Citizen Petition: Attention – Michelle (Revised from 7/21/06)
Ms Jennie C. Butler, Director
Division of Dockets Management
FDA, Mail: HFA 305
Rockville MD 20857 Phone 301 827 6857

Honorable Ms Butler,
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). It should 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. It shall be located on the front of the container directly below the drug's name, 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. (1). However, the expiration date imprints on drug products are often poorly legible. The problem is so serious that a Journal's Editor felt it deserved FDA's attention (2). The FDA shared our concerns, and advised us to contact the Pharmaceutical Research Manufacturer's Association (3); we wrote to them but received no reply.

Our research has revealed the following problems with the expiration date imprints on drug products (4,5):
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

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get covered after arming of inhaler canisters, and in spatial orientations different than the drug's name (landscape vs. portrait).
2. Date location on drug containers (front, top, back, bottom side) varies considerably requiring the user to turn the container around to search for the date.
3. Poorly legible and locatable expiration dates have a myriad of ramifications (6):
a. 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. Legibility becomes even more critical for the 30% of healthcare workers who are presbyopic (the amplitude of visual accommodation is 14 diopters at age 10, 4 diopters at age 45, and only 1 diopter at age 60 years), and the 8% of adults who have trouble seeing even with glasses (7). To paraphrase from *Alice in Wonderland* – what good is the printed word if readers can't read it?
b. Socially, some physicians avoid dispensing free drug samples and deprive their patients of a financial benefit and convenience.
c. Fiscally, many samples become outdated resulting in wastage – a weighty consideration as I 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 (8)!
d. Legally, physicians may inadvertently dispense expired medicines resulting in potential reduced efficacy, patient dissatisfaction, litigation or harm (9).
e. Administratively, outdated medicines may remain in circulation and draw the ire of credentialing and managed care authorities.
f. 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.
g. Finally, discarding unused drug samples into regular trash my cause them to end up in unintended hands with adverse health and legal ramifications.
h. These problems led me to devise a specialized stratification and storage system for drugs; a national medical journal found my proposal worthy of publication (6).

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 0.01% of the total cost of the drug. It should increase neither 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.

Exhibits:

1. Joan Powers, Center for Drug Evaluation and Research, personal communication, August 4, 2005.
2. Bowman M. Editor, Journal of the American Board of Family Practice, personal communication, March 15, 2004.
3. Brenda Stodart, Center for Drug Evaluation and Research, personal communication, October 25, 1999.
4. Lohiya S. The variable location, content and legibility of expiration dates on medicine containers. *J Am Board Fam Pract.* 2004;17:395-397
5. Lohiya S. Expiry date display on drug packages. West J Med 1996;164:365-6.
6. Lohiya S. A simple stratification & storage system for samples and supplies. *J Natl Med Assoc.* 2006;98:405-407
7.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
8. 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.
9. Wessels I, Bekendam P, Calvin W. Open drops in ophthalmology offices: expiration and contamination. *Ophthalmic Surg Lasers Imaging.* 1999;30:540-546.

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EXAMPLES OF POORLY LEGIBLE EXPIRATION DATE INSCRIPTIONS: