

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 1

[Docket No. 98N-0583]

Exports; Notification and Recordkeeping Requirements; Stay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; stay.

SUMMARY: The Food and Drug Administration (FDA) is staying the final rule on notification and recordkeeping requirements for persons exporting human drugs, animal drugs, biological products, devices, food, and cosmetics that may not be marketed or sold in the United States. This action is in response to four requests for a stay because certain parties would not be able to comply with the effective date of March 19, 2002.

DATES: Effective [*insert date of publication in the Federal Register*]; 21 CFR 1.101 is stayed until June 19, 2002.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0587.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 19, 2001 (66 FR 65429), FDA (we) published a final rule entitled "Exports: Notification and Recordkeeping Requirements." The final rule established the export notification and recordkeeping requirements for persons exporting human drugs, animal drugs, biological products, devices, food, and cosmetics that may not be marketed or sold in the United States. The final rule implements certain statutory changes made by the FDA Export Reform and Enhancement Act and will be codified at § 1.101 (21 CFR 1.101).

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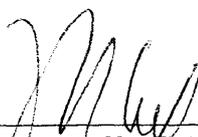
The final rule was to become effective on March 19, 2002. On March 1, 2002, and later on March 8, 11, and 12, 2002, we received three petitions for stay of administrative action and one letter requesting that we stay the final rule's effective date by 6 months. In general, the petitions and letter stated that certain parties would be unable to comply by the original March 19, 2002, effective date and that some parties were confused as to the final rule's applicability to certain products.

On March 18, 2002, we notified the parties that the agency intended to grant the petitions and the letter's request, in part, by extending the final rule's effective date by 3 months, and that the agency would publish a notice document in the **Federal Register** staying the rule under 21 CFR 10.35(e). This stay should allow the parties and other affected industry members more time to understand and to establish programs and policies for complying with the regulatory requirements that apply to exported products that may not be marketed or sold in the United States. The new effectiveness for § 1.101 is June 19, 2002.

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(3)(A). Alternatively, the agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(3)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The agency is staying § 1.101 until June 19, 2002, because the agency has determined that it is appropriate to allow affected industry members more time to understand and to establish programs and policies for complying with the regulatory requirements that apply to exported products that may not be marketed or sold in the United States.

This action pertains solely to the requirements of the final rule. Affected industry members must continue to comply with the statutory requirements for exports under section 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 and 321).

Dated: 5/6/02
May 6, 2002.



Margaret M. Botzel,
Associate Commissioner for Policy.

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