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Cook Group Incorporated

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June 16, 1999

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

Re: Docket No. 98N-0583 - Exports: Notification and Recordkeeping Requirements

Dear Sir or Madam:

The Cook Group submits this comment in response to the United States Food and Drug Administration's ("FDA's") April 2, 1999 *Federal Register* publication of a proposed rule to establish notification and recordkeeping requirements for persons exporting human drugs, biologics, devices, animal drugs, food and cosmetics that may not be marketed or sold in the United States.

First, the proposed regulations are not mandated by the FDA Export Reform and Enhancement Act. Second, there is no discussion in either the legislative history or the preamble to the proposed regulations that would justify the burdensome recordkeeping requirements that the proposed regulations would impose upon exporters. Third, the system as implemented under the FDA Export Reform and Enhancement Act is working very well and additional requirements are not needed.

Cook is a holding Company of international corporations engaged in the manufacture of diagnostic and interventional products for radiology, cardiology, urology, gastroenterology, emergency medicine and surgery. Cook has pioneered numerous products to improve patient treatment and care, including devices used in the Seldinger technique of angiography and in techniques for interventional radiology and cardiology. Many Cook products benefit patients by providing doctors with the means of diagnosis and therapeutic intervention without necessitating open surgical procedures. Cook sells over 15,000 different products which can be purchased in 130,000 different combinations.

Prior to the FDA Export Reform and Enhancement Act (Pub. L. 104-134, as amended by Pub. L. 104-180), the statutory scheme required exporters to obtain FDA approval for all drugs and medical devices exported to other countries. This scheme was troublesome to Congress for two reasons. First, an exporter had to obtain FDA

P.O. Box 1608, 47402-1608, 405 N. Rogers Street, Bloomington, IN 47404-3780 U.S.
Phone: 812 331-1025 Telefax: 812 331-8990

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approval to export a drug or device to a country even when the importing country's own regulatory system had approved the drug or device. The overall effect of this limitation was to put FDA in a position to control U.S. medical good exports to the rest of the world. Second, Congress was troubled by the economic burdens that FDA approval placed upon U.S. manufacturers. In order to export, a manufacturer had to compile significant data and obtain a letter from the importing country's government verifying that the drug or device was approved for use in that country. This specific requirement added further delays to an already time-consuming process.

It is important to recognize that the practice of medicine is worldwide. Physicians are using the latest technologies in all industrialized countries. If a manufacturer is to compete, for example, in the European market, it must be able to make its products available just as quickly as its European competitors. This could not be done under the regulatory scheme prior to 1996, and many manufacturers had no choice but to move their manufacturing for foreign markets abroad.

Congress recognized that the public health was not enhanced by the process and sought to keep jobs and profits in the U.S. To this end, Congress simplified statutory export requirements and enacted the FDA Export Reform and Enhancement Act in 1996. The Act simplified the export process by requiring exporters to provide a simple notification to the FDA that identifies the drug or device being exported and the country to which it is sending its goods.

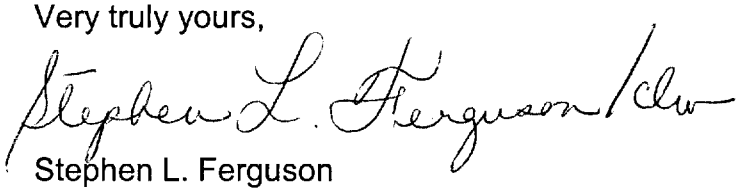
Now FDA is departing from what Congress enacted and rather than simplifying the export process, the FDA's proposed regulations would impose, under the guise of recordkeeping, delays and restrictions on exports similar to those that existed prior to the enactment of the FDA Export Reform and Enhancement Act in 1996. The proposed regulations would require that the exporter obtain documentation prior to export (a letter from an appropriate government agency) that demonstrates that the exported product does not conflict with the importing country's laws. Proposed Section 1.101(b)(2). In a number of countries, obtaining the required document could take weeks, if not months. This delay would occur even though the device complies with the importing country's premarket requirements and the quality system. The current system places responsibility on the manufacturer to comply with the importing company requirements and certify this to FDA. This is where the responsibility should be placed, not with FDA.

As discussed above, the underlying purpose of the 1996 act was to eliminate delay so that exporters could compete on the world market. Since the medical community is a global community, any hindrance that the FDA seeks to impose will result in lost jobs and lost revenue without a public benefit. The net result will be that

medical device companies will simply move their manufacturing facilities offshore, and that result is wrong.

In conclusion, Cook believes that the proposed regulations will just cause similar delays to those that existed prior to the 1996 act. The present system of simple notification to the FDA works for exporters: it allows exporters to compete in the global marketplace while keeping both jobs and revenues here in the U.S. and places responsibility on the U.S. company and the exporting country. There is no current rationale for implementing restrictive and burdensome regulations that could very well chase jobs and revenues out of the U.S.

Very truly yours,



Stephen L. Ferguson

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about them, available, without undue restrictions, not just to the American people, but to other people around the world.

Respectfully submitted,

Jeff Katke
Chief Executive Officer

Beverly Chin
General Counsel

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CERTIFIED

P 268 918 966

MAIL

Metagenics®
Genetic Potential Through Nutrition
971 Calle Negocio
San Clemente, CA 92673

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20857+0001

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