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March 1, 2002

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Food and Drug Administration  
Department of Health and Human Services  
Room 1-23  
Rockville, MD 20857

## Petition for Stay of Action Docket No. 98N-0583 Exports: Notification and Recordkeeping Requirements

Dear Sir or Madam:

This petition is submitted under 21 C.F.R. § 10.35 in response to the Final Rule on "Exports: Notification and Recordkeeping Requirements" Docket No. 98N-0583 published by the Department of Health and Human Services, Food and Drug Administration, in the December 19, 2001 *Federal Register* (66 Fed. Reg. 65429). By this submission, we hereby request a 180-day stay of the effective date for compliance with the new export notification and recordkeeping requirements contained therein, as well as a 180-day stay in any enforcement activities associated with compliance of these new provisions. Sandler, Travis & Rosenberg, P.A. represents clients who would be adversely affected if the effective date were not stayed.

### A. Decision Involved

The Food and Drug Administration published its Final Rule on "Exports: Notification and Recordkeeping Requirements" on December 19, 2001, (66 Fed. Reg. 65429) (Docket No 98N-

98N-0583

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0583), establishing notification and recordkeeping requirements for exporters of drugs, biological products, food, and cosmetics which are not marketed or sold in the United States.

#### B. Action Requested

The effective date of the Final Rule, published on December 19, 2001, is March 19, 2002, thus allowing for only a 90-day implementation time frame. This petition requests a 180-day stay until September 19, 2002 is to allow companies affected by the new regulations to clarify issues that were not fully understood or analyzed during the comment period. Companies have been awaiting the final rule to develop and deploy policies and procedures to ensure that they will be in compliance with all applicable requirements. As published, however, the final rule does not provide the necessary clarification as to the scope of certain issues arising out of these regulations and allows an insufficient time to implement them, thereby making it extremely difficult for large multi-category, multi-facility manufacturers to comply.

#### C. Statement of Grounds

##### 1. Limited Implementation Time

The Final Rule was published on December 19, 2001 immediately prior to the holiday season. Most large manufacturing companies traditionally close during the holidays; therefore, they have had even less time to establish internal procedures and training. A 90-day time frame may be practical for a small, single commodity exporting company, but for large multi-category manufacturing companies, the logistics, coordination, and implementation of a program across multiple plants and facilities is complex and exceptionally difficult to accomplish within such a short window.

For example, in many companies, centralizing the FDA compliance functions in order to meet the requirements of these new regulations is neither practical nor feasible from a business perspective; therefore, these companies are being required to develop policies and procedures to ensure consistent compliance across the board. The new practices must then be communicated to the various facilities, followed by educational and training sessions to the appropriate individuals in each location. Once the facilities have been educated and had time to implement the new procedures, responsible companies need to undergo testing to ensure that each facility has implemented the procedures. Finally, the companies need to specify and communicate a response plan for future FDA audits on these procedures.

Clearly, the goal for a large multi-category manufacturer (as well as for FDA) is to automate the process wherever possible to reduce the risk of human error and to increase compliance. In some cases, the necessary records may already be on hand in a different department or a different

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format, but the companies must first analyze their systems to make those determinations and whether any new records need to be created to ensure compliance. The companies must also ensure that any new records created are compliant with 21 CFR Part 11 for Electronic Records and Electronic Signatures.

One of the most difficult requirements of the new regulations is obtaining a letter from the appropriate foreign government agency or department that the exported product does not conflict with the importing country's laws. Clearly, obtaining a letter from a foreign government agency may be difficult or impossible to obtain. Those that are willing to comply may not feel sufficiently obligated to provide the documentation timely, thereby challenging the ability of companies to meet the 90-day implementation deadline. Based on the comments received to the proposed regulations and recognizing the inherent difficulties in obtaining this documentation, the FDA revised this requirement in the Final Rule by allowing, as an alternative, a notarized certification by a responsible company official in the U.S. stating that the exported product is not in conflict with the foreign country's laws. However, even providing this certification is not a simple process and requires lengthy legal research and evaluation of foreign import laws to ensure that such certification is in fact accurate. Once again, the limited time frame for implementation makes it difficult to accurately substantiate the legal requirements in order to prepare these certifications.

Similarly, the limited implementation schedule makes it difficult for companies to analyze the foreign labeling for products to determine whether adjustments are required in order to be in compliance. In some cases, additional wording on the label for compliance with Section 801(f) of the FDA Export Reform and Enhancement Act ("the Act") may not be viable or may make a drug appear unsafe. So a company may choose to comply with the requirements of Section 802 of the Act, thereby ensuring that the products will also comply under the provisions of Section 801(e). However, this analysis and subsequent development of procedures takes time and may not be completed by the March 19<sup>th</sup> implementation date.

## 2. Scope Issues

When the final rules were published, it was hoped that there would be additional details that would clarify the intended scope of the regulations. Clearly, products which are marketed or marketable for export are covered by the regulations, but there are many gray areas where the scope of the regulations is unclear.

For example, there is nothing in the Final Rule to clarify whether research and development materials, samples, bulk products, intermediaries, subassemblies, raw materials and IND or IDE products are covered by the notification and recordkeeping requirements. Queries to the FDA for clarification to date have left these questions unanswered. It appears that even the FDA has not

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contemplated the full ramifications of the notification requirements to its own staff. Components of drugs are still considered drugs by definition so, under the new regulations, it would appear that the first export of every component, such as silica to be used in toothpaste, would need to comply with the Act's Section 802 notification procedures, even though silica is a common material and can have any number of end uses which are not drug related. At the same time, in conversations with the FDA, it appears that they are unsure that they want to receive notifications for those types of exports.

Similarly, there has been little thought as to how the FDA wants mixes of products and product categories to be handled, such as toothbrushes with dentifrice, menstrual pads with antiperspirant, etc. Where should the notifications be sent – to the location for devices or the location for human drug products or to both? A similar situation exists with products that are called "on packs" or free samples that are given free to consumers, but are attached to other products. If there is a mixed product, where should the notifications be sent? And when are notifications required to be submitted relative to the actual export? The act requires that exporters provide the notification "when they actually export the drug or device," so does that mean that notification must be mailed at the time of export, received by FDA at the time of export, or within a certain number of days after export?

### 3. General Compliance Issues

Lastly, in general, there are concerns as to the administration of the new regulations. Because the scope is unclear in the Final Rule, it is anticipated that the administration and enforcement of these regulations may prove uneven. Different companies may take different approaches as to how they comply with respect to gray areas. Likewise, without clear direction, FDA auditors may take different attitudes as to whether a company is in compliance given the ambiguities in the regulations.

Large manufacturing companies have seen the same inconsistencies within other agencies when they have attempted to implement similar guidelines. For example, when the Environmental Protection Agency implemented regulations for compliance with the Federal Insecticide, Fungicide, and Rodent Act, the scope of that regulation was also ambiguous and as a result there has been uneven application of the exporting requirements among different companies and inconsistent enforcement within the agency. Companies drafting policies and procedures would prefer to have definitive requirements to ensure that they can communicate and implement those requirements consistently and effectively, and minimize the risk of any ambiguities or non-compliance in an audit environment.

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D. Conclusion

In light of the short implementation time frame and the remaining ambiguities as to the scope of the regulations, we respectfully submit that, for both the FDA and for exporting companies, a 180-day stay in the implementation date of the recordkeeping and notification requirements and any enforcement activities associated with the new regulations is appropriate. Such a stay, effective until September 19, 2002, will allow the FDA to clarify the details of the program and allow for multi-category, multi-facility companies to establish and implement procedures to ensure compliance.

Thank you in advance for your consideration of this request. Should you have any further questions, please do not hesitate to contact the undersigned at (312) 236-6555.

Sincerely yours,

**SANDLER, TRAVIS & ROSENBERG, P.A.**

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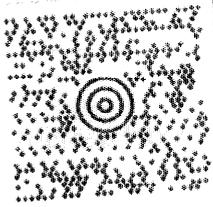


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