SCHWARZ
PHARMA

Comments on:

Requirements on Content and Format of Labeling
For Human Prescription Drugs and Biologics;
Requirements for Prescription Drug Labels;
Proposed Rule (65 Federal Register 81082 (12/22/00))
Docket No. 00N-1269

Schwarz Pharma, Inc. (SPInc) hereby submits the following comments to the above cited proposed rule published in the Federal Register of 12/22/00.

Highlights Section

In regards to the appropriateness of a Highlights section and the effects this section would have on manufacturers' product liability, SPInc asserts that a Highlights section is not appropriate for inclusion in the labeling of any prescription drug product. The Federal Register notice states that the proposed revisions to product labeling, including the proposed Highlights section, would make it easier for health care practitioners to access, read and use information in prescription drug labeling. In addition, the proposed changes would enhance the safe and effective use of prescription drugs. The Federal Register notice presents no evidence that the proposed insert, especially the Highlights section, actually results in an improvement in the accuracy of information a doctor, or any reader, obtains from the insert. It appears illogical that further condensing information regarding a drug product would lead to safer and more effective use of the product.

A drug product manufacturer's liability is certainly significantly impacted by providing limited information in a Highlights section, which has a high probability of being the only information reviewed by the reader. The proposed disclaimer to be placed at the end of the Highlights section would be a weak legal defense in a society where an alleged injured party does not hesitate to initiate legal action.

SPInc suggests that the use of the proposed index and the reorganization of the comprehensive prescribing information would meet the objectives stated in the Federal Register notice while avoiding the risks connected to the use of a Highlights section. The index would quickly and easily direct the reader to the section of the labeling which includes complete and accurate information regarding the drug. To take this information which has already been deemed by the FDA to be necessary for the safe and effective use of the product, and reprint selected portions of it in a Highlights section would be a tremendous disservice to the health care practitioner and the patient.

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In addition, adding a Highlights section would significantly lengthen the size of the labeling. In some instances, labeling currently formatted as product inserts may no longer fit in the approved bottle/container. As a result, these inserts would need to be redesigned as package outserts. This leads to a considerable monetary and administrative burden for the manufacturer, as packaging equipment may need to be purchased to accommodate the new package outsert and since the removal of the insert affects the product's approved container/closure system, additional stability studies must be conducted to support the change to the container/closure system.

Boxed Warnings

If a Highlights section is required as a part of the final rule, a boxed warning contained in this section must contain the full text. Information considered to be so vital to the safe and effective use of the product, requiring a boxed warning, cannot be adequately summarized for purposes of adhering to a formatting length limitation within the Highlights section.

The proposed exclamation mark icon (!) to indicate a boxed warning does not sufficiently capture a reader's attention, as the icon can easily flow into the style and content of the text. In addition, it may be difficult to recognize an exclamation point in small font. SPInc believes that the use of the box, itself, to indicate the warning adequately alerts the reader to the information, as the box is easily recognizable and its function is familiar to health care practitioners.

Recent Labeling Changes/Labeling Revision Date

SPInc seeks clarification regarding the time limit of the information to be included in the proposed Recent Labeling Changes section. Section III B.1.e. (page 81089) of the Federal Register notice states that this information is permitted to remain in the labeling after the 1-year period until the next labeling *revision*. However, proposed §201.57(a)(5) (page 81114) of the Federal Register notice states that the information included in the Recent Labeling Changes section "must be retained in the labeling for at least 1 year after the date of the labeling change, and may be retained until such time that the labeling is *reprinted* for the first time following the change" (italics added). SPInc suggests that the labeling change information be allowed to remain beyond the 1-year period, until the time of the next labeling revision. Since removal of the labeling change information would, in itself, constitute a labeling revision, manufacturers would incur increased and unnecessary administrative and material costs to remove information that has absolutely no effect on the safe and effective use of the product.

In addition, since multiple changes can occur to a product's labeling within a 1-year time period, SPInc suggests dates (mm/yy) appear after each description of a labeling change to ensure practitioners are aware of the date of the most recent labeling revision.

Although SPInc objects to the inclusion of a Highlights section, should the section remain in the final rule, the proposed placement of the labeling revision date at the end of this section should be reconsidered. In order to allow for accountability and tracking mechanisms utilized by manufacturers, the labeling revision date must appear at the top of the product labeling, near the labeling bar code.

Indications and Usage

SPInc does not believe it is possible to adequately summarize a drug product's indications and usage information while maintaining safe and effective prescribing practices of the product. If a Highlights section is required, this information should be taken verbatim from the Comprehensive Prescribing Information.

Index

As previously stated in this correspondence, SPInc believes the addition of an Index section, along with the proposed reorganization of the Comprehensive Prescribing Information, would significantly improve access and use of a drug product's information. An index will quickly refer the health care practitioner to the specific desired information and assure the information is complete and accurate. SPInc suggests that it may be less cumbersome for a health care practitioner to use the index to direct him/her to the desired section than it would be for a health care practitioner to read truncated information in a Highlights section only to have to read an additional section to access the complete information.

Warnings/Precautions Headings

SPInc feels it is not necessary to require standardized headings in this section. A manufacturer should be allowed flexibility to compose and format this section so that it communicates the information in a fashion most appropriate for the particular drug product.

Contacts for ADR Reporting

SPInc strongly opposes the inclusion of a Highlights section and suggests that if removed, FDA may consider moving the ADR reporting contacts information to the beginning of the labeling, allowing for a more prominent and easily accessible location of the information. Should the proposed Highlights section be required as part of the final rule, SPInc believes that the ADR reporting contact information should be included in the Highlights section as well as in the Comprehensive Prescribing Information section.

Bolded Information

SPInc believes this method of adding visual prominence to certain information is sufficient.

One-half Page Limit of Highlights Section

Once again, for reasons previously discussed, SPInc restates its objection to inclusion of a Highlights section. In the event that a Highlights section is retained in the final rule for prescription drug labeling, SPInc feels that a one-half page limit is insufficient to assure that all necessary information is captured in the Highlights section. It may not be possible to condense information on complex and/or combination drug products to one-half page in length. In addition, manufacturers with drugs which are the subject of class labeling may choose to include different information in the limited Highlights section of labeling for their respective products.

While FDA presented an example of a reformatted insert which includes a one-half page Highlights section, FDA must recognize that a large number of product labeling contains vital information which cannot be easily or accurately compressed into a one-half page section. Thus, the very real possibility exists that the length limitation applied to a Highlights section could result in increased medication errors because manufacturers were required to truncate or otherwise compress important information.

Font Size

SPInc opposes the proposed minimum 8-point font size and suggests that the currently utilized smaller font sizes (6-7 point) are appropriate. A larger font size would have a significant impact on the size of the labeling, equipment used for printing and packaging and the ability/inability to attach the labeling to the approved bottle. In addition, labeling requirements for OTC drug products allows for a font which is smaller than the proposed 8-point font size. SPInc suggests that the same font size standards be applied to labeling for prescription drug products. A smaller font size should not impact readability for physicians, since they typically access a product's labeling through the use of the Physician's Desk Reference or means other than trade packages.

A larger font size could be used for printed patient information. The proposed 8-point font be may an appropriate minimum standard for printed information directed to the patient.

Patient Information

SPInc requests clarification on proposed §201.57(c)(17) and §201.80(f)(2) which requires "any approved printed patient information" to be reprinted immediately following the labeling. SPInc has several products with separate patient instruction inserts that contain

only technical information concerning the use of the dosage forms. These products include aerosols, which require the patient to fill an applicator, an injectable that requires reconstitution of the drug product in a vial or cartridge, and a transdermal delivery system with application instructions. The patient instructions are now included in separate patient information inserts which are packaged with the products. Since the separate patient information inserts are directed toward the patient rather than the health care practitioner, larger fonts, illustrations and colors are often used. To incorporate this information into the package insert would considerably lengthen the insert, leading to redesign of the insert and possibly the outer carton, and increasing expense.

It may be noted that at this time, §201.57(f)(2) also calls for the full text of any approved printed patient information to be reprinted at the end of the labeling. However, FDA has not required that SPInc reprint patient instructions with such technical information in full at the end of the package inserts. It is hoped that this practice would continue, but SPInc believes that clarification of the regulations is required, given the wider scope of the new proposed regulations.

Drug Labels

SPInc does not agree with the proposal to eliminate dispensing information from drug labels in order to lessen overcrowding of the label. Removing this information from the labeling and including it only in the product's package circular would lead to increased inefficiencies and frustration for the dispensing pharmacist. Overworked pharmacists should not have to retrieve a package circular to locate information that is currently easily and quickly accessible on the product label.

SPInc appreciates the opportunity to respond to the proposed rule for prescription drug labeling and drug product labels.

Respectfully submitted,

SCHWARZ PHARMA, INC.

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Director
Regulatory Affairs and Quality Assurance

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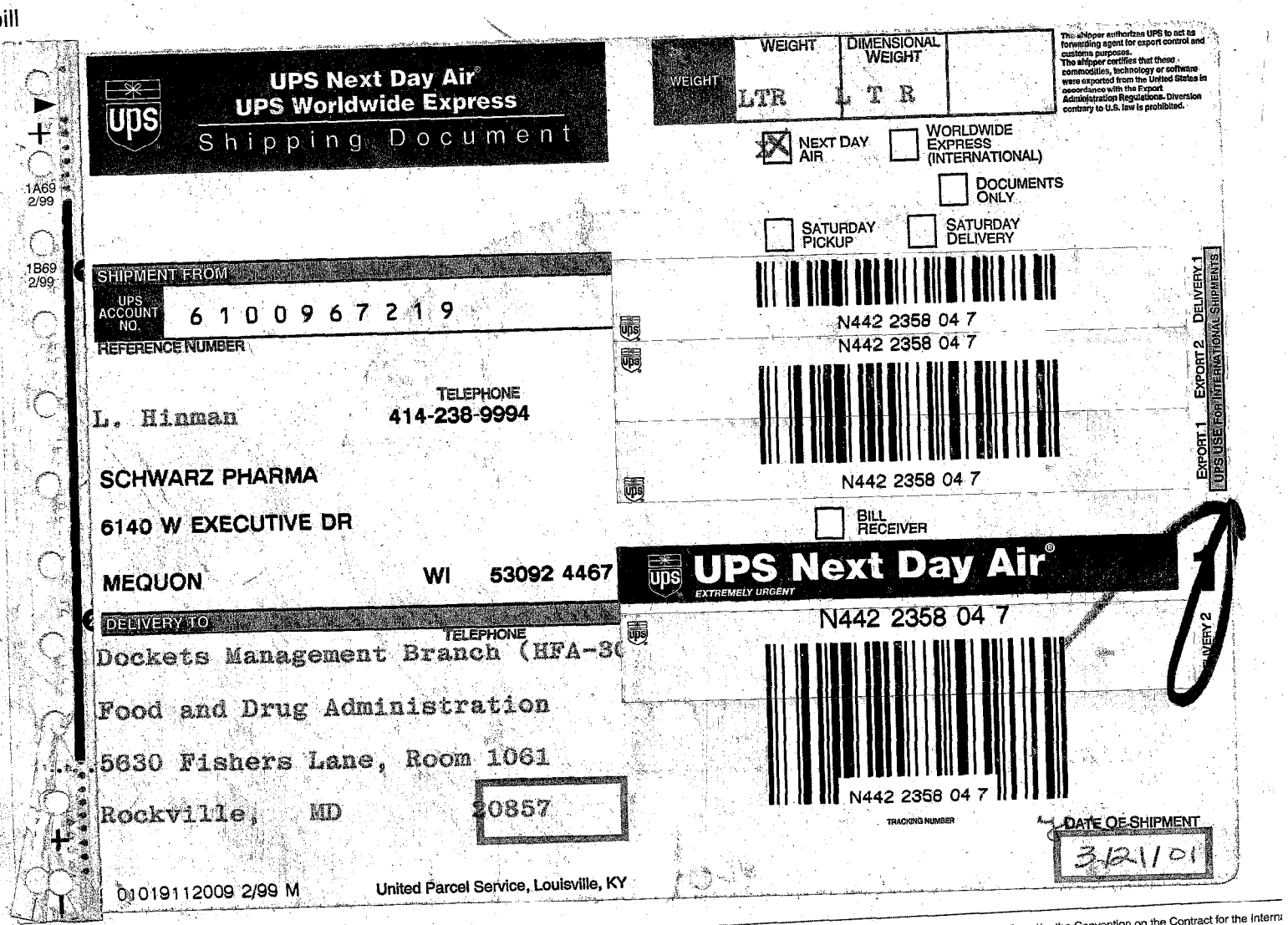

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