DuPont Pharmaceuticals Company

6377 '01 MAR 23 P1:03

March 20, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20857

SUBJECT: COMMENTS ON FDA PROPOSED RULE
Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics
Requirements for Prescription Drug Product Labels
Docket No. 00N-1269

Dear Sir or Madam:

Reference is made to the above-mentioned proposed rule, which was published in the December 22, 2000, edition of the FEDERAL REGISTER.

In response to this notice, enclosed are comments submitted by the DuPont Pharmaceuticals Company to this proposed rule.

We appreciate the opportunity to comment on this proposed rule.

Sincerely,

Jamie Warner

Jamie Warner
Director, Regulatory Affairs
Labeling and Emerging Markets

Submitted in Duplicate

Enclosure

00N-1269

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COMMENTS ON FDA PROPOSED RULE
REQUIREMENTS ON CONTENT AND FORMAT OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS
REQUIREMENTS FOR PRESCRIPTION DRUG PRODUCT LABELS
Docket No. 00N-1269

OVERALL COMMENT ON PROPOSED RULE

The comments provided in this document reflect those of the DuPont Pharmaceuticals Company. We agree that the proposed rule makes viable upgrades to current labeling design and will improve the utility of prescription drug prescribing information. However, we believe that the proposed rule needs to balance the needs of prescribers with those of pharmaceutical manufacturers by establishing appropriate criteria for content; for example, in the proposed HIGHLIGHTS Section. These criteria would foster consistent inclusion of information for all products by all manufacturers. We also think that repetitive information within the HIGHLIGHTS and COMPREHENSIVE PRESCRIBING INFORMATION Sections of the proposed labeling should be discouraged since it will cause the final labeling to be longer and more complicated than necessary. We agree with the future use of electronic media to facilitate access to prescribing information as long as appropriate measures are in place to ensure that this access is available to all interested parties.

HIGHLIGHTS SECTION

General Comments

- We agree with inclusion of HIGHLIGHTS Section but recommend that a bulleted format be used to avoid repetition of information already included in Comprehensive Prescribing Information. This approach would enhance the purpose of the section, which is to foster focus on most critical information.

- We believe that more specific criteria needs to be established regarding information to be included in this section to ensure consistent presentation for all products, especially in light of the proposal to limit the size of this section.

- In addition to inclusion of manufacturer and MedWatch telephone numbers for reporting adverse reactions, suggest that manufacturer website address also be included since this is another viable reporting method.

Recent Labeling Changes

- Recommend that heading be revised to "Latest Labeling Revisions" since revisions may not be "recent," depending upon last time prescribing information was revised.

- Do not recommend time limit to removal of information in this section. Recommend that section remain until next labeling revision. Inclusion of date of last revision will define age of revision. By mandating removal of section, could result in additional labeling revisions not necessarily driven by substantive labeling changes.

- With regard to handling editorial revisions such as name changes, if this is only revision impacting prescribing information, it would not fit into definition of "substantive" labeling changes. Would recommend that when labeling changes are made for non-substantive reasons only, that this section indicate main non-substantive reason for revision (i.e., company name change, phone number are two types of revisions that cannot wait until a more substantive revision to the labeling is made).

Indications and Usage

- Agree with bulleted format in HIGHLIGHTS Section rather than duplication of information contained in comprehensive prescribing information.

Dosage and Administration

- Tabular format is a useful way to present this information. We also suggest that a bulleted format be an acceptable alternative due to potential space limitations.

COMPREHENSIVE PRESCRIBING INFORMATON: INDEX

- While we agree with the Agency's assessment that the HIGHLIGHTS Section and INDEX serve distinctly different purposes, we believe it is worthwhile to explore the possibility of consolidating the information of the two sections.

COMPREHENSIVE PRESCRIBING INFORMATION

- Recommend that the How Supplied/Storage and Handling Section remain at the end of the COMPREHENSIVE PRESCRIBING INFORMATION for ease in location by prescribers. By placing it as the fourth section, it may be difficult to locate depending upon the length of the previous three sections.

- Under the proposed rule, only responses that are noxious (ie, injurious to health) and unintended would be considered an adverse reaction. We recommend that specific criteria be established by the Agency to ensure consistent application/determination by all sponsors as to whether or not an event is injurious to health as well as causality.

- With regard to the proposal to "reprint" all approved printed patient information under Patient Counseling Information, we believe that it would be more effective to continue to prepare these documents separately from the COMPREHENSIVE PRESCRIBING INFORMATION document to encourage dissemination of this critical information to the patient. If this information is "reprinted" as part of the COMPREHENSIVE PRESCRIBING INFORMATION, it may not be appropriately disseminated and will potentially be a smaller font than provided in currently-distributed patient information.

FORMAT PROPOSALS

- We agree with use of different bolding techniques and symbols to highlight or distinguish information; we do not recommend use of color. However, if the Agency decides to use color, specific Pantone colors must be assigned by the Agency to ensure consistent application by all sponsors. In addition, a standard for use of color should be established, i.e., for specific sections or specific types of information.

- Believe that an 8-point font is sufficient size; 10-point font will greatly impact manufacturer's ability to meet content requirements as well as packaging specifications (i.e., size of package inserts distributed with product).

- Need to assess impact of 1/2 page restriction to HIGHLIGHTS Section. At an 8-point font, it will be difficult to accommodate all of the requirements of the HIGHLIGHTS Section into the allotted space (1/2 of an 8 1/2" x 11" page). This limitation could increase company liability by forcing the need to eliminate information that would have been considered critical had there not been a space limitation.

- Use of vertical line to designate new information is very effective tool.

CONTAINER LABELS

- With regard to removal of statement from container label referring user to full prescribing information for dosage information, we believe that this statement can be removed prior to revisions to package insert. The package insert already contains dosing information that should not be impacted by requirements of proposed rule.

- Recommend that the statements related to storage and handling currently on the container labels remain on container labeling as an added reminder for prescribers and users to ensure proper handling and dispensing of product.

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