



Producers of Quality
Nonprescription Medicines and
Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

March 8, 2002

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

2736 102 199-8 01:10

PETITION FOR STAY OF ACTION DOCKET No. 98N-0583

The undersigned, the Consumer Healthcare Products Association (CHPA), submits this petition under 21 C.F.R. § 10.35 to request that the Commissioner of Food and Drugs stay the effective date for compliance and stay enforcement activities for the Final Rule in Docket No. 98N-0583. CHPA is the 121-year-old trade association representing manufacturers and distributors of nonprescription, over-the-counter medicines and dietary supplements. CHPA represents members who would be adversely affected if the effective date were not stayed.

A. Decision involved.

On December 19, 2001, the Food and Drug Administration published a final rule on "Exports: Notification and Recordkeeping Requirements." *See* 66 Fed. Reg. 65429 (December 19, 2001)(Docket No. 98N-0583). This rule establishes notification and recordkeeping requirements for persons who export drugs, biological products, food, and cosmetics that may not be marketed or sold in the United States. Compliance with the rule requires companies to clarify certain issues which may not have been fully contemplated in the rule's development, and to coordinate internal systems among geographically diverse facilities.

B. Action requested.

The final rule was published on December 19, 2001, and is effective March 19, 2002. To allow companies to clarify issues not fully contemplated in the rule's development, such as

98N-0583

PSA 2

sample products or products for testing which do not fall under an Investigational New Drug application; and to allow companies to fully coordinate their internal systems among geographically diverse facilities, we request that the Commissioner of Food and Drugs stay the effective date for compliance and stay enforcement activities for the final rule for six months (September 19, 2002).

C. Statement of grounds.

Timing. The rule will require extensive efforts to review, establish and coordinate compliance procedures within companies with diverse products lines. At the same time, for a large company with food, cosmetic, and drug facilities, creation of one centralized system may not be practical, instead requiring slightly different but still consistent approaches for all locations.

To establish this process in three months requires: ▪ creating new forms; ▪ automating the program where possible; ▪ educating and training all appropriate individuals at each location; ▪ testing the system; ▪ assuring that the system is Part 11 compliant; and ▪ specifying a response plan for an FDA audit in this area. Three months is too short a time period to ensure existing systems can be modified to meet these requirements. This is compounded given the three month period overlapped with the end of the year holidays, effectively shortening compliance time. Time is also needed for companies to establish processes for compliance, including notification, of certain unapproved drugs or devices under section 802 of the Food, Drug & Cosmetic Act, in situations where they could otherwise have chosen to export but not notify under section 801(f). While the latter alternative can be legally possible, labeling a drug product as “not approved” in the U.S. can be counter-productive to sound business.

Scope. While commercially marketed or marketable products are squarely within the rule, the rule’s scope is unclear for things such as research & testing materials which do not fall under an IND, samples, bulk product, intermediates, subassemblies, or raw materials. Similarly, the scope is unclear for mixes of products in different categories. For example, how would a

March 8, 2002

Page 3

single package with both a toothbrush and a dentifrice, or menstrual pads with an antiperspirant be handled? Labeling for one element in the package could track U.S. labeling, while differing for the other. Similarly, how would a single shipping container or pallet with a mix of devices, drugs, and/or cosmetics be handled?

Compliance. Given some of the questions as to scope, there is also concern that the rule may be unevenly applied by both FDA and industry. Some of our member firms have noted an uneven application of exporting requirements under the Federal Insecticide, Fungicide and Rodenticide Act for similar reasons, and seek to avoid that here.

Last, the rule is silent as to when notifications are required to be submitted – before, concurrently, or after shipment.

D. Conclusion.

The rule involves very detailed steps to be incorporated into complex existing commercial systems, something that can only be done with sufficient planning. Key details of the rule are not contained in the legislation, so firms were awaiting the final regulation in order to insure that the changes they put in place actually met the final regulation. To establish compliant systems, more time is needed, and we request FDA stay for six months the compliance date.

Respectfully submitted,



David C. Spangler
Vice President – International
& Assistant General Counsel
Consumer Healthcare Products Association
1150 Connecticut Avenue, N.W.
Washington, D.C. 20036
tel: (202) 429-9260

cc: Philip L. Chao, HF-23

exprt-ext02/dcs



**CONSUMER HEALTHCARE
PRODUCTS ASSOCIATION**

1150 Connecticut Avenue, N.W.
Washington, D.C. 20036-4193

First Class Mail
First Class Mail

Dockets Management Branch
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857