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5806 September 17, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket No. 00N-1663; Proposed Rule, Investigational New Drugs: Export Requirements for Unapproved New Drug Products; 67 Federal Register 41642 (June 19, 2002)

Dear Sir/Madam:

The following comments on the above-proposed rule are submitted on behalf of the Pharmaceutical Research and Manufacturers of America (*PhRMA*). *PhRMA* represents the country's leading research-based pharmaceutical and biotechnology companies. Our member companies are devoted to inventing medicines that allow patients to lead longer, happier, healthier, and more productive lives. In 2001, our members invested over \$30 billion in the discovery and development of new medicines.

*PhRMA* appreciates this effort by the Agency to simplify the existing requirement for export of investigational new drugs and we support this proposed rule. The following comments are given for consideration in preparing the final rule.

FDA states that it interprets section 802(c) of the FDA Export Reform and Enhancement Act of 1996 (FEREA) as permitting investigational drugs to be sent to principal investigators in a listed country for use by him or her in an unlisted country, if the studies in the unlisted country are conducted in accordance with the laws of both the listed and the unlisted countries. In our view, this interpretation is tantamount to an acceptance of transshipment, which the agency says is not permitted under FEREAs or the proposed regulation, although it is clear from FDA's justificatory language that it accepts that the law could be open to other interpretations and has been interpreted by some in other ways in the past. We believe that this point should be addressed more conclusively in the Final Rule. The reality is that, once a drug *is* exported from a listed country, even a conscientious investigator may have little ability to control how the drug is moved, stored and used if he or she is not supported by the laws of the land. To expect him or her to require and enforce the laws, regulations and practices of the listed country in the unlisted country (even assuming that there are no contradictions between them) is, we believe, quite unrealistic and exposes the investigator, the sponsor and, not least, patients, to significant risks. We propose that (a) transshipment of drugs from listed countries to unlisted countries should not be permitted; (b) exports of drugs

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*Pharmaceutical Research and Manufacturers of America*

sourced from US to unlisted countries should be allowed under the FDA proposed rule; and (c) FDA should work diligently to assess the regulatory system in unlisted countries, and add them following approval to the listed countries.

In the FR notice, FDA solicits comments on whether information on clinical studies of investigational drugs exported under the 312 program should be made available to the public. Section 113 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) requires FDA to provide information on studies conducted under an IND with certain investigational drugs. It is clear that the law is intended to provide the American population with information from which they could benefit by, for example, seeking to be included in ongoing clinical studies or seeking treatment with newly approved drugs that available data indicate to be safe and effective. For studies with exported drugs not conducted under an IND, we believe that FDA has no legal basis upon which to collect or disclose information, and that it would impose a significant additional reporting burden upon sponsors without contributing a corresponding benefit to Americans. It is *PhRMA's* position that in keeping with Congressional intent, only those trials taking place at US research sites are required to be posted to the data bank. Thus, any requirements for the export of clinical trial material should not be created based on this FDAMA provision, as the trials will not be conducted in the US.

The proposed text of 21 CFR 312.110 contains several references to FERE that greatly complicate the reading and practical understanding of the regulation. For example, paragraphs (b) (2), b) (3), and (b) (4) (d) all contain cross-references to FERE that are critical to the immediate understanding of the text of the regulation, whose meaning is not apparent unless those sections of FERE are, with some difficulty, "read into" the text of the regulation. *PhRMA* suggests that the clarity of the regulation would be improved by incorporating the references from FERE directly into the text of the regulation.

Proposed section 312.110(b)(4) requires that "the drug is promoted in accordance with the labeling." *PhRMA* questions the need for this requirement. The proposed rule already limits exports to investigational new drugs, which are not the subject of promotion. Therefore, we view this requirement as unnecessary.

*PhRMA* thanks the FDA for the opportunity to comment on this proposed rule and is prepared to respond to any questions that the Agency might have.

Sincerely,

