7/21/06
Citizen Petition
Division of Dockets Management, FDA
5630 Fishers Lane #1061
Rockville MD 20852

Honorable Commissioner,
I submit this petition under the Federal Food, Drug, and Cosmetic Act to request you to amend regulations in Title 21 of the Code of Federal Regulations (CFR), Part 201.17.

A. Action Requested: Amend an existing regulation.
(1) Exact wording of existing regulation: When an expiration date of a drug is required, e.g. expiration dating of drug products required by Sec 211.137of this chapter, it shall appear on the immediate container and also the outer package, if any, unless it is easily legible through such outer package.
(2) Exact wording of the proposed order: Add the following to the existing regulation: *Such expiration date imprint shall be readily legible (minimum font size 8, printing in ink instead of inkless embossment), and have a uniform format (month-day-year), an identifying caption (Expiration Date, Exp Date, Expires) and a spatial orientation (landscape or portrait) identical to that of the drug's name. The date imprint shall be located on the front or top of the container, and not on ointment tube crimps or on parts of inhaler canisters that get covered after arming.*

B. Statement of grounds
Section 211.137 (Title 21 CFR) mandates expiration-dates on drug products to ensure their "identity, strength, quality, and purity". Besides the drug's name and strength, it is this date that users look for on a drug container. Section 211.17 (Title 21 CFR) stipulates that such date "shall appear on the immediate (product) container" without specifying a particular location. The regulation is silent about the print size, legibility and content of the date inscription.

FDA requires that any word, statement, or other information required to appear on the label or labeling must be prominently placed thereon with such conspicuousness (as compared to other words, etc.) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. (Exhibit 1: Joan Powers, Center for Drug Evaluation and Research, personal communication, August 4, 2005). This is not true in practice, however, for expiration dates as disclosed by my research (1). The editor of the journal, in which my research was published, advised me to submit my recommendations to the FDA (Exhibit 2). My research disclosed the following problems:
1. The expiration dates are often poorly legible due to small font size, 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, embossment on ointments' narrow (2-4 mm wide) crimps or on parts that get covered after arming of inhaler canisters, and differing spatial orientation than the drug's name (landscape vs. portrait).

2. Date location on drug containers vary considerably requiring the user to turn the container around to search for the date.

Poorly legible expiration dates have a myriad of ramifications (2):
1. Clinically, physicians waste valuable time in finding and deciphering these dates, especially if they handle scores of such medicines daily; this reduces the physician's face-to-face time with the patient. This task would be even more cumbersome for the nearly 8% of adult Americans (including many presbyopic healthcare professionals) who have trouble seeing (3).
2. Socially, some physicians avoid dispensing free drug samples and deprive their patients of a financial benefit and convenience.
3. Fiscally, many samples become outdated resulting in wastage -- a weighty consideration as we battle escalating healthcare costs. For background, the value of drug samples distributed in the United States in 1998 was an astounding $6.6 billion (roughly $25 per American); waste of even a small proportion of the samples is worth a substantial amount of money (4)!
4. Legally, physicians may inadvertently dispense expired medicines resulting in potential undereffectiveness, patient dissatisfaction, litigation or harm (5).
5. Administratively, outdated medicines may remain in circulation and draw the ire of credentialing and managed care authorities.
6. Procedurally, it can be a time-consuming and labor-intensive exercise to periodically identify and weed out the outdated samples from the numerous unexpired samples.
7. Finally, discarding unused drug samples into regular trash my cause them to end up in unintended hands with adverse health and legal ramifications.
8. These problems led me to devise a specialized stratification and storage system for drugs; a national medical journal found my proposal worthy of publication (2).
9. The FDA also shared my concerns about poorly legible expiration dates (Exhibit 3: Brenda Stodart, Center for Drug Evaluation and Research, personal communication, October 25, 1999).

Unfavorable information: See Economic Impact.

C. Environmental Impact:
This amendment would generate no new toxic waste and cause no impact on traffic. It should qualify for categorical exclusion under Sec 25.30, 25.31, 25.32, 25.33 or 25.34. Improved legibility of the expiration dates will actually enhance use of the drugs before expiration and thus minimize waste.

D. Economic Impact:
Proposed rule may require an initial capital investment for purchase of new or modification of existing dating equipment. Such expense is expected to be nominal and a one time outlay. It should be hugely offset by the benefits (increased use of drugs before expiration, time savings in locating and reading the dates, convenience). Most of the cost of drugs is for research and drug manufacturing. The dating process probably accounts for less than 0.1% of the total cost of the drug. It should neither increase cost to the industry, nor prices to consumers or government.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

References:

1. Lohiya S. The variable location, content and legibility of expiration dates on medicine containers. *J Am Board Fam Pract.* 2004;17:395-397

2. Lohiya S. A simple stratification & storage system for samples and supplies. *J Natl Med Assoc.* 2006;98:405-407

3.Centers for Disease Control and Prevention. Quickstats: percentage of adults who reported trouble seeing even with glasses or contact lenses. National Health Interview Survey 2003. www.cdc.gov/nchs/nhis.htm. Accessed 07/20/06

4. Ma J, Stafford R, Cockburn I. A statistical analysis of the magnitude and composition of drug promotion in the United States in 1998. *Clin Ther.* 2003;25:1503-1517.

5. Wessels I, Bekendam P, Calvin W. Open drops in ophthalmology offices: expiration and contamination. *Ophthalmic Surg Lasers Imaging.* 1999;30:540-546.

(signature) Sapna Lohiya

SAPNA LOHIYA (Student, University of California, Los Angeles CA)
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services

Food and Drug Administration
5600 Fishers Lane
HFD-240, Room 12B-05
Rockville, MD 20857

August 4, 2005

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

Dear Ms. Lohiya:

This is in response to your letter June 2, 2005, to the Food and Drug Administration (FDA) concerning expiration dates on medication containers. Your letter was forwarded to the Center for Drug Evaluation and Research (CDER), one of the six centers within FDA, for reply. I'm sorry that you did not receive an answer to your first letter. We have no record of receiving it.

All drug products regulated by FDA, unless exempt, must contain expiration dates. The expiration date must appear on the immediate container and also the outer package, if one exists. As for the print size of expiration dates on drug products, FDA regulations do not state that a specific print size has to be used. The regulations require that any word, statement, or other information required to appear on the label or labeling must be prominently placed thereon with such conspicuousness (as compared to other words, etc.) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

The way industry, consumer groups, and individuals can influence FDA to make a change in a regulation or to take other action is to submit a citizen petition. Petitions require careful preparation by the submitter. I have enclosed the FDA publication entitled "Making Your Voice Heard at FDA: How to Comment on Proposed Regulations and Submit Petitions." This article outlines the citizen petition process should you wish to make your opinions known further to the agency. Also provided are sections 10.30, 10.33 and 10.35 of Title 21 Code of Federal Regulations (21 CFR). These sections are the FDA regulations that describe in detail the process for submitting a citizen petition.
Thank you for writing to the FDA. I hope this information is helpful. Please do not hesitate to contact me if I can provide assistance in the future.

Sincerely,

Exhibit 1

Joan Powers
Consumer Safety Officer
Division of Drug Information, HFD-240
Office of Training and Communications
Center for Drug Evaluation and Research

Enclosures

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

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

Food and Drug Administration
Rockville MD 20857

October 25, 1999

Sonia Lohiya
Royal Medical Group
1120 W. Warner Avenue
Santa Ana, CA 92707

Dear Ms. Lohiya,

Thank you for your letter dated October 1, 1999 to the Food and Drug Administration (FDA) concerning "Expiry Date Display on Drug Packages." Your letter was forwarded to the Center for Drug Evaluation and Research (CDER), one of the five centers within the Food and Drug Administration (FDA), for reply.

I wish to thank you for your comments and suggestions and to also ensure you that your concerns are shared by the Food and Drug Administration (FDA). You may also wish to contact the trade organization for pharmaceutical manufacturers, Pharmaceutical Research and Manufacturers of America (PhRMA) , at the following address:
Pharmaceutical Research and Manufacturers of America
1100, 15th Street . NW. #900
Washington, DC 20005
Phone: 202-835-3400

As far as your recommendations are concerned, I do wish to point out the regulations on expiration dates as stated in the 21 Title of the Code of Federal Regulations (CFR), Part 201.17 which states:

When an expiration date of a drug is required, e.g., expiration dating of drug products required by Sec. 211.137 of this chapter, it shall appear on the immediate container and also the outer package, if any, unless it is easily legible through such outer package. However, when single-dose containers are packed in individual cartons, the expiration date may properly appear on the individual carton instead of the immediate product container."
Thank you for writing to the FDA. I hope this information is helpful to you, and again extend our appreciation to you for your comments.

Exhibit 3

Sincerely,

Brenda L. Stodart
Consumer Safety Officer
Drug Information Branch
Division of Communications Management
Office of Training and Communications
Center for Drug Evaluation and Research