From: Loretta.Robertson@frx.com
Sent: Friday, June 22, 2001 11:16 AM
To: fdadockets@oc.fda.gov
Subject: Docket No. 00N-1269 - Labeling for Human Prescription Drug/Biolog ic Products

Dear Dockets Management,

Forest Laboratories submitted comments to Docket No. 00N-1269 (Labeling for Human Prescription Drug/Biologic Products) using the text box entry form on FDA's internet website. Our assigned comment number was EC-30. We would like to provide you with our comments in the attached .pdf file, in case document formatting was lost in the text box entry. Thank you for assistance in this matter.

<<Forest Comments_Docket 00N-1269.PDF>>

Sincerely,

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FDA's Proposed Rule: "Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels"
[Federal Register Vol. 65, No. 247] December 22, 2000

I. General Comments

Forest agrees with the FDA's objective to make prescription drug labeling more accessible, readable, and useable. Forest believes that this objective is best met by the FDA's proposed reorganization of sections in the Comprehensive Prescribing Information. Forest questions the appropriateness of including the Highlights of Prescribing Information because of product liability issues and because of potential conflicts among labels in drugs of the same class. Forest supports the inclusion of the Index and believes this section will be useful to prescribers looking for targeted information in a package insert and will be useful in future electronic labeling.

Forest questions whether the labeling proposal will have an impact on avoidable adverse drug events, as assumed in the agency's economic analysis. Trying to decrease medication errors by improving drug package inserts is much like trying to decrease car accidents by improving automobile owner's manuals. Though it is certainly useful to provide understandable information, it is the system itself and the operators of the system that incur the risk of accident.

II. Specific Comments

A. Highlights of Prescribing Information [proposed § 201.57(a)]

1. Product Liability

Forest questions the appropriateness of including the Highlights section in the package insert. Forest believes that inclusion of this section is definitely a product liability concern, despite FDA's comment that this is "highly speculative." If the Highlights section is ultimately retained in the final rule, Forest recommends moving the "Highlights limitation statement" [proposed § 201.57(a)(15)] from the end of the section to the beginning so that it appears first in the Highlights section. Given the reality of time constraints in today's healthcare system, Forest is concerned that prescribers may not consult the Comprehensive Prescribing Information if presented with a shorter option.

2. Class Labeling

Forest is concerned that the Highlights section may become problematic if companies are left to extract their own Highlights. This could be particularly problematic with drugs of the same class, as different companies will apply different criteria to determine what should be included/excluded in the Highlights section. The section could turn into a marketing vehicle if the agency does not standardize wording across drugs in the same class.

3. Recent Labeling Changes

Companies should not be required to remove information from this section within a fixed time limitation. Removal of old information should be allowed at the next labeling revision. The section could be renamed "Last Labeling Revisions" to remove the connotation that revisions were recent, since years could elapse between revisions. Also, FDA should establish parameters regarding which changes should be included in the revision section, as not all labeling changes are clinically significant.

B. Index to Comprehensive Prescribing Information [proposed § 201.57(b)]

Forest supports the addition of the Index. This will help healthcare providers orient themselves to the new labeling format and provide a reference for targeted searches of the package insert. However, the Index adds length to the labeling, which would be compounded if a Highlights section is included as well.

C. Comprehensive Prescribing Information [proposed § 201.57(c)]

1. Duplication of black box

In the current proposal, the black box would be printed twice in the labeling, adding even more length to the insert. However, it would be inappropriate to shorten a black box warning in the Highlights section since this wording is already succinct and carefully negotiated with FDA. Shortening the black box warning implies that some of the information is less important, which contradicts the purpose of a black box warning.

2. Inclusion of company phone number

Forest is in favor of making company phone numbers accessible, but would like the Agency to consider the possible impact on companies in terms of increased number of calls and possible increases in personnel to process calls. Inclusion of a company phone number in the package insert is likely to increase workload for company call centers, particularly in spontaneous reporting by patients who commonly have access to professional labeling in today's climate of patient empowerment.

D. New Format Requirements [proposed § 201.57(d)]

1. Font

The proposal to require 8-point font is not likely to benefit prescribers since they do not often come into contact with the product packaging. As FDA acknowledges in the proposal, prescribers are most likely to consult the PDR for labeling information. Will the PDR be changed to meet the 8-point font requirement? If so, this is likely to increase the size of the PDR dramatically. Additionally, the increase in package insert size will be a production burden, potentially requiring new package configurations and new equipment. FDA will likely be overwhelmed by waiver requests from companies unable to implement the new font size.

2. Color

Forest opposes requiring the use of color in package inserts. The use of color would significantly increase the cost and complexity of the printing process. Additionally, colored inks are more prone to bleeding, which would lead to more printing re-runs.

3. Vertical Line

Forest opposes the use of a vertical line to highlight revisions. The vertical line may draw undue attention to revisions that do not have clinical significance. Also, vertical lines would introduce another element of complexity in the printing process and would be very distracting in the case of extensive revisions.

E. Revisions to Prescription Drug Labels

1. Dispensing Information

Forest opposes the removal of dispensing information from the label, particularly in cases where special dispensing instructions are required (e.g. protect from light). Burying this information in the package insert would have a negative impact on pharmacies, particularly in a hospital setting where products are frequently repackaged and are frequently stocked on shelves without immediate access to the package inserts.

2. Inactive Ingredients

Forest opposes the wholesale removal of inactive ingredients from labels. The inclusion of inactives should be allowed if related to potential allergens. Exclusion of this information would be a liability and a public health concern.