Rcd 10/3/07

Honorable Commissioner, FDA
Division of Dockets Management
Room 1061, 5630 Fishers Lane,
Rockville, MD 20852.

Re: Citizen Petition

A. Action Requested: Amend existing regulation 21CFR, Part 202.1 (e)(1).

(1) Exact wording of existing regulation:

All advertisements for any prescription drug...shall present a *true statement* of information in brief summary relating to the drug's side effects, contraindications and effectiveness.

(2) Exact wording of the proposed order:

Add the following to the existing regulation: *This True Statement shall be in a "font size of a style and size that is large enough to be easily legible such as Times New Roman 10 point font, with adequate paragraphing, column spacing and bold facing".*

B. Statement of grounds

The drug's True Statement is often poorly legible in drug ads because of small font, and reduced paragraphing, boldfacing and column spacing (Exhibit). In one case, an illegible ad page was cramped with 6345 words compared to only 675 words on the adjacent text page (Exhibit). Poorly legible True Statements defeat the intent of the regulation while technically "complying" with it, and are even more problematic for the third of the population that has presbyopia.

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It is crucial to have a legible True Statement in an ad. Physicians often learn about a new drug through an ad, and would naturally prefer to read a drug's side effects in the ad itself instead of searching for them elsewhere. A legible True Statement is a safety net against inaccurate ad claims.

Legibility of printed material depends on font size and style, line and letter spacing, boldfacing, paragraphing and contrast. Acknowledging the significance of good legibility, FDA has promulgated rules for prescription drug labels that require a minimum font size 8, boldfacing and adequate spacing (21CFR,201,314,601). Likewise, for Pharmaceutical Marketing Applications, FDA suggests a font size "of a style and size that is large enough to be easily legible (such as) Times New Roman 12 point font" (FDA. Common Technical Document. Submitting Marketing Applications). However, no such criteria exist for journal ads. There is a clear need for regulatory action to improve legibility of drug ads.

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 drug advertisements may reduce waste [unreadable printed pages).

D. Economic Impact:

More pages may be required to print a legible True Statement in drug ads. The additional advertising cost, however, will be readily offset by several benefits. The ad dollars will

not be wasted on printing pages that are poorly legible and therefore not read. A legible ad can increase a drug's popularity by making the prescribers more knowledgeable about it. If ad cost still remains a concern, then space can be budgeted out of the ad's promotional slogan-image pages. There will be no increase in cost to the 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.

Exhibit:

Lohiya S, Lohiya S. The suboptimal legibility of prescribing information in pharmaceutical advertisements. Journal American Board of Family Medicine. 2007;20:314-315.

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