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Dockets Management Branch
Food & Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Ref: Docket 00N-1269-21CFR Part 201-Proposed Rule
Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels.

Dear Sir or Madam:

Vijuk Equipment, Inc. (VEI), is pleased to provide comments on the Food and Drug Administration's December 22, 2000, "Federal Register Notice Requesting Comments on the Proposed Revisions to FDA's Regulatory Requirements for Prescription Drug Product Labeling."

It is a shame that the current leaflets have very little use to the average reader because the type is too small to read or they are written in terminology that the average educated person doesn't understand. Pharmaceutical companies are currently spending millions of dollars on leaflets that aren't being used, so why not spend a fraction of a percent more and produce a new leaflet that will truly serve the main purpose that they are intended for? The other shortcoming of the current system is that leaflets don't end up in the hands of the right people. The FDA should make it mandatory that all physicians, pharmacists and, most of all, consumers receive this vital informational leaflet.

VEI would like to commend the FDA for taking the initiative to revise professional product labeling, and we hope it will produce more useful and user-friendly prescription product labeling for everyone who is involved with prescription drugs/information throughout the United States.

With over 270 million people, including 300,000 physicians, 75,000 pharmacists, as well as other medical professionals, the entire population will benefit from this new FDA proposal. Consumers will benefit the most, because they will receive better service from the medical community and they will be better educated about their medicines.

Following are Vijuk Equipment's comments and answers to the FDA's questions:

00N-1269 C51

1. *Whether, and under what circumstances, it may be inappropriate to include the proposed "Highlights of Prescribing Information" section in the labeling of a particular drug or drug class.*

VEI agrees with the proposal that "Highlights of Prescribing Information" will enhance the usefulness of labeling for providing prompt, important information to the reader. This information is invaluable to a certain population of readers and should be available for quick, easy access by individuals in need of that information.

2. *Does the inclusion of a highlights section have a significant effect on manufacturers' product liability concerns and, if so, is the concern adequately addressed by: (a) Titling this section "highlights" rather than "summary"; and (b) including the following statement, in bold, at the end of the highlights section: "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." If these are not sufficient, could the agency take different or additional measures to alleviate product liability concerns without eliminating the highlights section altogether or lengthening it to an extent that it would no longer serve its intended purpose*?

No comment.

3. *Whether the full text of any boxed warnings should be included in the proposed "Highlights of Prescribing Information" section, regardless of length.*

We feel that the boxed warning should be included in the proposed "Highlights of Prescribing Information." However, we are not convinced that the entire boxed warning need be included in this section. May we suggest using a brief summary of the boxed warning with an index number showing where the person reading this can obtain additional information.

4. *What different types of icons could be used to signal a boxed warning and what are their costs and benefits?*

If an icon is used to signal a boxed warning, it will only be beneficial if the icon is a universal worldwide symbol. For example, we would recommend that the boxed warning be indicated by a symbol of a stop sign, a universal symbol that everyone recognizes and acknowledges. The inclusion of this feature does not have any impact on the cost of inserts.

5. *Whether there should be a time limit by which the "Recent Labeling Changes" section must be removed.*

We believe that there should be a time limit to "Recent Labeling Changes." We would like to see the changes remain for at least one to three years of time. This proposed rule would keep everyone up-to-date on the most recent change regarding that prescription. Also, every change should include the effective date (month/year).

6. *Whether the information required under the "Indications and Usage" subsection in the proposed "Highlights of Prescribing Information" section should be presented verbatim from the comprehensive labeling section or summarized in a bulleted format.*

We recommend that this information be summarized in a bulleted format. However, after every bullet, we recommend including a reference number indicating where the individual would find more comprehensive information within the leaflet. This will be directly related to the new index system.

7. *Whether it is necessary to include the proposed requirement for an index section given the proposed requirement for a highlights section (i.e., do the additional purposes served by the index justify its inclusion?)*

The index is an excellent and universal way for finding information that a particular reader is looking for. Most things of value that reference vital information have an index enclosed, so there is no reason why documents as important as pharmaceutical leaflets should not have an index. This will greatly reduce the time it takes to find vital information, and it will increase the overall usefulness of the leaflets.

8. *Whether or not including standardized heading in the "Warnings/Precautions" section is appropriate. If it is believed that specific standardized headings should be included, FDA requests comment about what they should be.*

No comment.

9. *Whether it is necessary to include a contact number for reporting suspected serious adverse drug reactions in the proposed "Comprehensive Prescribing Information" section as well as the proposed "Highlights of Prescribing Information" section.*

Providing a contact number for reporting suspected serious adverse reactions in the leaflet would help gather vital information. Doing so would increase the chances of the individual reporting reactions because it is easy, convenient and not time consuming. It has been proven that, if it is inconvenient to do so, people will not report their findings.

Our recommendation is to include a contact number in this section.

10. *Whether the potential impact of the proposed rule on small entities has been accurately estimated by the agency, and whether small business concerns have been adequately addressed.*

No comment.

11. *Whether the proposed requirement to bold certain information in proposed Sec. 201.57 (d) (5) will serve its intended purpose of ensuring the visual prominence of the bolded information, or whether the different highlighting methods may be more effective.*

We feel that it is good to bold certain information within a leaflet. Because headings are so important and, at times, need to be noticed quite quickly, we suggest that all headings should be in bold type and, possibly, two (2) point sizes larger than the rest of the body. This will enable individuals to find their information as quickly as possible.

12. *Whether the proposed one-half page limit on the "Highlights of Prescribing Information" section (not including boxed warning(s) contraindication (s)) is adequate or whether there are alternatives that would be more appropriate and under what circumstances such alternatives should be considered.*

This "Highlights of Prescribing Information" is intended for the reader to get important and brief information pertaining to the product as rapidly as possible. Due to the fact that there are so many important highlights for any one product, it would be in the best interest of everyone that this section should be a minimum of a half-page in length. Every highlight should reference the index number indicating where to find the complete information.

13. *What means (other than the vertical line proposed in Sec. 201.57 (d) (9)) could be used to facilitate access to, and identification of, new labeling information in the proposed comprehensive prescribing information sections.*

No comment.

14. *Whether the proposed minimum 8-point font size for labeling is sufficient or whether a minimum 10-point font size would be more appropriate.*

Currently the font size in package inserts is not large enough for the majority of the population to read without difficulty. This has been a complaint for many years, and we are happy to see that the FDA will correct this shortcoming in the future.

With the best interests of the entire population in mind, we would recommend that the font size be a minimum of 8-point type. It is also our recommendation that if a section, or a specific leaflet, is intended for the general public, it should be in a minimum of 10-point type. Also to make this more user-friendly and easier to read, we would like to suggest that all headings be at least 2 point sizes larger than the balance of the body.

Even though this new proposed type size would incrementally increase the size of the insert, there may be a general concern among manufacturers that there could be problem in producing an insert with this expanded type size; however, we would like to assure you that there is a solution to this problem. Even if this leaflet would grow 50%, 75%, or 150%, equipment is available to produce these leaflets at a very economical cost. Also, these manufacturers will point out the additional cost of this new proposal, but everyone knows that this cost will be passed on to the consumers. Most of the population knows that there is always a cost associated with the provision of good information. When dealing with someone's life, those costs are acceptable for such vital information.

15. *Whether the revised format and content requirements should be applied 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 of the final rule, or that has been approved from 0 up to and including 5 years prior to the effective date of the final rule, or whether alternative application criteria should be used.*

VEI feels that, in the best interest of the entire population, this new proposal should cover any and all prescription medications, and adherence to this proposal should be required as quickly and efficiently as possible. If this new proposal is designed to help the entire public, there is no reason why older medications should be excluded. The older medications are still being used today and are being prescribed by new physicians and filled by new pharmacists for new patients. With this in mind, the FDA owes it to those populations to provide them with the most up-to-date leaflet format available.

Below, please find a schedule that is feasible for the pharmaceutical industry.

Original Approval Date	Timing for Newly Revised Leaflet
1 year	1 year
2 years	2 years
5 years	3 years
10 years	4 years
20 years and beyond	5 years

General Comments and Suggestions

- Knowledge about a new product (one being marketed in the last three years) is very important to the reader. Because of this, the FDA should find a universal sign that could be used on all leaflets which would indicate to the reader that it is a *new* product. If the reader would visually see this sign, it may trigger them to read additional information to learn more about the product. This may reduce some of the problems and casualties related to new products.

- This new proposal will benefit each and every one of us in North America and will probably benefit future children of this country. Considering that this new proposal and format will be that valuable to the entire population, there seems to be no logical reason, whatsoever, why this proposal shouldn't be mandated on all new and existing medicines. With the positive benefits from this proposal, we owe it to the entire population to provide them with as much and as up-to-date information as possible; and this new proposal is the tool to make that happen.

- The proposal indicates that there is a need to educate physicians and pharmacists on this new proposal regarding requirements, content and format of labeling for human prescriptions, drugs and Biologics. Because these leaflets are not only used by physicians and pharmacists, it would be best to open up this educational program to the entire population. With the fact

that more patients are reading their leaflets, the only conclusion is that the FDA has an obligation to educate the entire population.

- Because drug manufacturers are advertising and marketing their products in many different formats, it is their obligation to educate the consumers on the entire products. The advertising being done by the manufacturer only highlights the positive aspects of the product and does not address many of the negative consequences. It is only fair to the consumer that, if the manufacturer points out the positive aspects of the product, they should also provide detailed information to the consumer on the negative aspects, as well. If drug manufacturers continue to advertise in this manner, then they should be obligated to provide these informational leaflets to every consumer who is using their product. The manufacturer should be responsible for getting a leaflet into every one of their consumers' possession.

- Due to the fact that there are multiple changes occurring in product labeling in any given year, the FDA should implement in their proposal that the leaflets should be dated with the most recent revision number. This date would help the reader know if there are any new updates or changes to that particular leaflet.

- There is a strong consensus among the entire population that the FDA should mandate drug manufacturers to provide a leaflet to every patient. Patients should know specifically what they are taking and what the pros and cons are for that medication. The truth of this situation is that most patients do not know anything about their medication because they were never provided with proper, thorough, and easy-to-read information. The FDA has a fiduciary responsibility of protecting people, so they should mandate that drug manufacturers provide leaflets to every patient who is taking their product. What other product does any person purchase or consume that does not come with a complete set of directions or information? Why are prescription drugs excluded from this universally-accepted procedure?

- There is a need for clarification of what products this new proposal will cover. The one product category that does not seem to be covered by this new proposal is product samples. Pharmaceutical companies give away millions of samples a month, and they should be obligated to also provide a leaflet with every sample. If these companies give away free samples to consumers and physicians to promote their products, they should also be responsible to provide them with all the information regarding it. We recommend that the FDA include product samples in this new proposal.

- There seems to be an organized movement towards providing electronic information or paperless inserts. We believe that the electronic avenue is an extremely strong tool and that they should continue providing information via the information highway (Internet). However, the fact is that no one wants to search for information when they desperately need it. There is no product in the world that comes with no information or directions and, instead, refers the consumer to the Internet for complete information. Imagine, for example, that your new car didn't come with an instruction booklet, you get a flat tire on a country road, and the only direction you have is to go to www.ford.help. It isn't imaginable that the FDA would even consider an alternative to having complete information enclosed with a product.

Considering that the physicians in training, pharmacists, nurses, pharmaceutical scientists, pharmacy students, pharmacy technicians, etc., are most likely to read the approved product labeling when they are up against time-sensitive and unusual, complicating consequences, it is imperative and life-threatening that the complete product labeling be readily available at a moment's notice. If a particular individual needs the label information immediately, there is not always time to connect electronically to a database to acquire that time-sensitive information. The information highway is a very good tool; however, in most cases it is not a viable option when dealing with pharmaceutical products and, ultimately, people's lives. Although manufacturers are pushing for a paperless insert, there is no way the FDA should allow this, because it would have a drastic impact on people's lives, and the National Academy of Sciences' statistics regarding U.S. deaths annually due to medical errors would show a great increase.

- All positive changes have an associated cost. Most drug manufacturers will be against this proposal, because there will be added costs to produce these new leaflets. However, when you compare this cost to the revenues of these humongous corporations, there is no financial impact, whatsoever. But when considering the cost as opposed to the lives that will be saved because of the reduced medical errors, *there is no comparison.*

Conclusion

In conclusion, Vijuk Equipment, Inc. supports the FDA proposal for requirements on content and format of labeling for human prescription drugs and Biologics. We believe that the industry's responsibility is to provide information with their products which will be rapidly available, more user-friendly, and informative to all of their various readers.

Finally, we appreciate the opportunity to comment on this important issue in the proposed rule. We hope that the FDA will make their decision based on the best interests of the consumer, as well as medical professionals. We also hope that the FDA can expedite this proposal, so that it can be implemented as soon as possible for the immediate benefit of everyone.

If the FDA has any questions, or if you would like VEI to provide additional pertinent information, please contact me at (630) 530-2203.

Sincerely,

VIJUK EQUIPMENT, INC.

Roger B. Mattila

Roger B. Mattila
Manager, Administration and Sales

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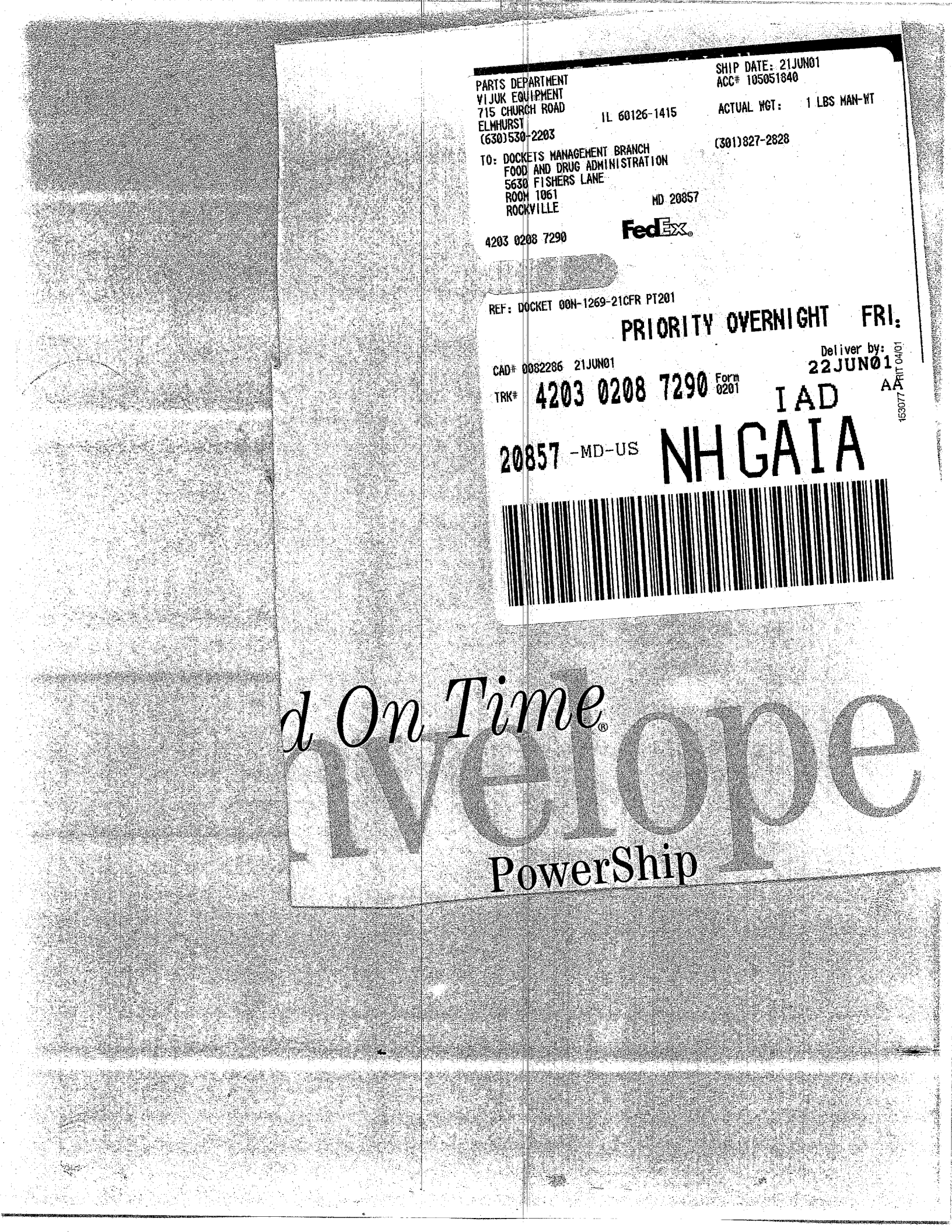
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