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Dockets Management Branch (HFA-305)
Docket No. 00N-1269
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

COMMENTS ON PROPOSED NEW FORMAT FOR DRUG PACKAGE INSERTS:

We appreciate the enormous work that has gone into the proposed revision and support its adoption, with the inclusion of the recommendations that:

1. All future labels should be required to be in a standard format, which specifies size of paper, color of type and size of font, as in the proposed label for Capoton Tablets. Elongated narrow labels in tiny type should be prohibited.

2. The date of the most recent revision of the drug labeling should be conspicuously displayed in a designated area on the first page.

3. The name and address of the FDA division responsible for determining the appropriate labeling for the drug should be displayed in a designated area of the label.

4. The name and address of the FDA division to which an adverse drug reaction should be reported should be displayed in a designated area of the label. The label should not suggest that reporting an adverse drug reaction to the manufacturer of the drug is an adequate substitute for reporting to the FDA, since since manufacturers are not required to report "incidents" to the FDA and, in some instances, there has historically been significant manufacturer underreporting to the FDA.

5. If the drug has been approved for use in pregnancy, or labor and delivery, or lactation this should be explicitly stated in the "*Indications and Usage*" section of the label.

6. The FDA should make all FDA approved drug labelling available to health practitioners and the public via the Internet on an FDA sponsored website. Such a step would:
   - Increase the ready availability of important drug information
   - Facilitate the detection and reporting of adverse drug reactions.
   - Overcome the growing problem created by drug manufacturers who choose to omit their drug labelling from the Physicians Desk Reference(PDR),

7. The FDA should initiate an FDA sponsored Pharmacopeia to serve as a printed source of FDA approved drug labels.

Respectfully submitted,

00N-1269

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