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Dockets Management Branch
ISA-305
5630 Fishers Lane Rm. 1061
Rockville, MD 20857

Re: Docket No.OON- 1269
RIN091o-AA94
Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels

To Whom It May Concern:

I have the following comments on the proposed changes to the requirements for content and format of labeling for drugs and biologics. First, I applaud the Agency's interest in improving the readability and usefulness of labeling. It is an evolving process and should be reviewed regularly for content and format issues as well as issues concerning the media by which labeling information can be conveyed to practitioners and consumers.

My comments include a request for attention to the proper use of the apostrophe. For instance, it is not used to indicate a plural when using initials. For instance, it is not correct to refer to ADR in the plural by using an apostrophe with an "s". The plural of ADR is ADRs, not ADR's. ADR's indicates the possessive, not plural. This misuse of the apostrophe is rampant in the document.

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Also, when including the black box warning in the 'Highlights" section, it is imperative that you consider all interpretations of the summarized warning. The example provided for captopril has the following ambiguous summary of a black box warning:

"**!WARNING:** USE IN **PREGNANCY"**

The uninitiated or those for whom English in not a first language might read that warning as instructions to use the drug in pregnant women, not that use of the drug in pregnancy is a problem. I recommend that a more accurate summary of the information you want the prescriber and the patient to comprehend would be:

"!WARNING: DO NOT USE IN **PREGNANCY"**

The addition of a couple of words to clarify the actual content of the warning is a simple change and one that will more accurately convey the important, black boxed information.

I will also take this opportunity to address a problem that affects physician reporting of ADRs. That is, the inaccessibility of safety information contained in the AERS and other databases. Most physicians I talk to about the importance of ADR reporting comment to me that they have no idea how the data are used and have no interest in submitting information to a black hole. I understand the many issues surrounding public access to this type of unconfirmed data. I was an epidemiologist with CDER from 1984 through 1988 and was Director of the Office of Surveillance and Biometrics at the Center for Devices and Radiological Health from 1994 through 1995. I also understand the frustrations of practicing physicians who want to know more about potential side effects of medical products they use and recommend for their patients. I strongly urge the Agency to consider providing access other than FOIA to the AERS and other databases. Physicians and other practitioners can learn to use or interpret the spontaneously reported data contained in the medical product post-market safety databases. It will require patience on the part of FDA and manufacturers as well as formal teaching and trial and error learning by health care providers and researchers, However, I strongly believe that the benefits of access would outweigh the risks of misuse.

I hope my comments have been helpful.

Sincerely,

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