wife's a pharmacist, and the "brief summaries" in pharmaceutical magazines are just as illegible and unreadable.

Perhaps I can be of some help if you want to look at the reading level of the PIs.

I think you're really on to something; what are the ethical implications of giving consumers and health care professionals information that's both illegible and unreadable? Why isn't the pharmaceutical information written in anything close to "plain English?"

I'll send you some of my work on this subject.

Mark Hochhauser, Ph.D.  
Readability Consultant  
3344 Scott Avenue North  
Golden Valley, MN 55422-2748  
Phone: 763-521-4672  
Cell: 612-281-1517  
Fax: 763-521-5069  
email: MarkH38514@aol.com (MarkH38514@aol.com)

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**Support Letter:**

Date: Tue, 8 Jan 2008 15:18:13 -0500  
From: Gail Guzzo <[guzzog@tds.net](mailto:guzzog@tds.net)>  
Reply-To: Gail Guzzo <[guzzog@tds.net](mailto:guzzog@tds.net)>  
Subject: expiration dates  
To: [lohiyas@ucla.edu](mailto:lohiyas@ucla.edu)

Dear Sapna Lohiya

RE: FDA Docket 2006P-0307

I can across your citizen petition while researching FDA rules for expiration dating on drug products. As a consultant pharmacist I have repeated found examples of foreign manufactured products which use MM/DD/YY, DDMMYY, MMY and YYMM and wondered how this could be allowed. Just today I pulled a whole box of Hemoccult which was in use past its expiration due to the date format. The problem with biologicals, especially vaccines, seems to me to be increasing in occurrence

My question is one of follow-up. I do not see any FDA documents pertaining to your petition since August 2006. Please let me know if you have made progress, or if you have need of any support.

Thank you so much for your time and effort.

Gail Guzzo

Gail J. Guzzo, R.Ph., Ph.D  
Cape Romain Health  
815 Pinckney Street  
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## Lohiya's Petition Docket # 2006P-0307/CP1



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, MD 20892

JAN 25 2007

Sapna Lohiya  
Royal Medical Group  
1120 W. Warner Avenue, #A  
Santa Ana, CA 92707

Re: Docket No. 2006P-0307/CP1

Dear Ms. Lohiya,

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received by the Agency on August 2, 2006. Your petition requests that we amend our regulations to add requirements concerning the location and appearance of expiration dates on drug product containers.

We have been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(c)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research