

C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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March 12, 2002

E. EDWARD KAVANAUGH
P R E S I D E N T

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

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

Dear Sir or Madam:

The undersigned, The Cosmetic, Toiletry, and Fragrance Association (the "Petitioner"), submits this petition under 21 CFR Section 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 (hereafter the "Final Rule").

A. Decision involved

On December 19, 2001 FDA published the Final Rule that establishes the notification and recordkeeping requirements for persons exporting human drugs, biological products, devices, animal drugs, food, and cosmetics that may not be marketed or sold in the United States.

B. Action requested

The Petitioner requests that FDA stay the effective date for compliance of the Final Rule from March 19, 2002 to September 19, 2002.

C. Statement of grounds

The Final Rule, published on December 19, 2001, reflects the Agency's consideration of 18 comments on the proposed rule of April 2, 1999 as well as

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several comments on the draft export guidance document published on June 12, 1998. Reflecting the provisions of the FDA Export Reform and Enhancement Act "...[which] significantly changed and simplified the export requirements for unapproved human drugs, biological products, devices, and animal drugs," [66 FR 65429] the Final Rule was conceived and written to encompass the broad and diverse range of product categories regulated by the Agency.

While the Agency's stated intent of this rulemaking is to simplify the notification and recordkeeping requirements for exported products, industry must take extensive measures to implement its provisions. Three months is too short a period of time to ensure that existing systems can be modified and new systems designed and implemented to meet the requirements of the regulation.

Concerns of safety would not arise if the Agency were to extend the effective date for compliance and stay enforcement activities by 180 days. The Agency rightly presumes that industry already maintains most of this information, but it fails to recognize the time necessary to create and implement new recordkeeping and notification requirements outlined by the Final Rule.

Industry intends to comply fully with all aspects of the Final Rule, but more time is needed to ensure its implementation in a consistent and uniform manner. The Final Rule has an impact on every plant and facility – both large and small. Large companies that export several categories of products from numerous plants and facilities will need to develop extensive practices and procedures within and between existing locations to coordinate a consistent approach for all locations. This process includes creation of new forms and automatic programs where possible; education and training of personnel at each location, testing the program; and development of additional procedures for FDA audits in this area.

Additional time is necessary because outstanding and significant issues of interpretation between the proposed and Final Rules prevented industry from developing and implementing procedures until the Final Rule was published. Several important aspects of the rulemaking were unclear in the proposed rule. For example, the Final Rule clarifies the Agency's interpretation of section 801(e)(1)(D) of the act as it pertains to multiple batches of the same product for domestic commerce or export. Clarification of recordkeeping requirements was necessary before industry would know what to create and enforce, *e.g.*, the definition of a "consignee," or the period of time required for keeping records.

In addition to the issue of timing for this request, Petitioner also seeks an extension of time to understand and evaluate the scope of the rule. It is unclear what products may be subject to the rule in addition to commercially marketed or marketable products. For example, significant interpretation will be required to assess the impact of the Final Rule for product combinations that mix product

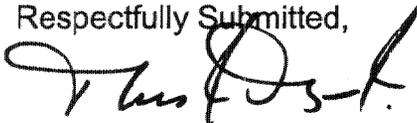
categories, e.g., devices and drugs or for shipments that mix categories of products such as devices, drugs, and cosmetics. As written in the preamble to the Final Rule, "FDA agrees that implementing sections 801 and 802 of the act is difficult because the statutory requirements apply to different products in different ways." [66 FR 65429, 65444]

In addition to these reasons for requesting an extension of the effective date to September 19, 2002, Petitioner requests a stay of enforcement activities because of serious concern for uneven application by both FDA and industry when the scope of the Final Rule is still unclear.

D. Conclusion

For these reasons we urge FDA to extend the effective date for compliance and stay agency enforcement activities to September 19, 2002.

Respectfully Submitted,



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Vice President – Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance Association

cc: Philip L. Chao, HF-23