I.V. Systems / Medical Products
Regulatory Affairs

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Baxter

March 21, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5230 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Federal Register Notice December 22, 2000 (FR Vol 65, No. 247, Pages 81082-81131)

Docket No. 00N-1269

Dear Colleague:

Baxter Healthcare Corporation is submitting comments on the Proposed Rule entitled "*Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels* ", released for comment on December 22, 2000. General comments are presented first, followed by specific comments with reference to the applicable section numbers.

General Comments:

1. Baxter appreciates and supports the Agency's initiatives to simplify drug product labels and reduce the possibility of medication errors. The proposed rule states that the revised content and format requirements will be applied only to drug products with an NDA, BLA, or efficacy supplement that is pending at the effective date of the final rule, submitted on or after the effective date, or that has been approved in the 5 years prior to the effective date of the final rule. Please clarify that the proposed rule does not apply to other types of supplements, such as chemistry, manufacturing and controls or geriatric labeling supplements, that may be pending at the effective date of the final rule or submitted on or after the effective date, or submitted in the 5 years prior to the effective date.

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2. We request clarification as to the impact on affected applications, which are received by the Agency after the effective date, but within 120 days of issuance. We feel that the applications should not be subject to a Refuse to File from the Agency based on the revised label requirements.

Specific Comments:

Section III. A Description of the Proposed Labeling Requirements

(2) We believe the inclusion of a highlights section may have a significant effect on product liability because it by design does not include all the information needed to prescribe the drug safely and effectively. If the Agency believes that a highlights section is necessary, we recommend that the following disclaimer statement be moved to the **top** of the highlights section, appearing directly under the section title, and stated in bold.

"These highlights do not include all the information needed to prescribe (name of drug) safely and effectively. See (name of drug)'s comprehensive prescribing information provided below."

(5) We question the value of including "Recent Changes" as part of the highlights section. We believe the addition of this section would be overly burdensome for manufacturers because it would require additional labeling changes to keep this section current. Alternatively, the section could be renamed "Labeling Changes" so that a period of time is not implied.

(6) Information presented in the highlights section should not be verbatim from the comprehensive prescribing section. This is redundant and presents an opportunity for error when information is presented in two different locations. Accurately summarizing the information in a bulleted format may also be difficult. We recommend that the highlights section emphasize key phrases from the prescribing information and include references back to the complete section.

(7) The Index section is a valuable addition to the label and we feel it should be included in the proposed rule. An index will provide emphasis on the key information contained in the direction insert and where to locate it within the text.

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(8) Standardized headings are not necessary for the "Warnings/Precautions" section.

(9) The inclusion of a contact number for reporting suspected serious adverse drug reactions in the proposed highlights section is duplicative and not necessary. Physicians will need to review the comprehensive prescribing information with respect to adverse reactions and providing a contact number therein should be sufficient.

(11) The proposed requirements to bold certain information in 201.57(d)(5) should serve the intended purpose of ensuring visual prominence.

(12) The proposed one-half page addition of the highlights section will in some cases be difficult to achieve based on the existing size of most of Baxter's current drug direction inserts. Adding a one-half page highlights section plus an additional index section will have a large impact on manufacturers with automated printing and packaging equipment. We also question the need to include a highlights section at all on direction inserts that do not currently exceed a certain size in length, i.e. one page.

(13) New labeling information should be summarized and included in the highlights section under a section entitled "Labeling Changes". The use of revision marks within the text of the comprehensive prescribing information provides little value without referencing the previous label version.

(14) It is our opinion that the proposed rule should not contain a limitation on font size. Many factors other than font size contribute to the readability of an insert, such as font type, color and printing quality. As such, the requirement should instead be on the clarity and legibility of the print without restricting the font size. The direction insert provided as an example at the end of the proposed rule was completely clear and legible, and from the appearance seems to represent an approximate 6.5-point font size. Imposing an unnecessary limit of 8 or 10-point font size would be overly burdensome for manufacturers when trying to provide the additional sections required by the proposed rule because it may require an overall increase in insert size and associated manufacturing costs.

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Baxter appreciates the opportunity to comment on this important proposed rule. If you have any questions regarding our comments, please contact Judy Kannenberg or myself at (847) 270-2577.

Sincerely,

for Marcia Marconi
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