DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 10 2010

Rec'd 11/10/10

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

Re: Docket No. FDA-2006-P-0135

Dear Mesdames Lohiya:

This responds to your citizen petition received by the Food and Drug Administration (FDA) on August 2, 2006, as supplemented by letter dated September 24, 2006 (Petition), requesting that we amend our regulations to add requirements concerning the location and appearance of expiration dates on drug product containers and packaging.[1] We have carefully reviewed the Petition.[2] For the reasons stated below, the Petition is denied.

I. BACKGROUND

The Federal Food, Drug, and Cosmetic Act (the Act) and FDA regulations contain legal requirements concerning expiration dates on the labeling of human drug products. Section 502(c) of the Act (21 U.S.C. 352(c)) states that a drug is misbranded:

> [i]f any word, statement, or other information required by or under authority of [the] Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) 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.

Under 21 CFR 211.137(a), to ensure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, the product must bear an expiration date determined by appropriate stability testing under 21 CFR 211.166. Section 211.137(d) states that expiration dates must appear on labeling in accordance

[1] This citizen petition was originally assigned docket number 2006P-0307/CP1. The number was changed to FDA-2006-P-0135 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

[2] You submitted a document dated September 27, 2007 regarding prescription drug advertising that was designated by the FDA's Division of Dockets Management as an amendment to your August 2, 2006, petition. You also submitted a second citizen petition regarding prescription drug advertising, which FDA received on November 20, 2007 (formerly docket number 2007P-0456/CP1 and now docket number FDA-2007-P-0416). In a letter dated April 22, 2008, you withdrew your September 27, 2007 submission. The second petition (docket number FDA-2007-P-0416) remains pending before the Agency and will be answered in a separate response.

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with the requirements in 21 CFR 201.17. Section 201.17 states that when an expiration date is required for a drug (e.g., under § 211.137), the date must appear on the drug's immediate container and the outer package, if any, unless it is easily legible through the outer package. Section 201.17 further states that when single-dose containers are packed in individual cartons, the expiration date may appear on the individual carton instead of the immediate product container.

II. DISCUSSION

You request that we revise § 201.17 concerning the location and appearance of expiration dates on drug packaging because you maintain that expiration date imprints are often poorly legible. You state that your research has revealed several problems with the expiration date imprints on some drug products.[3] You state that expiration dates are often poorly legible because of small font size, superficial embossment, inadequate contrast between letters and background, glare from three-dimensional carving, dot matrix printing, embossment on ointments' narrow crimps or on inhaler canister parts that are covered when the inhaler is armed, and spatial orientations that differ from that of the drug's name (i.e., landscape versus portrait). You state that the location of the date (e.g., front, top, back, bottom, or side of container) varies considerably, which requires the drug's user to turn the container to search for the date.

You state that poorly legible expiration dates have the following ramifications:

- Physicians waste time finding and deciphering expiration dates, and this reduces their face-to-face time with patients. The task of finding and deciphering expiration dates is even more cumbersome for some adults, including healthcare workers who have trouble seeing.

- Some physicians avoid dispensing free drug samples, thus depriving their patients of a financial benefit and convenience.

- Many samples become outdated, resulting in wasted drugs.

- Physicians may inadvertently dispense expired medicines, possibly resulting in reduced efficacy, patient dissatisfaction, litigation, or harm.

- Outdated medicines may remain in circulation and draw the ire of credentialing and managed care authorities.

- Periodically identifying and weeding out outdated samples from unexpired samples can be time-consuming and labor-intensive.

[3] Your survey of the location, content, and legibility of the expiration dates of 84 drug products was published in *The Journal of the American Board of Family Practice*, Vol. 17, pages 395-397, September 2004.

- Discarding unused samples into regular trash may cause them to end up in unintended hands, with adverse health and legal ramifications.

To address these concerns, you ask that we revise § 201.17 by adding the following provisions:

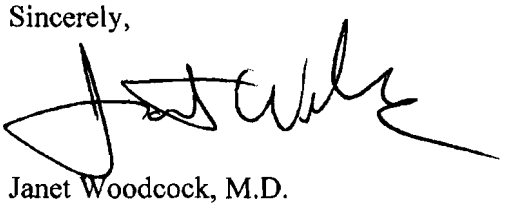
> Such expiration date imprint shall be readily legible (minimum font size 8, printing in ink instead of inkless embossment). It should have a uniform format (month-day-year), an identifying caption (Expiration Date, Exp. Date, Expires) and a spatial orientation (landscape or portrait) identical to that 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.

We believe that you raise valid points about the importance of the legibility of expiration dates for drug products. We share your concern that expiration dates be placed on drug product containers in such a way that they can be read and understood, in accordance with the Act and FDA regulations.

After careful consideration of the information you have provided in the Petition, however, we have determined that it is not necessary or appropriate to revise the regulations on drug expiration dates at this time. We already have sufficient legal authority to take action under the Act in the case of specific instances in which a drug product's expiration date is not prominently placed on the label or labeling with such conspicuousness that it is likely to be read and understood by the ordinary individual under customary conditions of purchase and use (see, e.g., sections 301(a) (21 U.S.C. 331(a)) and 502(c) of the Act). The information you submitted in the Petition does not persuade us that there is a need to revise our regulations to further address the placement and legibility of expiration dates on drug products. We also believe that revising the regulation as you have suggested would not allow us the flexibility that we believe is needed to accommodate the wide variety of dosage forms, package types, and package sizes. For example, the use of ink may not be appropriate with some soft plastic drug product containers.

For these reasons described above, the Petition is denied. Thank you for your interest regarding this issue.

Sincerely,



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