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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 98N-1063]

**Announcement of a New Format for Export Certificates**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing a new format for export certificates. The new format features the use of several security measures in the paper used to print export certificates to deter falsification of or tampering with FDA-issued export certificates. The new format may also help authenticate export certificates.

**DATES:** The agency will begin issuing export certificates using the new format after January 1, 1999.

**FOR FURTHER INFORMATION CONTACT:** Philip L. Chao, Office of Policy (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380.

**SUPPLEMENTARY INFORMATION:** Firms exporting products from the United States are often asked by foreign customers or foreign governments to supply a certification relating to products subject to the Federal Food, Drug, and Cosmetic Act (the act) and other FDA-administered acts. Certification is the process by which a formal or official attestation is made concerning a product's regulatory status or the system by which a commodity is manufactured. Certification does not show that FDA has "approved" the product for export; however, some certificates reflect that the product has been approved for marketing in the United States.

FDA currently issues several types of certificates. In brief, the principal certificates are:

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1. Certificates to Foreign Government—used for products that may be legally marketed, sold, offered for sale, or distributed in the United States. For food products, these are commonly known as “certificates of free sale” or “certificates of export.”

2. Certificates of Exportability—used for products that meet the requirements for export under section 801(e) or 802 of the act (21 U.S.C. 381(e) or 382)) but may not otherwise be marketed, sold, offered for sale, or distributed in the United States.

3. Certificates of a Pharmaceutical Product—used for pharmaceutical products and conform to the format in the World Health Organization’s “Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.”

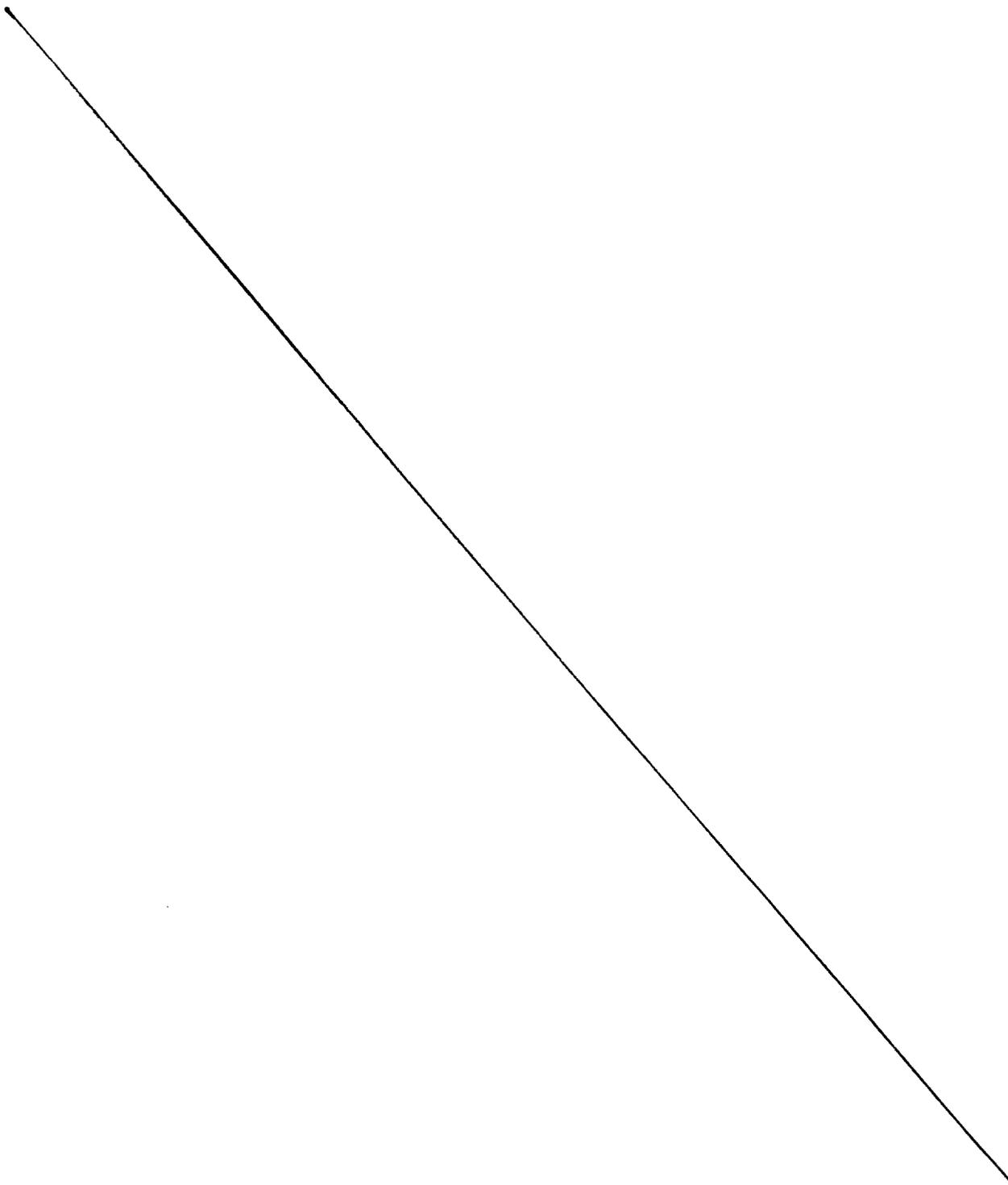
FDA’s Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition, and Center for Veterinary Medicine receive and process requests for export certificates for products subject to their respective authorities.

Recently, there has been an increasing demand for export certificates, as well as requests from foreign governments to authenticate certificates and instances where FDA has found counterfeit or falsified certificates. Consequently, to facilitate the issuance and tracking of export certificates, deter unscrupulous persons from making counterfeit or false certificates or otherwise tampering with export certificates, and to help foreign governments identify authentic, FDA-issued export certificates more readily, FDA has adopted a new format for its export certificates. The new format features the use of several security measures in the paper used for export certificates.

FDA will begin using the new format on certificates issued after January 1, 1999. The procedures for requesting and issuing export certificates, as well as the text of the certificates themselves, will remain unchanged.

However, FDA will not use the new format on European Union (EU) Export Health Certificates. These certificates are for fishery products intended for import into the EU and are not considered to be FDA certificates.

FDA is notifying foreign embassies and its counterpart government agencies of the new format and also advising them that otherwise valid export certificates issued before January 1, 1999, remain



valid. Consequently, persons whose export certificates were issued before January 1, 1999, but expire after that date, should not need to replace those certificates.

Dated: 12/4/98  
December 4, 1998



William K. Hubbard  
Associate Commissioner for Policy Coordination

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