8/12/08, 6/18/08 **Lohiya's Petition Docket # 2006P-0307/CP1**

To: Mr. Bryan Pendleton Phone: 301 796 3504
Fax: 13018276870

I wonder if you have now made a decision on my petition. I would be grateful for your kind approval. Can you please reply by email to lohiyas@ucla.edu. Thanks a lot!

Sapna Lohiya

Sincerely,
Sapna Lohiya

****

Attention: Ms. Carolyn Kachovec
Division of Dockets Management Fax 13018276870
Office of Management
5630 Fishers Lane, Rm 1061
Rockville, Maryland 20852

Citizen Petition: 2006P 0307/CP1

Dear Ms. Carolyn Kachovec

Per my phone call with Mr Bryan Pendleton today, I hereby withdraw my 9/27/07 supplement to Petition 2006P0307/CP1. In doing so, I hope that you will recommence work on my original petition.

I am very passionate about my proposed amendment which calls for the standardization of expiration dates on medicine containers. I trust that you will find my request worthy of prompt approval.

Can you please note the following contact information for me:
Email: lohiyas@ucla.edu, Phone 949 202 9425
Mailing address: POB 26098, Santa Ana CA 92799

Thank you very much!
With best regards,

Sapna Lohiya

Sapna Lohiya
Pre-Dental Student
University of California, Los Angeles CA 90024
lohiyas@ucla.edu, Phone 949 202 9425
POB 26098, Santa Ana CA 92799

8/12/08, 6/18/08 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. 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 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
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

Exhibit 1

Research Letter

The Variable Location, Content, and Legibility of Expiration Dates on Medicine Containers

Sapna Lohiya, MD

Royal Medical Group, Costa Mesa, CA

To the Editor: Law mandates expiration-dates on drug products to ensure their "identity, strength, quality and purity."[1] It stipulates that such date "shall appear on the immediate (product) container" without further specifying a particular location.[2] It is silent about the legibility and content of the date inscription. Besides the medicine's name and strength, users look for this date on a medicine container. To assess the ease of reading and locating these important dates, I evaluated a global sample of all medicines in a traditional, urban family practice office. Descriptors of the 84 study medicines, marketed by 49 US companies, were formulation (oral, 44; topical, 23; injection, 10; inhaler, 7), source (samples, 68; purchased, 16), and nature (brand, 70; generic, 14).

Expiration-date locations were: container bottom 27 (32%), side 24 (29%), rear 14 (17%), front 12 (14%), and top 7 (8%). Date formats were: month-year, 76; day-month-year, 5; month-day-year, 2; and year-month, 1 (Figure 3). One inscription read "02/04," which could mean either February 2004 or April 2002 (Figure 3, #3). The dates were preceded by the following captions: "Exp.", 53; "Exp. Date", 16; "Ex", 1; none, 14 (Figure 3). On 11 packages, dates were printed in landscape while the adjacent text was in a portrait or inverse orientation (Figure 3, #2). For 3 inhalers, an opaque dispenser required removal to see the date on the canister.

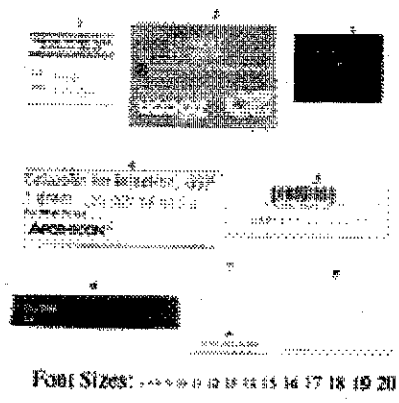

Figure 3. Expiration-date inscriptions illustrating variable legibility, format (standard, inverse), background (black, white, color), caption (none, "Exp. Date," "Exp"), printing (dot matrix, laser), and content (month-year, month-date-year, date-month-year). Notice the poor legibility of the embossed inscriptions (#6 to 8). Numbered fonts are shown at the bottom for letter size comparison.

Legibility was good for 36 (80%) and fair for 9 (20%) of the 45 printed inscriptions. Among the 39 embossed dates, legibility was good for 8 (21%), fair for 16 (41%), and poor for 15 (38%); it was impossible to decipher the full date in one case (Figure 3, #6 to 8). Causes of poor legibility were superficial embossment, inadequate contrast between letters and background (due to lack of ink), glare from 3-dimensional carving (worse on glossy surfaces or a dark background), dot matrix printing, small font size, and embossment on ointments' narrow (2- to 4-mm wide) crimps. These problems discouraged one clinic physician from accepting or dispensing the samples. Samples of three medicines (14 containers) had passed their expiration dates and required discarding.

The expiration date location on medicine containers varies. This forces the user to look for it by turning the container around. Such search can be annoying to physicians who dispense several medicine samples daily. Although the date-search requires only a few seconds, such time may be critical in an emergency, or a busy schedule, particularly as it nips into the physician's face-to-face interaction with the patient. The date location on medicine containers requires standardization. Ideally, it should be on the container's front, directly above or below the medicine's name; this would eliminate the need to turn the container to check multiple surfaces. To avoid confusion or distraction, this area should contain few other numbers. Dating should follow the national convention: month-day-year in the United States, day-month-year in the United Kingdom. A month-year format causes waste because uninformed consumers may discard a medicine on the month's first day although it officially expires on the last.[3] For inhalers, the date should be printed on that canister's bottom (the end that remains visible after dispenser assembly), or the dispenser should be transparent. A standardized caption (eg, "Exp. Date," "Expires") should always precede the date.

To improve legibility, dates should be printed in black or red ink against a white background, in a common font (eg, Times New Roman) of modest (>10 points) size, on a non-glare surface, and not on ointment crimps. On smaller containers (eg, eye/ear drops, injections), necessary space for a legible date should be found by moving less consumer-relevant information (eg, lot number, manufacturer name) to another surface. Good legibility is crucial because millions of medicine-users are older persons with presbyopia.

Conventional research wisdom might cast some doubt on the findings of this study as it was based on observations in one single medical practice. However, the study site was typical of others in the community, it did not manufacture any of the medicines, it was not affiliated with any drug manufacturer, and the medicines came from a large number of US companies.

The law requires physicians to exercise the same level of care as pharmacists when dispensing medicines.[4] Thus, physicians must check the expiration-date on each individual medicine sample container. Any efficiency that makes this financially nonremunerative date-reading task less cumbersome will enhance sample dispensing by physicians, reduce waste, and thus even facilitate the manufacturers' marketing effort.

This study highlights real-life problems, and proposes simple remedies. Its recommendations should apply also to nonprescription medicines and other dated items, such as food products. Industry should modify its date-inscribing practice so that human perfection is not required to find and read the dates. To paraphrase Alice in Wonderland, what good is an inscription "if I can't read it!"

References

1. Expiration Dating. 21 C.F.R. Sect. 211.137 (1995).

2. Expiration Dating. 21 C.F.R. Sect. 201.17 (1995).

3. US Pharmacopeia/National Formulary. 22nd ed. Rockville (MD): US Pharmacopeial Convention Inc.; 1985. p. 9.

4. Medical Board of California. Legal requirements for distribution of drug samples. Action Report 1996; 56: 3.

The Journal of the
American Board of
Family Practice

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

Support Letter:

Date: Sat, 19 Jan 2008 18:02:55 EST
From: MarkH38514@aol.com
Reply-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)

Support Letter:

Date: Tue, 8 Jan 2008 15:18:13 -0500
From: Gail Guzzo <guzzog@tds.net>
Reply-To: Gail Guzzo <guzzog@tds.net>
Subject: expiration dates
To: 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, MMYY 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
PO Box 368
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8/12/08, 6/18/08 Lohiya's Petition Docket # 2006P-0307/CP1

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

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(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

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